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Clinical Trials on Alzheimer's Disease



December 8-10, 2016 SAN DIEGO

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Congress secretariat

ANT Congrès - E-mail: ctad@ant-congres.com - Tel: + 33 4 67 10 92 23



Dear Colleague,

The development of the next generation of Alzheimer's disease treatments is among the most important health needs worldwide, but presents huge challenges. The goal of the meeting is to bring together today's worldwide leaders in the treatment of Alzheimer's disease to discuss new results, candidate therapeutics, and methodological issues important to the development of the next generation of Alzheimer's disease treatments.

Clinical trial teams from worldwide centers will report on their efforts to identify new biomarkers of disease as well as more sensitive clinical assessment tools to identify those at risk for AD, to predict progression, and assess the effectiveness of new treatments.

The future of clinical trials may lie in revisiting all drugs known to be safe and evaluate their relevance in AD treatment. We learned at CTAD 2015 of the importance of non-pharmaceutical trials and that anti-amyloid treatment for AD should begin early on in the disease process. Furthermore we also learned more of another pathway with Tau Biomarkers, and their implications for AD. Again in 2016 Clinical teams will present their population studies on subjects in the early stage of the disease or even at the asymptomatic stage.

CTAD 2016 will highlight the latest on trying to get these trials off the ground.

Overall, the aim of the conference is to overcome the hurdles and speed the development of effective treatments.

We are delighted to be welcoming you to San Diego!

Organizing Commitee



Paul Aisen
MD Alzheimer's
Therapeutic Research
Institute (ATRI) University
of Southern California
(USC), San Diego, USA



Jacques Touchon MD, PhD University Hospital of Montpellier, France



Bruno Vellas
MD, PhD University
Hospital of Toulouse,
France



Mike Weiner
MD University
of California
San Francisco
(UCSF), USA

Keynote speakers



Paul S. Aisen has conducted therapeutic research on Alzheimer's disease for over 25 years. After graduating from Harvard College, Cambridge, Massachusetts, Dr Aisen received his medical degree from the Columbia University College of Physicians and Surgeons in New York City and pursued his clinical training as a resident in the Department of Medicine at University Hospitals in Cleveland, Ohio, and in the Department of Medicine at Mount Sinai Hospital in New York City. He completed his fellowship in the Division of Rheumatology at the New York University Medical Center before returning to Mount Sinai Hospital as chief resident in the Department

of Medicine. Dr Aisen is a diplomate of the American Board of Internal Medicine, with specialty certification in rheumatology. After 15 years on the faculty at Mount Sinai, Dr Aisen moved to Georgetown University, Washington, DC, in 1999 as professor in the departments of neurology and of medicine and became vice chair of the Department of Neurology in 2004. From 2007 until 2015 he was professor of neurosciences at the University of California, San Diego in La Jolla, California, and Director of the Alzheimer's Disease Cooperative Study. At present he is Director of the University of Southern California Alzheimer's Therapeutic Research Institute, located in San Diego, California. Dr Aisen has collaborated extensively with the biotech and pharmaceutical industries for many years. He has led numerous multicenter trials, and has authored more than 300 scientific papers.



Randall Bateman, the Charles F. and Joanne Knight Distinguished Professor of Neurology at Washington University School of Medicine, received BS degrees in Biology and Electrical Engineering from Washington University, and his MD from Case Western Reserve University School of Medicine. Dr. Bateman is the Director of the Dominantly Inherited Alzheimer Network Trials Unit (DIAN-TU) which coordinates with pharmaceutical, regulatory, and patient advocacy groups for clinical trials in the DIAN. Dr. Bateman serves as Principal Investigator of the DIAN and the Washington University DIAN Performance Site. Dr. Bateman's laboratory

investigates causes and future diagnostic tests and treatments of Alzheimer's disease utilizing many assays and techniques from quantitative measurement of stable-isotope labeled proteins to clinical translational studies for Alzheimer's disease. Recent awards include the Glenn Award for Research (2011), the Metlife Promising Investigator Award (2012), the Chancellor's Entrepreneurship and Innovation Award (2013), and the MetLife Award in Medical Research (2015).



Maria Carrillo is Chief Science Officer, Medical and Scientific Relations, at the Alzheimer's Association. Dr. Carrillo has a wide range of responsibilities, including oversight of the Association's grantmaking process and communication of scientific findings within and outside of the organization. Dr. Carrillo directly manages several Alzheimer's Association initiatives, including the Research Roundtable, the World-Wide Alzheimer's Disease Neuroimaging Initiative, and the Global Alzheimer's Association Interactive Network. She is co-author of the National Institute on Aging-Alzheimer's Association revised criteria for the diagnosis of Alzheimer's, and the

Appropriate Use Criteria for Amyloid Imaging. She is on the Advisory Committee for the World Health Organization Dementia Setting Priorities & Portfolio Analysis.



Nick Fox is Professor of Clinical Neurology and Director of the Dementia Research Centre at UCL's Institute of Neurology and Consultant Neurologist at the National Hospital for Neurology and Neurosurgery, Queen Square London. He has been involved in dementia research for over twenty years with particular interests in improving diagnosis and in using imaging biomarkers to accelerate the search for effective therapies. His group's research includes a number of multimodal longitudinal cohort studies in sporadic and familial AD, frontotemporal dementia and normal ageing. Nick's first degree was in Physics and Physiology from

Cambridge University. He subsequently graduated with honours in medicine and surgery from the University of London and then specialised in cognitive neurology. He is an elected Fellow of the Academy of Medical Sciences and an NIHR Senior Investigator. He was a member of the Prime Minister's Dementia Research Champions Group. He has contributed to advisory boards or steering committees for a number of clinical trials and natural history studies in dementia. He serves on the steering group of the Dementias Platform UK. He chairs UCL's Dementia Strategy Board and co-chairs the Alzheimer's Society UK's Research Strategy Council.



David Michelson received his medical degree from the Albert Einstein College of Medicine in New York. He trained in psychiatry at Yale University, where he was also a chief resident and faculty member before moving to the intramural program of the NIMH in 1990. In 1996 he joined Eli Lilly, eventually assuming responsibility for the early phase clinical development group in neuroscience. In 2006 he joined Merck Research Laboratories as vice president and therapeutic area head for clinical neuroscience. He has overseen the clinical development of number of novel drugs, including atomoxetine (Strattera), tafluprost (Zioptan), suvorexant (Belsomra) and

sugammadex (Bridion), as well as a number of programs in Alzheimer's Disease, including MK-8931, the BACE inhibitor currently being studied in two large phase 3 trials.

2016 Recepient of the C7AD Lifetime Achievement Award



Dr. Neil Buckholtz served as the Director of the Division of Neuroscience at the National Institute on Aging (NIA) at the National Institutes of Health (NIH). During his twenty-five year tenure at NIA, Dr. Buckholtz was responsible for developing and managing many signature extramural research programs including the Alzheimer's disease (AD) drug discovery and development program, the preclinical drug toxicology evaluation contract, the AD Cooperative Study (ADCS), the AD Neuroimaging Initiative (ADNI), the Dominantly Inherited Alzheimer's Network (DIAN), the Accelerating Medicines Partnership-AD, and the 2012 and 2015 AD Research Summits. He has extensive experience providing information on all aspects of AD research to media as well as to lay and professional groups. Currently, he is consulting with the NIA and other public and private entities on AD prevention, treatment, and diagnostic research strategies.

Dr. Buckholtz received his B.S. degree in psychology from the Ohio State University and his M.S. and PhD degrees in physiological psychology from the University of Wisconsin, Madison. He was a post-doctoral fellow and Assistant and Associate Professor in biochemistry and psychiatry at the Medical University of South Carolina from 1970 to 1983 where he did research on the neuropharmacology of psychotomimetic drugs, the serotonergic system, and psychopharmacology of learning and memory. He came to the NIH in 1983, first as guest researcher/pharmacologist in the National Institute of Mental Health (NIMH) intramural program working on the neuropharmacology of psychotomimetic drugs and receptor correlates of bulimia and depression followed by serving as a Scientific Review Administrator in the NIMH extramural program. He moved to the NIA in 1990 as a Health Scientist Administrator.

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Program at a glance

Thursday, December 8 Marina Ballroom DEFG - Level 3 7.45 - 8.15 a.m WELCOME BY THE ORGANIZING COMMITTEE and presentation of the CTAD Lifetime Achievement Award 8.15 - 8.45 a.m **KEYNOTE 1** Alzheimer's Association: Initiatives & Public Health Perspectives 8.45 - 10.00 a.m **ORAL COMMUNICATIONS SESSION** Coffee Break and poster sessions 1 San Diego Ballroom - Lobby Level 10.30 - 11.30 a.m Symposium 1 Time-to-Event Endpoints for Clinical Trials in Early Alzheimer's Disease 11.30 - 12.00 p.m **ORAL COMMUNICATIONS SESSION** 12.00 - 12.30 p.m **KEYNOTE 2** AD Trial Design: Continuing Progress Lunch Break and poster sessions 1 1.30 - 3.00 p.m **ORAL COMMUNICATIONS SESSION** 3.00 - 3.30 p.m **KEYNOTE 3** An Industry Perspective on Drug Development 3.30 - 4.00 p.m **ORAL COMMUNICATIONS SESSION** 4.00 - 4.30 p.m Coffee Break and poster sessions 1 San Diego Ballroom - Lobby Level 4.30 - 5.15 p.m ORAL COMMUNICATIONS SESSION 5.15 - 6.15 p.m Symposium 2 Non-pharmacological intervention in populations at high risk of AD dementia: results of the MAPT and LipiDiDiet studies 6.15 - 7.45 p.m **EXPEDITION 3: A phase 3 Trial of Solanezumab in Mild Dementia due** to Alzheimer's Disease Presentation and Panel Discussion 7.45 - 10.00 p.m Fourth Level South Tower Welcome Reception Coronado Terrace Marriott Marina Hotel

Program at a glance

Friday, December 9

7.30 - 8.15 a.m	ORAL COMMUNICATIONS SESSION	Marina Ballroom DEFG - Level 3
8.15 - 10.00 a.m	ORAL COMMUNICATIONS SESSION Animal Models Marina Ballroom DEF - Level 3	ORAL COMMUNICATIONS [Marina Ballroom G - Level 3]
	Coffee Break and poster sessions 2	San Diego Ballroom - Lobby Level
10.30 - 11.30 a.m	Symposium 3 Stem cells for Alzheimer's disease therapeutics Marina Ballroom DEF - Level 3	ORAL COMMUNICATIONS SESSION Marina Ballroom G - Level 3
11.30 - 12.30 p.m	ORAL COMMUNICATIONS: Parallel sess	Marina Ballroom DEFG - Level 3
	Lunch Break and poster sessions 2	
1.30 - 2.00 p.m	KEYNOTE 4 What have we learned and what can we ex	Marina Ballroom DEFG - Level 3 pect from brain imaging for Alzheimer trials
2.00 - 2.30 p.m	PRESENTATION AND PANEL DISCUSSION Re-Evaluation of the NIA-AA Guidelines for	
2.30 - 3.30 p.m	Symposium 4 Marina Ballroom DEF - Level 3 The European Prevention of Alzheimer's Dementia (EPAD) Programme: From Readiness Cohort to Clinical Trial and the ethical framework for risk disclosure	2.30 - 5.00 p.m Marina Ballroom G - Level 3 Workshop New Trends in Clinical Trial Designs In Search of Next Generation Treatments
	Coffee Break and poster sessions 2 San Diego Ballroom - Lobby Level	
4.00 - 4.30 p.m	PRESENTATION Marina Ballroom DEF - Level 3 AND PANEL DISCUSSION 'Subject Enrollment'- A major barrier for developing treatments for dementia/Alzheimer's	
4.30 - 6.15 p.m	ORAL Marina Ballroom DEF - Level 3 COMMUNICATIONS SESSION	

Saturday, December 10 Marina Ballroom DEFG - Level 3

7.30 - 9.00 a.m	ORAL COMMUNICATIONS SESSION	
9.00 - 9.30 a.m	KEYNOTE 5 Alzheimer's disease: from Proteinopathy to Prevention	
9.30 - 10.30 a.m	ORAL COMMUNICATIONS SESSION	
	Coffee Break and poster sessions 3	San Diego Ballroom - Lobby Level
11.00 - 1.00 p.m	Symposium 5 Collaborative efforts to prevent Alzheimer's disease	

San Diego 8



Thursday, December 8

7.45 a.m	Welcome by the Organizing Committee and presentation of the CtaD Lifetime Achievement Award to Dr. Neil Buckholtz Paul Aisen, Jacques Touchon, Bruno Vellas, Mike Weiner	[Marina Ballroom DEFG - Level 3]
8.15 a.m	KEYNOTE 1 Alzheimer's Association: Initiatives & Public Health Perspectives Introduction: Jacques Touchon, Bruno Vellas Maria Carrillo, The Alzheimer Association, Chicago, USA	[Marina Ballroom DEFG - Level 3]
8.45 a.m	ORAL COMMUNICATIONS SESSION Chairs: Maria Carrillo, Lon Schneider	Marina Ballroom DEFG - Level 3
8.45 a.m	OC1 - Phase 3 trial of tau aggregation inhibitor therapy with LMTM in mild Alzheimer's disease Lon S Schneider, MD¹, Serge Gauthier, MD², Howard H Feldman, MD³, Gordon K Wilcock, MD, DSc⁴, Giovanni B Frisoni, MD⁵ Jiri Hardlund, MD⁶, Karin Kook, PhD⁷, Damon J Wischik, PhD⁶, Bjoern O Schelter, PhD⁶, John M D Storey, PhD⁶, Charles R Harrington, PhD⁶, Claude M Wischik, MD, PhD⁶, (1) Keck School of Medicine of the University of Southern California, Los Angeles, CA, USA, (2) McGill Centre for Studies in Aging, Verdun, Quebec Canada, (3) University of California San Diego, CA, USA, (4) Oxford University, Oxford, UK, (5) University of Geneva, Geneva, Switzerland, (6), TauRx Therapeutics Ltd., Singapore, (7) Salamandra LLC, Bethesda, Maryland, MD, USA, (8) University of Aberdeen, Aberdeen, UK	
9.00 a.m	OC2 - Collaboration for Alzheimer's Prevention: A structured approach to data on CAP principles and recommendations Maria C.Carrillo ^a , Stacie Weninger ^b , Billy Dunn ^c , Paul S.Aisen ^d , Randall J.Bateman ^e , Joanne D.K McDade ^a , Susan L. Mills ^a , Eric M. Reiman ^f , Reisa Sperling ^a , Anna M. Santacruz ^a , Pierre N.Tario (a) Medical & Scientific Relations Division, Alzheimer's Association, Chicago, IL, USA, (b) F-Prime Biomed MA, USA, (c) Division of Neurology Products, U.S. Food and Drug Administration, Silver Spring, MD, USA, Alzheimer's Therapeutic Research Institute, San Diego, CA, USA, (e) Department of Neurology, Washingto Banner Alzheimer's Institute, Phoenix, AZ, USA, (g) Department of Neurology, Brigham and Women's Hospital of Neurology & Psychiatry, Duke University, Durham, NC, USA	Cotz ^b , Jessica B.Langbaum ^f , Eric t ^f , Kathleen A. Welsh-Bohmer h lical Research Initiative, Cambridge, (d) University of Southern California on University, St Louis, MO, USA, (f)
9.15 a.m	OC3 - Effect of PF-06648671, a novel gamma secretase modulator, on CSF beta a oral single and multiple-dose administration in healthy subjects Ruolun Qiu, PhD¹, Richann Liu, MS¹, Anne-Marie Wills, MD MPH¹,³, Fernando Dela Cruz, MS², MD PhD¹, Eva Hajos-Korcsok, PharmD PhD¹, Terrence Fullerton, PharmD⁴, Claire Leurent, PhD (1) Pfizer Inc, Neuroscience & Pain Research Unit, Cambridge, MA, USA, (2) Pfizer Clinical Research Massachusetts General Hospital, Neurology, Boston, MA, USA, (4) Pfizer Inc, Global Innovative Pharma, Clini	Charles Carrieri, MS ² , Ping He, D ¹ , Robert Alexander, MD ¹ Units, New Haven, CT, USA, (3)
9.30 a.m	OC4 - Phase 3 study designs to evaluate treatment with a bace inhibitor, LY3314814/AZD3293, in patients with early alzheimer's disease John R. Sims, MD¹, Jamie A. Mullen, MD², Jennifer A. Eads, PharmD¹, AnnCatherine M. Downing, PharmD¹, Alette M. Wessels PhD¹, Scott W. Andersen, MS¹, Jennifer A. Zimmer, MD¹, Katherine J. Selzler, PhD¹, Pierre N. Tariot, MD³ (1) Eli Lilly and Company, Indianapolis, IN, USA, (2) AstraZeneca Pharmaceuticals, Cambridge, MA, USA, (3) Banner Alzheimer's Institute Phoenix, AZ, USA	
9.45 a.m	OC5 - A phase IB, randomized, double-blind, placebo-controlled, multiple dose s and tolerability of escalating doses of crenezumab in patients with mild-to-mod Helen Lin, MD, PhD (1), Veronica Asnaghi, MD (2), Michael Rabbia, MA (3), Michael Ward, P (1), Lee Honigberg, PhD (1), Susanne Ostrowitzki, MD, PhD (1), Jillian Smith (2), Robert Paul, PhD (1) (1) Genentech, Inc., a member of the Roche Group, South San Francisco, CA, USA, (2) F. Hoffman-La Roche AG, Basel, Switz York, NY, USA	lerate ad hD (1), Angelica Quartino, PhD MD, PhD (1), William Cho, MD,
10.00 a.m	Coffee Break and poster sessions 1	San Diego Ballroom - Lobby Level

Thursday, December 8

10.30 a.m	SYMPOSIUM 1 Marina Ballroom DEFG - Level 3
	Time-to-Event Endpoints for Clinical Trials in Early Alzheimer's Disease Moderator: Mary Sano, PhD, Alzheimer's Disease Research Center, Icahn School of Medicine at Mount Sniai, New York, NY, USA
	1. History of Time-to-Event in AD Clinical Trials
	Mary Sano PhD¹, Barbara Schauble MD, PhD², Robert Lasser MD, MBA²
	(1) Alzheimer's Disease Research Center, Icahn School of Medicine at Mount Sinai, New York, NY, USA, (2) F. Hoffmann-La Roche Ltd, Basel, Switzerland
	2. Value of Time-to-Event in the Current Era
	<u>José Luis Molinuevo</u> MD, PhD¹, Christin Bexelius PhD², Susanne Ostrowitzki MD, PhD³
	(1) Scientific Director, Barcelona Beta Brain Research Centre, Pasqual Maragall Foundation, Barcelona, Spain, (2) F.Hoffmann-La Roche Ltd, Basel, Switzerland, (3) Genentech, South San Francisco, California, USA
	3. Establishing Clinical Relevance and Statistical Utility for Time-to-Event Endpoint Definitions
	Suzanne Hendrix PhD¹, Howard Mackey PhD², Chris J Edgar PhD³
	(1) Pentara Corp., Salt Lake City, Utah, USA, (2) Genentech, South San Francisco, California, USA, (3) Roche Products Limited, Welwyn Garden City, UK
11.30 a.m	ORAL COMMUNICATIONS SESSION Chairs: Pedro Pesini, Scott Turner Marina Ballroom DEFG - Level 3
11.30 a.m	OC6 - Resveratrol regulates neuroinflammation and induces adaptive immunity in Alzheimer's disease R. Scott Turner MD, PhD¹, Michaeline Hebron¹, Xu Huang¹, Hannah Brown¹, Paul Aisen MD², Robert Rissman PhD³, Charbel Moussa MD, PhD¹ (1) Department of Neurology, Georgetown University Medical Center, Washington, D.C., USA, (2) Alzheimer's Therapeutic Research Institute (ATRI), University of Southern California, San Diego, Ca., USA, (3) Alzheimer's Disease Cooperative Study (ADCS), University of California, San Diego, Ca., USA
11.45 a.m	OC7 - Results of phase I clinical trial of ABvac40, an active vaccine against Aß40 Ana Mª Lacosta, PhD¹, Pedro Pesini, PhD¹, Virginia Pérez-Grijalba, PhD¹, Ivan Marcos, PhD¹, Leticia Sarasa, PhD¹, Itziar San-José, MSc¹, Laura Nuñez, BSc², Mercé Boada, MD, PhD³, Lluis Tárraga, MSc³, Agustín Ruiz, MD, PhD³, Manuel Sarasa, PhD¹ (1) Araclon Biotech, Zaragoza, Spain, (2) Grifols S.A., Barcelona, Spain, (3) Fundaciò ACE. Barcelona Alzheimer Treatment & Research Center, Barcelona, Spain
12.00 p.m	KEYNOTE 2 Marina Ballroom DEFG - Level 3
	AD Trial Design: Continuing Progress
	Introduction: Jacques Touchon, Bruno Vellas Paul Aisen, <i>Keck School of Medicine, ATRI, USC, San Diego, CA - USA</i>
12.30 p.m	Lunch Break and poster sessions 1
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1.30 p.m	ORAL COMMUNICATIONS SESSION Chairs: Philip Scheltens, Michael Rosenblum
1.30 p.m	OC8 - Optimized machine learning method for automated prescreening of patients for clinical trials Sulantha Mathotaarachchi ¹ , MSc, Tharick A. Pascoal ¹ , MD, Monica Shin ¹ , MSc, Andrea L. Benedet ¹ , MSc, Thomas Beaudry ¹ , BSc, Min Su Kang ¹ , BSc, Vladimir Fonov ¹ , PhD, Serge Gauthier ¹ , MD, Pedro Rosa-Neto ¹ , MD, PhD (1) Translational Neuroimaging Laboratory, McGill University Research Centre for Studies in Aging, McGill University, Montreal, Canada
1.45 p.m	OC9 - Adaptive enrichment trial design to learn which subpopulations benefit from treatments, based on ApoE4 carrier status Aaron Fisher, PhD¹, Michael Rosenblum, PhD¹ Department of Biostatistics, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD USA
2.00 p.m	OC10 - Automated Classification of Adverse Events in Clinical Studies of Alzheimer's Disease <u>Gustavo A. Jimenez-Maggiora</u> , MBA¹, Rema Raman, PhD¹, Karin Ernstrom, MS¹, Michael S.Rafii, MD, PhD¹², Paul S.Aisen, MD¹ 1. Alzheimer's Therapeutic Research Institute, University of Southern California, San Diego CA, 2. Department of Neurosciences, University of California, San Diego, La Jolla CA



Thursday, December 8

2.15 p.m	OC11 - Quantitative PET study of the effects of the p38α kinase inhibitor VX-74 load in patients with Early Alzheimer's disease (AD) Philip Scheltens MD PhD¹, Niels Prins MD PhD¹, Adriaan A Lammertsma PhD², Maqsood Yaqub Alam MD⁴, Bart NM Van Berkel MD PhD² 1. Department of Neurology and Alzheimers Center, VU University Medical Center; and the Alzheimers Rese. 2. Department of Radiology & Nuclear Medicine, VU University Medical Center, Amsterdam, NL, 3. Anoixis Pharma LLC, Cambridge, MA, USA	PhD², Hui-May Chu PhD³, John arch Center (ARC), Amsterdam, NL,
2.30 p.m	OC12 - Outcomes from the Prevention of Alzheimer's Disease with Vitamin E ar <u>Erin L. Abner</u> , PhD ^{1,2} , Frederick A. Schmitt, PhD ^{1,3} , Richard J. Kryscio, PhD ^{1,4} (1) Sanders-Brown Center on Aging, University of Kentucky, Lexington, KY, USA, (2) Department of Ep Lexington, KY, USA, (3) Department of Neurology, University of Kentucky, Lexington, KY, USA, (4) Department of Neurology, Lexington, KY, USA, (4) Department of Neurology, Lexington, KY, USA, (4) Department of Neurology, Lexington, KY, USA	idemiology, University of Kentucky,
2.45 p.m	OC13 - A statistical approach to centralized risk-based monitoring of AD clinical open-source platform Rema Raman, PhD¹, Gustavo Jimenez-Maggiora, MBA¹, Yanxin Jiang, MS¹, Michael Donohu Karin Ernstrom, MS¹, Michael Rafii, MD, PhD¹², Paul Aisen, MD¹ 1. Alzheimer's Therapeutic Research Institute, University of Southern California, San Diego, CA, USA, 2. Depart of California, San Diego, CA USA	re, PhD¹, Chung-Kai Sun, MS¹,
3.00 p.m	KEYNOTE 3 An Industry Perspective on Drug Development Introduction: Serge Gauthier David Michelson, Merck Laboratories, New Jersey, USA	Marina Ballroom DEFG - Level 3
3.30 p.m	ORAL COMMUNICATIONS SESSION Chairs: Susan De Santi, Guoqiao Wang	Marina Ballroom DEFG - Level 3
3.30 p.m	OC14 - Allopregnanolone as a Regenerative Therapeutic for Alzheimer's Diseas Roberta Diaz Brinton ¹ , Ronald Irwin, PhD ² , Kathy Rodgers, PhD ^{3,2} , Gerson Hernandez, MD ² , NPhD ⁴ , Dogu Aydogan, PhD ⁴ , Wendy Mack, PhD ⁵ , Lon S. Schneider,PhD ⁶ 1. Department of Pharmacology and Neurology, College of Medicine, University of Arizona, Tucson, AZ USA, 2. Lof Pharmacy, University of Southern California, 3. Department of Neuroradiology, University of Southern California and Informatics Institute, Laboratory of Neuro Imaging (LONI), Keck School of Medicine, University of Southern California, 6. Department of Psychiatry, of Southern California	Meng Law, MD ³ , Yonggang Shi, Department of Pharmacology, School ifornia, 4.UC Stevens Neuroimaging outhern California; 5.Department of
3.45 p.m	OC15 - Effect of S 47445 on functional connectivity at rest and during a task, and or in elderly subjects Philippe Ciuciu, PhD¹, Salma Bougacha, PhD¹, Fawzi Boumezbeur, PhD¹, Severine Desmic Laurier¹, Jean-Robert Deverre, PharmD, PhD¹, Lucie Hertz-Pannier, MD, PhD¹, Nadège Tard PhD², Katy Bernard, PhD² (1) CEA/DRF/I2BM/NeuroSpin, Gif-sur-Yvette, France, (2) Pôle Innovation Thérapeutique Neuropsychiatrie, In	dt¹, Chantal Ginisty¹, Laurence y, PharmD², Maria Pueyo, MD,
4.00 p.m	Servier, Suresnes, France Coffee Break and poster sessions 1	San Diego Ballroom - Lobby Level
4.30 p.m	OC16 - Florbetapir F 18 PET: from dual-phase to dual-biomarker imaging Sergey Shcherbinin, PhD¹, Jennifer A. Eads, PharmD¹, Adam J. Schwarz, PhD¹, John R. Sims, M Neuroimaging Initiative² 1. Eli Lilly & Co, Indianapolis, IN, USA, 2. Data used in preparation of this abstract were obtained from the Initiative (ADNI) database (adni.loni.usc.edu)	D1, For the Alzheimer's Disease
4.45 p.m	OC17 - A novel disease progression model for clinical trials in dominantly inher Guoqiao Wang, PhD¹, Scott Berry, PhD², Eric M. McDade, MD¹, Chengjie Xiong, PhD¹, Jas Quintana, PhD², Randall J. Bateman, MD¹ (1) The Dominantly Inherited Alzheimer Network Trials Unit, Department of Neurology, Washington University (2) Berry Consultants, Austin, TX, USA	son Hassenstab, MD¹, Melanie
5.00 p.m	OC18 - Optimal reference region to measure longitudinal amyloid-beta change of Santiago Bullich ¹ , Victor L Villemagne ² , Christopher C Rowe ² , <u>Susan De Santia</u> (1) Piramal Imaging GmbH, Berlin, Germany, (2) Department of Nuclear Medicine and Centre for PET, Austin (3) Piramal Pharma Inc, Boston, MA, USA	

Thursday, December 8

Welcome Reception Coronado Terrace Marriott Marina Hotel

5.15- 6.15p.m	
	Non-pharmacological intervention in populations at high risk of AD dementia: results of the MAPT and LipiDiDiet studies Moderators: Miia Kivipelto, MD, PhD, <i>Karolinska Institutet, Sweden,</i> Bruno Vellas, <i>MD, PhD, University of Toulouse, France</i>
	 The MAPT study: results of multi-domain intervention on cognitive performance in amyloid beta positive subjects <u>Sandrine Andrieu</u>, MD, PhD¹, for the MAPT study group (1) INSERM, University of Toulouse UMR1027, Toulouse, France Department of Epidemiology and Public Health, Toulouse University Hospital, Toulouse, France
	 LipiDiDiet Program on multi-nutrient intervention in prodromal AD: converging mechanism from preclinical and clinical results <u>Tobias Hartmann</u>, PhD^{1,2}, for the LipiDiDiet study group (1) Deutsches Institut für Demenz Prävention (DIDP), Medical Faculty, Saarland University, Homburg, Germany, (2) Department of Experimental Neurology, Saarland University, Homburg, Germany
	3. New results of the LipiDiDiet study: a 24-month RCT investigating the effects of Fortasyn Connect in prodromal AD Hilkka Soininen, MD, PhD¹, for the LipiDiDiet study group (1) Department of Neurology, University of Eastern Finland and Kuopio University Hospital, Kuopio, Finland
6.15 p.m	EXPEDITION 3: A phase 3 Trial of Solanezumab in Mild Dementia due to Alzheimer's Disease Presentation and Panel Discussion

South Tower - Level 4

7.45 p.m





Friday, December 9

7.30 a.m	ORAL COMMUNICATIONS SESSION Chairs: Audrey Gabelle, Nicola Coley	Marina Ballroom DEFG - Level 3
7.30 a.m	OC19 - The active vaccine against Alzheimer tau protein "AADvac1" confirmed the favourable safety profile and showed persistent antibody response in the long-term follow-up study "AC-AD-002" Petr Novak, MD, PhD¹, Matej Ondrus, MD, MSc¹, Reinhold Schmidt, Prof., MD, PhD², Stanislav Katina, Assoc. Prof., PaedDr. RNDr., PhD¹, Eva Kontsekova, Prof., RNDr, PhD., DrSc.¹, Michal Novak, Prof., MVD, PhD., DrSc.¹ (1) AXON Neuroscience, Bratislava, Slovakia, (2) Department of Neurology, Medical University of Graz, Austria	
7.45 a.m	OC20 - Clinical pharmacology study of p38 alpha MAP Kinase Inhibitor, Neflamapomid (VX-745), in Mi Cognitive Impairment (MCI) Due to Alzheimer's Disease (AD) or Mild AD John Alam MD¹, Hakop Gevorkyan MD MBA²³, Stanford Jhee PharmD², Lovingly Park PhD²³, Jee-Hyun Kim², Noel Alaka², Lal Ereshefsky PharmD²⁴ (1) EIP Pharma LLC, Cambridge, MA, USA, (2) Los Angeles EPCU, PAREXEL International, Glendale, CA, USA, (3) California Clinical Tri. Medical Group, Glendale, CA, USA, (4) Currently retired Regents Professor The University of Texas at Austin and Follow the Molecule: Cl. Consulting	
8.00 a.m	double-blind, placebo-controlled phase 1B study in	M, MPH¹, Tianle Chen, PhD¹, Ahmed Enayetallah, MBBCh, PhD¹, Samantha Budd Haeberlein, PhD¹, Alfred Sandrock,MD, PhD¹
8.15 a.m	ORAL COMMUNICATIONS SESSION Animal Models Chairs: Jacques Hugon, Robert Rissman	ORAL COMMUNICATIONS SESSION Chairs: Diana Kerwin, Reisa Sperling Marina Ballroom G - Level 3
8.15 a.m	OC22 - Pre-clinical development of GMP-1, a compound that protects mitochondrial function of neurons by combating protein mis-targeting B.Winblad, MD, PhD¹.⁴, A. Bernadotte, MD, PhD².⁴, G. Johansson¹.⁴, G.Montero⁴, M.Windisch, MD, PhD³, P. Pavlov, PhD¹.⁴ (1) Dept NVS, Center for Alzheimer Research, Div of Neurogeriatrics, Huddinge, Sweden, (2) Dept of Medicinal Biochemistry and Biophysics, Karolinska Institutet, Stockholm, Sweden, (3) NeuroScios GmbH, Graz, Austria, (4) Great Matter Pharma AB, Sundbyberg, Sweden	OC23 - Drug Interaction between Intepirdine (RVT-101), a 5-HT6 Receptor Antagonist, and Memantine in Healthy Subjects Ilise Lombardo, MD¹, Lori Jones, MPT², Stephen C. Piscitelli, PharmD², Jason T. Olin, PhD¹, Lawrence Friedhoff, MD, PhD, FACP¹ (1) Axovant Sciences, Inc., New York, NY, USA, (2) Roivant Sciences, Inc., Durham, NC, USA
8.30 a.m	OC24 - Early prevention approaches targeting Aßlowering kinase inhibition Claire Paquet, Julien Dumurgier, François Mouton Liger, Marion Tible, Sarah Gourmaud, <u>Jacques Hugon</u> Memory Center, Lariboisiere Hospital Paris France, Inserm U942 Paris France Lariboisiere Hospital Paris France	OC25-Arandomized, double blind, place bo controlled trial to study difference in cognitive learning associated with repeated self-administration of remote computer tablet-based application assessing dual-task performance based on amyloid status in healthy elderly volunteers C.Leurent, E.Pickering, J.Goodman, S.Duvvuri, P.He, E.Martucci, S.Kellogg, D.Purcell, J.Barakos, G.Klein, JW Kupiec, R.Alexander
8.45 a.m	OC26 - TIO2-Nanowired cerebrolysin potentiates neuroprotective effects of anti-Tau (PHOSPHO S422) antibody in Alzheimer's disease ¹Aruna Sharma, ²José V.Lafuente, ³Dafin F.Muresanua, ⁴Rudy J.Castellani, ⁵Mark A.Smith, ⁶Ranjana Patnaik, ²z.Ryan Tian, ²Asya Ozkizilcikb, ⁶Herbert Mösslera, ¹Hari S.Sharma ¹International Experimental CNS Injury & Repair (IECNSIR), Laboratory of Cerebrovascular Research, Dept. Surgical Sciences, Anesthesiology & Intensive Care Medicine, Uppsala University Hospital, Uppsala University, SE-, 2Dept Neurosciences, University of Basque Country, Bilbao, Spain, 3Dept. Clinical Neurosciences, University Medicine & Pharmacy, Cluj-Napoca, Romania; a"RoNeuro" Institute for Neurological Research and Diagnostic, Cluj-Napoca, Romania, 4University of Maryland, Dept. of Pathology, Baltimore, MD, USA, 5Case Western Reserve Medical University, Dept. of Pathology, Cleveland, OH, USA, 6Schoolof Biomedical Engineering, Dept. of Biomaterials, Indian Institute of technology, Banaras Hindu University, Varanasi, India, 7Dept. Chemistry & Biochemistry & Biomedical Engineering, University of Arkansas, Fayetteville, AR, USA, 8Ever NeuroPharma. Oberburgau. Austria	OC27 - The A4 Study: Update on Enrollment and Preliminary Tau PET Analyses Reisa Sperling, MD (1) (2), Keith Johnson, MD (2), Dorene Rentz, PsyD (1), Aaron Schultz, PhD (2), Jason Karlawish, MD (3), Eric Siemers, MD (4), Roy Yaari, MD (4), Michael Rafii, MD (5), Tiffany Chow, MD (5), Cecily Jenkins, PhD (5), Michael Donohue, PhD (5), Paul Aisen, MD (5) (1) Brigham and Women's Hospital, (2) Massachusetts General Hospital, Harvard Medical School, Boston, MA, USA, (3) University of Pennsylvania, Philadelphia, PA, USA, (4) Eli Lilly & Co., (5) Alzheimer Therapeutic Research Institute, Keck School of Medicine, University of Southern California, San Diego, CA, USA

8Ever NeuroPharma, Oberburgau, Austria

Friday, December 9

ORAL COMMUNICATIONS SESSION

Animal Models (continued)

Marina Ballroom DEF - Level 3

ORAL COMMUNICATIONS SESSION

(continued)

Marina Ballroom G - Level 3

9.00 a.m

OC28 - Exogenous infusion of neprilysin induces neuroprotection in Alzheimer's Disease pathology. Potentiation with co-administration of nanowired cerebrolsyin

¹Hari S Sharma, ²José V Lafuente, ³Dafin F Muresanua, ⁴Rudy J Castellani, ⁵Mark A Smith, ⁶Ranjana Patnaik, ⁷z Ryan Tian, ⁷Asya Ozkizilcikb, ⁸Herbert Mösslera, ¹Aruna Sharma

1International Experimental CNS Injury & Repair (IECNSIR), Laboratory of Cerebrovascular Research, Dept. of Surgical Sciences, Anesthesiology & Intensive Care Medicine, Uppsala University Hospital, Sweden, 2Dept of Neurosciences, University of Basque Country, Bilbao, Spain, 3Dept. Clinical Neurosciences, University of Medicine & Pharmacy, Cluj-Napoca, Romania; a"RoNeuro" Institute for Neurological Research and Diagnostic, 37 Mircea Eliade Street, 400364, Cluj-Napoca, Romania, 4University of Maryland, Dept. of Pathology, Baltimore, MD, USA, 5Case Western Reserve Medical University, Dept. of Pathology, Cleveland, OH, USA, 6School of Biomedical Engineering, Dept. of Biomaterials, Indian Institute of technology, Banaras Hindu University, Varanasi, India, 7Dept. Chemistry & Biochemistry & bBiomedical Engineering, University of Arkansas, Fayetteville, AR, USA, 8Ever NeuroPharma, Oberburgau, Austria

9.15 a.m

OC30 - Increased hippocampal vulnerability in transgenic mice overexpressing APP and triple repeat tau

Andrew Arner, BS¹, Edward Rockenstein, BS¹, Michael Mante, BS¹, Jazmin Florio, BS¹, Deborah Masliah, BS¹, Anthony Adame, BS¹, Eliezer Masliah, MD¹, Robert A. Rissman, PhD¹ (1) University of California, San Diego, La Jolla, CA, USA

9.30 a.m

OC32 - Amyvid imaging in a murine model of Alzheimer's Disease (AD) as a non-invasive methodology to evaluate the reduction in beta amyloid plagues after cranial irradiation

Brian Marples PhD¹, Sarah A. Krueger PhD¹, Daniel B. Michael MD PhD², George D. Wilson PhD¹, Alvaro A. Martinez MD³, <u>James Fontanesi</u> MD⁴

(1) Department of Radiation Oncology, Beaumont Health Systems, Royal Oak, MI, (2) Beaumont Neurosurgery, Beaumont Health Systems, Royal Oak, MI; Michigan Head and Spine Institute, (3) 21st Century Oncology of Michigan, Farmington Hills, MI, (4) Department of Radiation Oncology, Beaumont Health Systems, Farmington Hills, MI

OC29 - Serum Protein Biomarkers of δ Fully Mediate Multiple AD Conversion Risks and Offer Targets for Intervention

<u>Donald R. Royall</u>, MD¹⁻⁴, Safa Al-Rubaye¹, Ram Bishnoi¹, Raymond F. Palmer, PhD³

(1) Department of Psychiatry, The University of Texas Health Science Center at San Antonio (UTHSCSA), San Antonio, Texas, USA, (2) Department of Medicine, UTHSCSA, San Antonio, Texas, USA, (3) Department of Family & Community Medicine. UTHSCSA, San Antonio, Texas, USA, (4) South Texas Veterans Health Administration Geriatric Research Education and Clinical Center (GRECC), San Antonio, Texas, USA

OC31 - Aducanumab 24-month data from prime: a Randomized, double-blind, placebo-controlled phase 1B study in patients with prodromal or mild alzheimer's disease

Vissia Viglietta, MD¹, John O'Gorman, PhD¹, Leslie Williams, DVM, MPH¹, Tianle Chen, PhD¹, Ahmed Enayetallah, MBBCh, PhD¹, Ping Chiao, PhD¹, Christoph Hock, MD², Roger M Nitsch, MD², Samantha Budd Haeberlein, PhD¹, Alfred Sandrock, MD, PhD¹

(1) Biogen, Cambridge, MA, USA, (2) Neurimmune, Schlieren-Zurich, and University of Zurich, Switzerland

OC33 - Safety, Tolerability and Pharmacokinetics of ABBV-8E12, a Humanized Anti-Tau Monoclonal Antibody, in a Phase 1, Single Ascending Dose, Placebo-Controlled Study In Subjects with Progressive Supranuclear Palsy

Tim West¹, Joel B. Braunstein¹, Ilana Fogelman¹, Adam L. Boxer², Helen Hu¹, Philip B. Verghese¹, Elizabeth John¹, David M. Holtzman³, Randall J. Bateman³, Bradley Boeve⁴, Yvette M. Bordelon⁵, Jared Brosch⁶, Daniel Claassen⁷, Jason Connor⁸, Erica Driver-Dunckley9, Lawrence S. Honig10, Irene Litvan11, Nick McFarland¹², Erik D. Roberson¹³, Zbigniew K. Wszolek14, Davis Ryman¹⁵, Hana Florian¹⁵, Sandra Goss¹⁵, Diana Kerwin¹⁶ (1) C2N Diagnostics LLC, Saint Louis, MO, USA (2) University of California San Francisco, San Francisco, CA, USA (3) Washington University, St. Louis, MO, USA (4) Mayo Clinic Rochester, Rochester, MN, USA (5) University of California Los Angeles, Los Angeles, CA, USA (6) Indiana University, Indianapolis, IN, USA (7) Vanderbilt University, Nashville, TN, USA (8) Berry Consultants, LLC, Austin, TX, USA (9) Mayo Clinic Arizona, Scottsdale, AZ, USA (10) Columbia University, New York, NY, USA (11) University of California San Diego, San Diego, CA, USA (12) University of Florida, Gainesville, FL, USA (13) University of Alabama at Birmingham, Birmingham, AL, USA (14) Mayo Clinic Florida, Jacksonville, FL, USA (15) AbbVie Inc, North Chicago, IL, USA (16) Texas Health Presbyterian Hospital, Dallas, TX, USA

Clinical Trials 000 Alzheimer S ISe as

CTAD 2016 Program



Friday, December 9

ORAL COMMUNICATIONS SESSION

Marina Ballroom DEF - Level 3

ORAL COMMUNICATIONS SESSION

Marina Ballroom G - Level 3

9.45 a.m

OC34 - BACE Inhibitor CNP520 proposed for the **Alzheimer's Prevention Initiative Generation Study** Ulf Neumann¹, Fonda Liu², Marie-Laure Rouzade-Dominguez¹,

Marie-Emmanuelle Riviere3, Mike Ufer1, Gunilla Huledal1, Nicole Pezous¹, Derya Shimshek¹, Carine Kolly¹, Ronald G. Thomas⁴, Angelika Caputo³, Jessica B. Langbaum⁵, Pierre N. Tariot⁵, Eric M. Reiman⁵, Ana Graf³, Cristina Lopez Lopez³ (1) Novartis Institutes for Biomedical Research, Basel, Switzerland, (2) Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA, (3) Novartis Pharma AG, Basel, Switzerland, (4) University of California San Diego, San Diego, USA, (5) Banner Alzheimer's Institute, Phoenix, OC35 - Effects of a Combined Transcranial Magnetic Stimulation (TMS) and Cognitive Training in Alzheimer Patients: Results of Medical Device **Pivotal Multi-Center Study**

Marwan N. Sabbagh MD1; Alvaro Pascual-Leone; MD PhD2; Carl H. Sadowsky, MD3; Babak Tousi, MD4; Marc E. Agronin, MD⁵; Gustavo Alva, MD⁶; Carmel Armon, MD⁷; Charles Bernick, MD8; Andrew P. Keegan, MD9; Stella Karantzoulis, PhD10

(1) Barrow Neurological Institute, Phoenix AZ USA, (2) Berenson-Allen Center for Noninvasive Brain Stimulation and Division of Cognitive Neurology, Department of Neurology, Beth Israel Deaconess Medical Center, Harvard Medical School, MA, (3) Department of Neurology, Nova SE University, Ft Lauderdale, FL, (4) Lou Ruvo Center for Brain Health Cleveland Clinic, Neurological Institute, Cleveland, OH, (5) Mental Health and Clinical Research, Miami Jewish Health Systems, Miami, FL, (6) ATP Clinical Research, Costa Mesa, CA, (7) Department of Neurology, Assaf Harofeh Medical Center, Zerifin, Israel, (8) Lou Ruvo Center for Brain Health, Cleveland Clinic, Las Vegas, NV, (9) Roskamp Institute Clinic, Sarasota, FL, (10) Alzheimer's Disease Center, Center for Cognitive Neurology, New York University Langone Medical Center, New York, NY

10.00 a.m

Coffee Break and poster sessions 2

San Diego Ballroom - Lobby Level

10.30 a.m

SYMPOSIUM 3

Stem cells for Alzheimer's disease therapeutics

Marina Ballroom DEF - Level 3

Chairs: Michael Schöll, Duygu Tosun

Brain Networks

ORAL COMMUNICATIONS SESSION

College, New York City, NY, USA

Marina Ballroom G - Level 3

Moderator: Lon S. Schneider, MD, Keck School of Medicine of the University of Southern California, USA

1. Stem cells for Alzheimer's disease: Abeta amyloidosis, tau pathology and gut microbiota Tristan Bolmont, PhD1,2, Alexei Lukashev, PhD2, Nikolai Tankovich, MD, PhD²

(1) Ecole Polytechnique Federale de Lausanne, Lausanne, Switzerland, (2) Stemedica International, Lausanne, Switzerland and San Diego, USA

2. Clinical development for mesenchymal stem cells

Barry Baumel, MD1 (1) University of Miami, Miami, USA

- 3. Phase 2a trial of allogeneic human mesenchymal stem cells for Alzheimer disease Aimee Pierce, MD, UCI, Irvine, USA
- 4. Discussion: Accelerating stem cell trials for Alzheimer's disease Lon S. Schneider, MD

a.m

10.30

a.m

OC37 - Early- and late-onset Alzheimer's disease show distinct tau pathology as examined with 18F-AV-1451 tau positron emission tomography

OC36 - Predicting Onset and Spatiotemporal

Spread of AD Tau Pathology using Graph

Diffusion Modeling on Intrinsic Structural

Duygu Tosun, PhD1,2, Roksana Sadeghi, MS2,

Ashish Raj, PhD, and Michael Weiner1,2, MD, for the

(1) Department of Radiology, University of California

Neurodegenerative Diseases, San Francisco, CA, USA, (3) Computer Science in Radiology, Weill Cornell Medical

San Francisco, CA, USA, (2) Center for Imaging of

Alzheimer's Disease Neuroimaging Initiative

Michael Schöll^{1,2}, Philip Insel^{1,3}, Olof Strandberg¹, Niklas Mattsson^{1,3}, Thomas Ohlsson, PhD⁴, Douglas Hägerström⁵, Jonas Jögi⁶, Ruben Smith³, Oskar Hansson^{1,7}

1 Lund University, Clinical Memory Research Unit, Department of Clinical Sciences, Malmö, Sweden, 2 MedTech West and the University of Gothenburg, Division of Clinical Neuroscience, Gothenburg, Sweden, 3 Skåne University Hospital, Department of Neurology, Lund, Sweden, 4 Skåne University Hospital, Department of Radiation physics. Lund, Sweden, 5 Skåne University Hospital, Department of Clinical Neurophysiology, Lund, Sweden, 6 Skåne University Hospital, Department of Clinical Physiology and Nuclear Medicine, Lund, Sweden, 7 Skåne University Hospital, Memory Clinic, Malmö, Sweden

10.45

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Friday, December 9

10.30 a.m	SYMPOSIUM 3	ORAL COMMUNICATIONS SESSION	
	Stem cells for Alzheimer's disease therapeutics (continued) [Marina Ballroom DEF - Level 3]	(continued) Marina Ballroom G - Level 3	
	(CONTINUED) [Marina Ballroom DEF - Level 3]	11.00 a.m OC38 - NILVAD: A European multicentre double-blind controlled phase III trial of Nilvadipine in mild to moderate Alzheimer's disease Brian Lawlor¹, Sean Kennelly¹, Sarah ODwyer¹, Fiona Cregg², Cathal Walsh², Robert Coen¹, Rose Anne Kenny¹, Robert Howard³, Caroline Murphy³, Jessica Adams³, Leslie Daly⁴, Ricardo Segurado⁴, Siobhan Gaynor⁵, Fiona Crawford⁶, Michael Mullan⁶, Ugo Lucca², Florence Pasquier⁶, Laetitia Breuilh⁶, Matthias Riepe՞, Janos Kalman¹o, Anders Wallin¹¹, Anne Borjesson¹¹, William Molloy¹², Magda Tsolaki¹³, Marcel Olde Rikkert¹⁴ 1 Mercer's Institute for Research on Ageing, St. James's Hospital, Dublin, Ireland, 2 Trinity College Dublin (TCD), Dublin, Ireland, 3 King's College London (KCL), London, UK 4 University College Dublin (UCD), Dublin, Ireland, 5 Molecular Medicine Ireland (MMI), Dublin, Ireland, 5 Molecular Medicine Ireland (MMI), Dublin, Ireland, 5 Archer Pharmaceuticals Inc, 2040 Whitefield Avenue, Sarasota, Florida, USA, 7 IRCCS—Istituto di Ricerche Farmacologiche "Mario Negri" (IRFMN), Milan, Italy, 8 Centre Hospitalier Regional et Universitaire de Lille (CHRU- LILLE), Lille, France, 9 Universitaire de Lille (CHRU- LILLE), Lille, France, 9 Universitaire (UGOT), Gothenburg, Sweden, 12 University College Cork (UCC), Cork, Ireland, 13 Aristotle University of Thessaloniki (AUTH), Greece, 14 Radboud Alzheimer Centre; Radboud University Medical Centre, Nijmegen, The Netherlands	
		11.15 a.m OC39 - Cognitive Improvement in Mild to Moderate Alzheimer's Patients: Preliminary Results of an Open Label, Phase 2A Study of T3D-959 John Didsbury, PhD¹; Suzanne de la Monte, MD² (1) T3D Therapeutics, Inc., Research Triangle Park, NC, USA, (2) Neurology Department, Rhode Island Hospital and the Warren Alpert Medical School of Brown University, Providence, RI, USA	
11.30 a.m	ORAL COMMUNICATIONS SESSION Chairs: Marco Bozzali, Michael Rafii Marina Ballroom DEF - Level 3	ORAL COMMUNICATIONS SESSION Chairs: Nathalie Compagnone, Craig Ritchie Marina Ballroom G - Level 3	
11 30 a m	OC40 - Tau PET imaging in Alzheimer's disease and	OC41 - Regions of initial amyloid-R accumulation in	

11.30 a.m

OC40 - Tau PET imaging in Alzheimer's disease and

other tauopathies

Ruben Smith¹, Tomas Ohlsson², <u>Michael Schöll</u>³, Martin Schain³, Andreas Hahn⁴, Olof Strandberg³, Jonas Jögi⁵, Oskar Hansson^{1,6}

1 Department of Neurology, Skåne University Hospital, Lund, Sweden, 2 Department of Radiation Physics, Skåne University Hospital, Lund, Sweden, 3 Clinical Memory Research Unit, Department of Clinical Sciences, Malmö, Lund University, Sweden, 4 Department of Psychiatry and Psychotherapy, Medical University of Vienna, Austria, 5 Department of Clinical Physiology and Nuclear Medicine, Skåne University Hospital, Lund, Sweden, 6 Memory Clinic, Skåne University Hospital, Malmö, Sweden

OC41 - Regions of initial amyloid-ß accumulation in Alzheimer's disease

<u>Sebastian Palmqvist</u>, MD, PhD^{1*}, Michael Schöll PhD^{1,2,3*}, Olof Strandberg PhD¹, Niklas Mattsson MD, PhD¹, Erik Stomrud MD, PhD¹, the Alzheimer's Disease Neuroimaging Initiative, the Swedish BioFINDER study, William Jagust, MD, PhD³, Susan Landau MD, PhD³, Oskar Hansson MD, PhD¹

1Lund University, Faculty of Medicine, Department of Clinical Sciences in Malmö, Clinical Memory Research Unit, Lund, Sweden, 2Gothenburg University, MedTech West and the Department of Clinical Neuroscience, Gothenburg, Sweden, 3University of California, Berkeley, Helen Wills Neuroscience Institute, Berkeley, California, USA



Friday, December 9

ORAL COMMUNICATIONS SESSION

Marina Ballroom DEF - Level 3

ORAL COMMUNICATIONS SESSION

Marina Ballroom G - Level 3

11.45 a.m

OC42 - PET Imaging of Tau Deposition in Down Syndrome: Results from the Down Syndrome Biomarker Initiative (DSBI)

Michael S. Rafii, MD, PhD^{1,2}, Ana S. Lukic, PhD³, Randolph D. Andrews³, MD, Robert A. Rissman², PhD, James B. Brewer², MD, PhD, William C. Mobley, MD, PhD², Seth Ness, MD, PhD⁴, Dawn C. Matthews, MS³

1 Alzheimer's Therapeutic Research Institute, University of Southern California, San Diego CA, 2 Department of Neurosciences, University of California, San Diego, La Jolla CA, 3 ADM Diagnostics, LLC, Chicago, IL, 4 Janssen Research and Development, LLC, Titusville, NJ

12.00 p.m

OC44 - The neurobiological substrates of dynamic cognitive reserve

Laura Serra PhD¹, Michela Bruschini PhD¹, Camillo Marra MD², Carlo Caltagirone MD³, Mara Cercignani PhD⁵, Marco Bozzali MD¹

1Neuroimaging Laboratory, Santa Lucia Foundation, IRCCS, Rome, Italy, 2 Institute of Neurology, Catholic University, Rome, Italy, 3Department of Clinical and Behavioural Neurology, Santa Lucia Foundation, IRCCS, Rome, Italy, 4Department of Neuroscience, University of Rome 'Tor Vergata', Rome, Italy, 5Brighton & Sussex Medical School, CISC, University of Sussex, Brighton, Falmer, UK

12.15 p.m

OC46 - An Assessment of Dependence Level Progression Using A Conversion Algorithm of ADCS-ADL to Dependence Scale and Data From a Double Blind Placebo Controlled Trial of Intepirdine (RVT-101)

<u>Ebenezer Asare</u>, MD¹; Carolyn Zhu PhD²; Yaakov Stern PhD³; Lawrence Friedhoff, MD PhD¹

(1) Axovant Sciences NY, NY, (2) Department of Geriatrics and Palliative Medicine, Icahn School of Medicine at Mount Sinai, NY, NY, (3) Cognitive Neuroscience Division, Department of Neurology and Taub Institute, Columbia University College of physicians and Surgeons NY, NY

OC43 - Xanamem™: an 11ß-HSD1 Inhibitor in current development for the management of Alzheimer's disease (AD)

Craig Ritchie MD PhD

Centre for Dementia Prevention, University of Edinburgh. UK

OC45 - Effectiveness of AlzU.org on Alzheimer's disease prevention clinical trial recruitment, registry enrollment and advocacy

Richard S. Isaacson, MD, ¹ Mark McInnis, BA, ¹ Bryant F. Ly, BA, ¹ Genevieve LaBelle, MS, ¹ Ciara N. Gaglio, BA, ¹ Jason Goldstein, BM, ¹ Nicole Haynes, BS, ¹ Chiashin Shih, PhD, ¹ Jessica Shum, BS, ¹ Katherine Hackett, BA, ¹ Jaclyn Chen, BS, ¹ Candace Haddox, MD, ² Max Lugavere, BS, ¹ Josefina Meléndez-Cabrero, PhD, ³ Matthew W. Schelke, BA, ¹ Mu Ji Hwang, ⁴ Cara Berkowitz, BA, ¹ Emily Caesar, BS, ¹ Alon Seifan, MD, MS, ⁵

(1) Weill Cornell Medicine, New York, NY, USA, (2) Mayo Clinic, Rochester, MN, USA, (3) Alzheimer's Prevention Clinic and Research Center, San Juan PR, USA, (4) Weill Cornell Medicine – Qatar, Doha, QATAR, (5) Nova Southeastern University, FL, USA

OC47 - Validation of ADFlag®, a diagnostic bloodtest for pre-dementia stages of Alzheimer's disease

Beatrice Blanc, PhD2,3, Nicolas Pelletier PhD1,2, Clotilde Biscarrat¹, Pauline Martinasso¹, Samantha Galluzzi, MD⁴ Moira Marizzoni PhD4, Jorge Jovicich PhD4,6, Giovanni B. Frisoni MD^{4,5}, Gianluidgi Forloni PhD⁷, Diego Albani MSc⁷, Jill Richardson PhD8, Lucilla Parnetti MD, PhD9, Magda Tsolaki MD, PhD¹⁰, Flavio Nobili MD¹¹, David Bartrez-Faz PhD¹², Mira Didic MD¹³, Peter Schoenknecht MD¹⁴, Pierre Payoux, MD, PhD¹⁴, Andrea Soricelli MD16, Paolo M Rossini MD, PhD17, Pieter Jelle Visser MD¹⁸, Regis Bordet MD, PhD¹⁹, Ute Fiedler PhD²⁰, Olivier Blin MD, PhD²¹, Julien Dupouey MD^{2,21}, Joëlle Micallef²², Laura Lanteaume²², Nathalie Sambuchi, PhD²³, Isabelle Muraccioli²³, Bernard Michel, MD, PhD²³, Nathalie Compagnone, PhD^{1,2,3} (1) ICDD, Translational Med. Dept, (2) ICDD, Pharmacog Project Mgmt., (3) ICDD, Diagnostic Dept Gemenos, France; (4) IRCCS Fatebenefratelli, Brescia, Italy; (5) University Hospitals, Geneva, Switzerland; (6) Center for Mind/Brain Sciences, University of Trento, Trento, Italy; (7) Department of Neuroscience, Mario Negri Institute for Pharmacological Research, Milan, Italy; (8) GlaxoSmithKline R&D, Stevenage, UK; (9) Ospedale Santa Maria della Misericordia, Perugia, Italy; (10) G. Papanikolaou Hospital, Aristotle, Thessaloniki, Greece; (11) University of Genoa, Genoa, Italy; (12) IDIBAPS, Barcelona, Catalunya, Spain; (13) APHM Hôpital Timone Adultes, Marseille, France; (14) University of Leipzig, Leipzig, Germany; (15) CHU de Toulouse, Toulouse, France; (16) SDN Istituto di Ricerca Diagnostica e Nucleare, Naples, Italy; (17) Catholic University, Rome, Italy; (18) VU Medical Centre, Amsterdam, the Netherlands; (19) University of Lille, Inserm, U1171 Lille, France; (20) Faculty of Medicine, LVR-Hospital Essen, University of Duisburg-Essen, Essen, Germany; (21) Aix-Marseille Univ., Marseille, France; (22) CHU la Timone, Marseille, France; (23) Hôpital Sainte Marguerite, Marseille, France

12.30 p.m Lunch Break and poster sessions 2

Friday, December 9

1.30 p.m

KEYNOTE 4

Marina Ballroom DEFG - Level 3

What have we learned and what can we expect from brain imaging for Alzheimer trials

Introduction: Reisa Sperling

Nick Fox, Dementia Research Centre, UCL's Institute of Neurology, London, UK

2.00 p.m

PRESENTATION AND PANEL DISCUSSION

Marina Ballroom DEFG - Level 3

Re-Evaluation of the NIA-AA Guidelines for Alzheimer's Disease

Chairs: Maria Carillo, Mike Weiner

Clifford R. Jack, Jr. MD.¹, David A. Bennett, MD.², Kaj Blennow, MD., PhD.³, Maria C. Carrillo, PhD.⁴, Cerise Elliott, PhD.⁵, Samantha Budd Haeberlein, MD.⁶, David Holtzman, MD., PhD.¹, William Jagust, MD.⁶, Frank Jessen, MD.⁶, Jason Karlawish, MD.¹₀, Enchi Liu, PhD.¹¹, Jose Luis Molinevo, MD.¹², Thomas Montine, MD.¹³, Creighton Phelps, PhD.⁵, Katherine P. Rankin, PhD.¹⁴, Christopher Rowe, MD.¹⁵, Philip Scheltens, MD.¹⁶, Eric Seimers, MD.¹७, Heather M. Snyder, PhD.⁴, Reisa Sperling, MD.¹⁶ (1) Radiology Department, Mayo Clinic, Rochester, MN, USA, (2) Neurology Department, Rush University Medical Center, Chicago, IL, USA, (3) Clinical Neurochemistry Laboratory, Sahlgrenska University Hospital, Mölndal, Sweden, (4) Medical & Scientific Relations, Alzheimer's Association, Chicago, IL, USA, (5) Division of Neuroscience, National Institute on Aging, National Institutes of Health, Bethesda, MD, USA, (6) Biogen idec, Cambridge, MA, USA, (7) Department of Neurology, Washington University, St Louis, MO, USA, (8) Department of Neurology, University of California, Berkley, Berkley, CA, USA, (9) Department of Psychiatry, University of Cologne, Cologne, Germany, (10) Departments of Medicine, Medical Ethics and Health Policy, and Neurology, University of Pennsylvania, Philadelphia, PA, USA, (11) Prothena Corporation, San Francisco, CA, USA, (12) Department of Neurology, ICN Hospital Clinic i Universitari and Pasqual Maragall Foundation, Barcelona, Spain, (13) Department of Pathology, Stanford University, Palo Alto, CA, USA, (14) Department of Neurology, University of California San Francisco, San Francisco, CA, USA, (15) Department of Neurology, University of Melbourne, Melbourne, Australia, (16) Alzheimer Center, VU University Medical Center, Amsterdam, Netherlands, (17) Biomedicines Business Unit, Alzheimer's Disease Platform Team, Eli Lilly and Company, (18) Department of Neurology, Harvard Medical School, Brigham and Women's Hospital and Massachusetts General Hospital, Boston, MA, USA

2.30 p.m

SYMPOSIUM 4

Marina Ballroom DEF - Level 3

Marina Ballroom G - Level 3

The European Prevention of Alzheimer's Dementia (EPAD) Programme: From Readiness Cohort to Clinical Trial and the ethical framework for risk disclosure

Moderator: Jose Luis Molinuevo, BBRC, Barcelona, Spain

1. Ensuring that the EPAD Readiness Cohort remains 'fit for purpose'

<u>Craig Ritchie</u> MD, PhD¹, Lisa Vermunt MD², Alina Soloman MD, PhD³, Luc Truyen MD, PhD⁴, Andrew Satlin MD, PhD⁵, Jose Luis Molinuevo MD, PhD⁶, Graciela Muniz Terrera MD¹, Brian Tom PhD²

(1) University of Edinburg, Scotland; (2) VUMC, Amsterdam, Netherlands; (3) Karolinska Institute, Stockholm, Sweden. (4) Janssen, Titusville, NJ, USA (5) Eisai Pharmaceuticals, Woodcliff Lake, NJ, USA. (6) BBRC, Barcelona, Spain (7) MRC Biostatistics Unit, University of Cambridge, UK

2. The EPAD Proof of Concept Trial: A Master Protocol for Increasing Efficiency

Scott Berry PhD¹, Shobha Dhadda PhD², Vlad Dragalin PhD³, Mark Fitzgerald PhD¹, Philip Hougaard PhD⁴, Melanie Quintana PhD¹, Kyle Wathan³

(1) Berry Consultants Ltd, Austin, Texas, USA (2) Eisai Pharmaceuticals, Woodcliff Lake, NJ, USA (3) Janssen, Titusville, NJ, USA (4) Lundbeck, Copenhagen, Denmark

3. From parent cohort to clinical trial in EPAD; the ethics of a stepped approach to disclosure and risk communication

Richard Milne¹, Ana Diaz⁴, Sonja Bemelmans PhD², Krista Tromp³, Eline Bunnik PhD³, Dianne Gove⁴, Shirlene Badger PhD¹, Edo Richard MD PhD², Marianne Maman⁵, Maartje Schermer³, Luc Truyen MD, PhD⁶, Carol Brayne PhD¹ (1) University of Cambridge, UK (2) Radboud University, Netherlands (3) Erasmus University, Netherlands (4) Alzheimers Europe, Luxembourg (5) Novartis, Bern, Switzerland (6) Janssen, Titusville, NJ, USA

WORKSHOP

New Trends in Clinical Trial Designs In Search of

Next Generation Treatments

Part I: Assessing a potential disease modifying effect: Delayed Start Design and Analysis

Paul Aisen, MD

Alzheimer's Therapeutic Research Institute, University of Southern California, San Diego, CA, USA

One of the key interests in developing the next generation AD treatments is demonstrating a potential disease modifying effect. Delayed start design has been proposed as a viable clinical trial design to assess whether an observed treatment effect is due to symptomatic effect or disease modifying effect. This approach was endorsed in the FDA draft guidance for clinical development of AD drugs. This short course will introduce the background of the Delayed Start design, provide key considerations of design elements, and describe novel statistical analysis methods and interpretation of results. Examples from actual clinical trials in AD that have implemented the design and analysis will be shared. There will be time for Q&A and interactions with participants.

3.30 p.m

Coffee Break and poster sessions 2

San Diego Ballroom - Lobby Level

Clinical Trials on Alzheimer's Disease

CTAD 2016 Program



Friday, December 9

4.00 p.m	PRESENTATION Marina Ballroom DEF - Level 3 AND PANEL DISCUSSION 'Subject Enrollment' – A major barrier for developing treatments for dementia/Alzheimer's
	[A 'Town-Hall' discussion on a proposal for a national campaign to raise public awareness] Weiner, M.W. 1, Carrillo, M.C. 2, Ryan, L.M. 3, Budd-Haeberlein, S.L. 4, Potter, W.Z. 5, and Khachaturian, Z.6. (1) Center for Imaging of Neurodegenerative Diseases, San Francisco VAMedical Center, San Francisco, CA, USA, (2) Alzheimer's Association, Chicago, IL, USA, (3) National Institute on Health / National Institute on Aging (NIH/NIA), Bethesda, MD, USA, (4) Biogen Corporation, Biogen, Cambridge, MA, USA, (5) National Institute of Mental Health (NIMH), Bethesda, MD, USA, (6) Editor in Chief, Alzheimer's & Dementia. Rockville MD, USA
4.30 p.m	ORAL COMMUNICATIONS SESSION Chairs: Susan Abushakra, Rema Raman [Marina Ballroom DEF - Level 3]
4.30 p.m	OC48 - Tramiprosate efficacy in APOE4 carriers with mild to moderate AD: sensitivity analyses by baseline severity suggest large effects in homozygous subjects with mild AD S. Abushakra¹, J. A. Hey¹, A. Power¹, P. Wang², L. Shen², S. Hendrix³, S. Gauthier⁴, B. Vellas⁵, A. Porsteinsson⁶, M. Kivipelto⁷, M. Tolar¹ 1 Alzheon Inc., Boston, MA, USA; 2 Pharmapace Inc., San Diego, CA; 3 Pentara Corporation, Salt Lake City, Utah; 4 McGill University and Montreal Neurological Institute, Montreal, Canada; 5 University of Toulouse, Toulouse, France; 6 University of Rochester, Rochester, NY, 7 Karolinska University Hospital, Stockholm, Sweden
4.45 p.m	OC49 - The effect of APOE genotype and low CSF Abeta 42 on DHA brain bioavailability in Alzheimer's disease Hussein N. Yassine¹, Wendy J. Mack², Joseph F. Quinn³, Karin Yurko-Mauro⁴, Eileen Bailey-Hall⁴, Paul S. Aisen⁵, Helena C. Chui⁶, Lon S. Schneider⁶.7 1Department of Medicine, Keck School of Medicine, University of Southern California, Los Angeles, USA, 2Department of Preventive Medicine, Keck School of Medicine, University of Southern California, Los Angeles, USA, 3Department of Neurology, Oregon Health and Science University, 4Clinical Research Department, DSM Nutritional products, Columbia, MD, USA, 5Alzheimer's Therapeutic Research Institute, University of Southern California, Los Angeles, USA, 6Department of Neurology, Keck School of Medicine, University of Southern California, Los Angeles, USA, 7Department of psychiatry and the behavioral sciences, Keck School of Medicine of the University of Southern California, Los Angeles, USA
5.00 p.m	OC50 - Highly specific modification of tau phosphorylation stoichiometry in AD CSF impacts T217, S199, S202 and T205 sites but not T181 Nicolas R. Barthélemy, PhD¹, Audrey Gabelle, MD, PhD², Chihiro Sato, PhD¹, Randall J. Bateman, MD¹, Sylvain Lehmann, MD, PhD² 1. Neurology Department, Washington University School of Medicine, St. Louis MO, USA, 2. CHU Montpellier, Montpellier, France

OC51 - Individualized trajectories in pre-symptomatic and prodromal AD: subject-specific Jack curves

Robin Wolz, PhD^{1,2}, Adam J. Schwarz, PhD³, Ricardo Guerrero,

1.IXICO Plc, London, UK, 2.Imperial College London, London, UK, 3.Eli Lilly and

estimated using statistical models

PhD1,2, Derek Hill, PhD1

Company, Indianapolis, USA

5.15 p.m

WORKSHOP (continued)

Marina Ballroom G - Level 3

Part II: Controlling for false positive findings among primary and key secondary outcomes: Multiple Testing Procedures

Steve Ruberg, PhD Eli Lilly and Company, Indianapolis, IN, USA

As the AD field is exploring earlier stages of the disease in searching for an effective treatment that alters the underlying disease pathology and slows or prevents the disease progression, special considerations need to be given to the most appropriate primary and secondary endpoints in clinical trials. This in turn presents the needs to control for false positive findings (Type I errors) for label implications and the subsequent technical challenge of how to control for multiple comparisons among primary and key secondary endpoints. Various statistical methods for controlling for multiple comparisons have been established and have been implemented in many other therapeutic areas. In this short course, an overview of the multiple testing strategies will be provided including logical explanations without the math. Various approaches will be described that may be appropriate for future AD trials, such as fixed sequence approach and more flexible and visual approaches. There will be time for Q&A and interactions with parsticipants

Friday, December 9

	ORAL COMMUNICATIONS SESSION (continued)	Marina Ballroom DEFG - Level 3
5.30 p.m	OC52 - Clinical Trials in CTE – Moving Ahead	
	Charles Bernick, MD, MPH, Cleveland Clinic, USA	
5.45 p.m	OC53 - Computerized iPad Cognitive Testing using NIH Toolbox & Cogsta Dorene M. Rentz PsyD ^{1,2,3} , Rachel F. Buckley PhD ^{1,2,4,5} , Kathryn P. Sparks BA ^{1,2} , Maria Sherman BA ¹ , Sarah Aghjayan BA ^{1,2} , Samantha Burnham PhD ⁷ , Reisa A. Sperling, MD ^{1,4} (1) Department of Neurology, Massachusetts General Hospital, Boston, Massachusetts, USA, (2) Department of Nassachusetts, USA, (3) Harvard Medical School, Boston, Massachusetts, USA, (4) Florey Institutes of Neurosci Melbourne School of Psychological Sciences, University of Melbourne, Australia, (6) Northeastern University, Boston, and Industrial Research Organization, Perth, Australia	Dekhtyar BA ^{1,2} , Courtney Martin ⁶ , Julia ,2,3 Neurology, Brigham and Women's Hospital, Boston, rience and Mental Health, Melbourne, Australia, (5)
6.00 p.m	OC54 - What is the best question? The Functional Activity Questionnaire reduction Intervention trial (SPRINT) and SPRINT-MIND Alan J. Lerner¹, Gordon Chelune², Carolyn Harmon-Still¹, Steve Rapp³, Kaycee Sink⁴, Virg Pajewski⁶ 1. Departments of Neurology and Medicine, Case Western Reserve University, Cleveland, OH, 2. Center for Alzheims Salt Lake City, UT, 3. Department of Psychiatry, Wake Forest School of Medicine, Winston-Salem, NC, 4. Department of Winston-Salem, NC, 5. Department of Medicine, UAB School of Medicine, Birmingham, AL, 6. Biostatistical Sciences, National Control of Medicine, UAB School of Medicine, Birmingham, AL, 6. Biostatistical Sciences, National Control of Medicine, UAB School of Medicine, Birmingham, AL, 6. Biostatistical Sciences, National Control of Medicine, UAB School of Medicine, Birmingham, AL, 6. Biostatistical Sciences, National Control of Medicine, UAB School of Medicine, Birmingham, AL, 6. Biostatistical Sciences, National Control of Medicine, UAB School of Medicine, Birmingham, AL, 6. Biostatistical Sciences, National Control of Medicine, UAB School of Medic	ginia Wadley ⁵ , Jeff Williamson ⁴ , Nicholas er's Care, Imaging and Research, University of Utah of Internal Medicine, Wake Forest School of Medicine,



Saturday, December 10

7.30 a.m	ORAL COMMUNICATIONS SESSIONS Chairs: Pierre-Jean Ousset, Lynne Shinto	Marina Ballroom DEFG - Level 3
7.30 a.m	OC55 - 36 Weeks of Treatment with PXT-864 in Mild Alzheimer's of Extension Study Jacques Touchon, MD PhD¹, Pierre-Jean Ousset, MD², Florence Pasquier, MD, MD, PhD⁵, Sophie Auriacombe, MD⁶, Jean-Marc Orgogozo, MD, PhD⁶, Jacques h Viviane Bertrand, PhDঙ, Rodolphe Hajj, PhDঙ, Peter Schmitt, MScঙ, Mickaël Gt Goedkoop, MDঙ (1) University of Montpellier, France, (2) Alzheimer's Disease Clinical Research Centre, Gérontopôle, Toulou Hospital Lille, France, (4) Univ Lille, U1171, Distalz, Memory Resources and Research Centre, Lille, Franc Sophia Antipolis, Nice, France, (6) Memory Research Resource Centre for Alzheimer's disease, University Hos CMRR Paris Nord Ile-de-France, Saint Louis-Lariboisiere, Fernand Widal Hospital, AP-HP, Paris, France, (8)	PhD³, Claude Guériot, MD⁴, Philippe Robert, Hugon, MD, PhD7, Anne-Claire Coyne, PhD8, uedj, PhD8, Daniel Cohen, MD, PhD³, René se University Hospital, France, (3) Memory Clinic, University e, (5) Memory Centre CHU -EA CobTeK, University of Nice spital Pellegrin, Bordeaux, France, (7) Memory Clinical Centre
7.45 a.m	OC56 - Unique methodology for a Phase 2 clinical trial evaluating of vascular cognitive impairment <u>Lynne Shinto</u> , ND, MPH¹, Lisa Silbert, MD¹, Hiroko Dodge, PhD¹.², Joseph Quinr MS¹, Diane Howieson, PhD¹, Jeffrey Kaye, MD¹, Gene Bowman, ND, MPH³.¹ (1) Neurology Department, Oregon Health & Science University, Portland, OR, USA, (2) Neurology Department and Brain Health, Nestle Institute of Health Sciences, EPFL campus, Lausanne, Switzerland	n, MD¹, Ashely Bailey, MS¹, Chad Murchison,
8.00 a.m	OC 57 - Prediction of conversion from mild cognitive impairment blood exosome protein profile Charisse N. Winston, PhD¹, Edward J. Goetzl, MD², Jonny Akers, PhD¹, Bob S. C Douglas R. Galasko, MD¹, Eliezer Masliah, MD¹, Robert A Rissman, PhD¹ (1) University of California, San Diego, La Jolla, CA, USA, (2) Jewish Home of San Francisco, San Francisco	Carter, MD, PhD¹, Edward Rockenstien, PhD¹,
8.15 a.m	OC58 - Outcomes of a 3-years, multicenter, randomized double-blin assess safety and efficacy of low-dose LADOSTIGIL in patients with Lon S. Schneider, MD¹, Yona Geffen, PhD², Reinhold Schmidt, MD³, Stefan Ropel Rabinowitz, PhD⁵, Martha Weinstock-Rosin, PhD⁶ (1) Keck School of Medicine of USC, Los Angeles, CA, USA, (2) Avraham Pharmaceuticals, Ltd, Yavne, Is California, San Diego, CA, USA, (5) Bar Ilan University, Ramat Gan, Israel, (6) Hebrew University, Jerusalem,	n Mild Cognitive Impairment le, PhD³, Ronald G. Thomas, PhD⁴, Jonathan srael, (3) Medical University, Graz, Austria, (4) University of
8.30 a.m	OC59 - Identification of Asymptomatic Individuals at Risk of Alz Observational Substudy as a True Historical Control to Identify Risk Nzeera Ketter ¹ , Nandini Raghavan ¹ , Ziad Saad ¹ , Chi Udeh-Momoh ^{2,3} ,, Martin Co Meeh ¹ , Dolores Szemborski ¹ , Robert Perneczky ² , Steve Einstein ¹ , Gary Romano ¹ (1) Janssen Neuroscience LLC, New Jersey, USA, (2) Neuroepidemiology and Ageing research unit, Imperial Bristol University, Bristol, UK	k Factors for Amyloid Pathology ohn², Nina Mansoor², Michael Arrighi¹, Sherry and Lefkos Middleton²
8.45 a.m	OC60 - 9-Months and 12-Months Safety and Exploratory Efficacy Dat in Mild-to-Moderate Alzheimer's Disease Patients Stephen Macfarlane, MD¹, Marco Cecchi, PhD², Paul Maruff, PhD³, Kristina M Kap (1) Caulfield Hospital, Melbourne, Australia, (2) Neuronetrix, Louisville, KY, USA, (3) Cogstate Ltd., Melbourn USA	piak ⁴ , Christopher U Missling, PhD ⁴
9.00 a.m	KEYNOTE 5 Alzheimer's disease: from Proteinopathy to Prevention Introduction: Zaven Khachaturian Randall Bateman, Washington University School of Medicine, St.Louis, MO, USA	Marina Ballroom DEFG - Level 3
9.30 a.m	ORAL COMMUNICATIONS SESSION Chairs: Emily Edmonds, Michael Egan	Marina Ballroom DEFG - Level 3
9.30 a.m	OC61 - Removal of subjects with a "false positive" diagnosis of Alzheimer's Disease Cooperative Study (ADCS) donepezil trial strent Emily C. Edmonds, PhD ^{1,2} , M. Colin Ard, PhD ³ , Steven D. Edland, PhD ^{3,4} , David P. W. Bondi, PhD ^{1,2} (1) Department of Psychiatry, University of California, San Diego, CA, USA, (2) Veterans Affairs San Diego, CA, Preventative Medicine, University of California, San Diego, CA, USA	ngthens positive effects Salmon, PhD³, Douglas R. Galasko¹.2.³, Mark Healthcare System, San Diego, CA, USA, (3) Shiley-Marcos
9.45 a.m	OC62 - The Montreal Cognitive Assessment (MoCA) in 8,724 SPRINT a screening tool in clinical trials Kaycee M Sink, MD, MAS ⁽¹⁾ ; Gordon Chelune, PhD ⁽²⁾ ; Laura Coker, PhD ⁽¹⁾ ; Sara Nichols, PhD ⁽⁴⁾ ; Nick M Pajewski, PhD ⁽¹⁾ ; Steve Rapp, PhD ⁽¹⁾ ; Virginia Wadley, Pl 1. Wake Forest School of Medicine, Winston-Salem, NC, USA 27157, 2. University of Utah, 3. Case Western of AlabamaA, USA	th Gaussoin, MS ⁽¹⁾ ; Alan Lerner, MD ⁽³⁾ ; Linda hD ⁽⁵⁾ ; Jeff Williamson, MD ⁽¹⁾

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Saturday, December 10

9.30 a.m	ORAL COMMUNICATIONS SESSION (continued) Marina Ballroom DEFG - Level 3	
10.00 a.m	OC63 - Effect of symptoms of depression on tau pathology in asymptomatic elderly individuals and individuals with early AD symptomology Duygu Tosun, PhD ^{1,2} , Scott Mackin ^{2,3} , PhD, Mitzi M. Gonzales, PhD ⁴ , David Bickford ³ , Craig Nelson ³ , MD, Michael Weiner ^{1,2} , MD, for the Alzheimer's Disease Neuroimaging Initiative 1 Department of Radiology, University of California – San Francisco, CA, USA, 2 Center for Imaging of Neurodegenerative Diseases, San Francisco, CA, USA, 3 Department of Psychiatry, University of California – San Francisco, CA, USA, 4 VA Northern California Health Care System, San Francisco, CA, USA	
10.15 a.m	OC64 - Baseline characteristics for participants enrolled in the phase II/III EPOCH Alzheimer's disease trial of the Bace inhibitor verubecestat (MK-8931) Michael Egan, MD¹, Tiffini Voss, MD¹, Yi Mo, PhD¹, Yuki Mukai, MD¹, Christine Furtek, MS¹, James Kost, PhD¹, Paul S Aisen, MD², Jeffrey L. Cummings, MD, ScD³, Pierre N. Tariot, MD⁴, Bruno Vellas, MD, PhD⁵, David Michelson, MD¹ (1) Merck & Co., Inc., Kenilworth, NJ, USA, (2) University of Southern California, San Diego, CA, USA, (3) Cleveland Clinic, Las Vegas, NV, USA, (4) Banner Alzheimer's Institute, Phoenix, AZ, USA, (5) Gerontopole, INSERM U 1027, Alzheimers' Disease Research and Clinical Center, Toulouse University Hospital, Toulouse, France	
10.30 a.m	Coffee Break and poster sessions 3 San Diego Ballroom - Lobby Level	
11.00 a.m	Collaborative efforts to prevent Alzheimer's disease Under the auspices of The Embassy of France in the United States; General Consulate of Los Angeles, Office for Science & Technology Opening Christophe Lemoine (Consul General of France in Los Angeles) Chairs: Paul Aisen (San Diego/USA), Howard Feldman (San Diego, USA), Jacques Touchon (Montpellier/France) 1. Alzheimer preventive trial: prevention regulatory scientific advices: Maria Isaac (London/UK) 2. ADNI to build Alzheimer's preventive trials: Mike Weiner, Philip Insel (San-Francisco/USA) 3. MAPT trials the MAPT 2 and MAPT 3 preventive trial: Bruno Vellas (Toulouse/France)	
11.50 a.m	Panel Round Table Chaired by: Jean Rosenbaum, Paul Aisen, Bruno Vellas with the participation of Sandrine Andrieu (Toulouse), Maria Carrillo (Chicago), Mathieu Ceccaldi (Marseille), Jean-François Dartigues (Bordeaux), Howard Feldman (San-Diego), Audrey Gabelle (Montpellier), Maria Isaac (London), L.Raime Fitten (Los Angeles), Reisa Sperling (Boston), Pierre Tariot (Phoenix), Mike Weiner (San-Francisco)	

POSTER SESSION 1 : Thursday, December 8		
P1-1 to P1-50		
POSTER SESSION 2 : Friday, December 9 P2-1 to P2-44	p. 30	
POSTER SESSION 3 : Saturday, December 10	p. 35	

POSTER SESSION 1: Thursday, December 8

THEME 1: Clinical Trials Methodology

San Diego Ballroom - Lobby Level

P1-1 INNOVATIVE PHASE II STUDY DESIGN FOR STUDYING THE GLUTAMINYLCYCLASE INHIBITOR PQ912 IN EARLY ALZHEIMER'S DISEASE

Niels D. Prins, MD, PhD(1), Frank Weber, MD(2), Suzanne Bruins, MSc(3), Inge Lues, PhD(2), Philip Scheltens, MD, PhD(1) (1) Alzheimer Centre and Department of Neurology, VU University Medical Centre, Amsterdam, The Netherlands, (2) Probiodrug AG, Halle, Germany, (3) Julius Clinical, Zeist, The Netherlands

P1-2 ALZHEIMER'S PREVENTION REGISTRY: LESSONS LEARNED IN DEVELOPING A SHARED RESOURCE TO THE SCIENTIFIC COMMUNITY

Nellie High (1), Jodie Nichols (1), David Gordon (1), Trisha Walsh (1), Raj Aggarwal (2), Paul S. Aisen (3), Marilyn S. Albert (4), Meryl Comer (5), Jeffrey L. Cummings (6), Jennifer J. Manly (7), Ronald C. Petersen (8), Reisa A. Sperling (9), Gabrielle Strobel (10), Michael W. Weiner (11), Eric M. Reiman (1), Pierre N. Tariot (1), Jessica B. Langbaum (1)

(1) Banner Alzheimer's Institute, Phoenix, AZ, USA, (2) Provoc, Washington, DC, USA, (3) Alzheimer's Therapeutic Research Institute, University of Southern California, San Diego, CA, USA, (4) Department of Neurology, Johns Hopkins University School of Medicine, Baltimore, MD, USA, (5) Geoffrey Beene Foundation Alzheimer's Initiative, Washington, DC, USA, (6) Cleveland Clinic Lou Ruvo Center for Brain Health, Las Vegas, NV, USA, (7) Department of Neurology, Columbia University College of Physicians and Surgeons, New York, NY, USA, (8) Department of Neurology, Mayo Clinic, Rochester, MN, USA, (9) Department of Neurology, Harvard Medical School, Boston, MA, USA, (10) Alzforum, Cambridge, MA, USA, (11) Department of Radiology and Biomedical Engineering, University of California San Francisco, San Francisco, CA, USA

- P1-3

 AGE INCREASES RATE OF Aß AND £4 RELATED MEMORY DECLINE IN PRECLINICAL ALZHEIMER'S DISEASE
 Paul Maruff [1,2], Yen Ying Lim [2], Peter Snyder [3], Victor Villemagne [2,4], Chris Rowe [2,4] Colin Masters [2]
 [1] Cogstate Ltd New Haven, CT, USA, [2] Florey Institute for Neuroscience, Melbourne, Australia, [3] Lifespan Hospital, RI, USA,
 [4] Austin Health. Heidelberg, Australia
- P1-4

 PHASE 3 CLINICAL TRIAL IN MCI DUE TO AD TARGETING HIPPOCAMPAL HYPERACTIVITY

 Richard Mohs (1), Sharon Rosenzweig-Lipson (1), Marilyn Albert (2), Michela Gallagher (1,3)

 (1) AgeneBio, Inc. Baltimore, MD USA, (2) Department of Neurology, Johns Hopkins School of Medicine, Baltimore, MD USA,

 (3) Department of Psychological and Brain Sciences, Johns Hopkins University, Baltimore, MD USA
- P1-5 PRIMARY PREVENTION TRIALS IN DOMINANTLY INHERITED ALZHEIMER'S DISEASE: CONSIDERATIONS IN THE DOMINANTLY INHERITED ALZHEIMER NETWORK TRIALS UNIT

Eric McDade, DO (1), Guoqiao Wang, PhD (2), Tammie Benzinger, MD, PhD (3), Anne Fagan, PhD (1), Jason Hassenstab, PhD (1), Chengjie Xiong, PhD (2), Randall J. Bateman, MD (1)

Washington University School of Medicine at St. Louis (1) Department of Neurology, (2) Department of Medicine, Division of Biostatistics, (3) Department of Radiology

P1-6 IMPROVING PRECISION AND POWER BY ADJUSTING FOR PROGNOSTIC BASELINE VARIABLES IN ALZHEIMER'S DISEASE CLINICAL TRIALS

Michael Rosenblum, PhD (1), Elizabeth Colantuoni, PhD (1), Jon Steingrimsson, PhD (1), Arnold Bakker, PhD (2), Michela Gallagher, PhD (3,4)

(1) Department of Biostatistics, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD USA, (2) Department of Psychiatry and Behavioral Sciences, Johns Hopkins Medical School, Baltimore, MD USA, (3) AgeneBio, Inc. Baltimore, MD USA, (4) Department of Psychological and Brain Sciences, Johns Hopkins University, Baltimore, MD USA

P1-7 SENSITIVITY OF TRIAL PERFORMANCE TO DELAYED OUTCOMES, ACCRUAL RATES, AND PROGNOSTIC VARIABLES BASED ON A SIMULATED RANDOMIZED TRIAL WITH ADAPTIVE ENRICHMENT

Michael Rosenblum, PhD (1), <u>Tianchen Qian</u> (PhD candidate) (1), <u>Elizabeth Colantuoni</u>, PhD (1), Aaron Fisher, PhD (1) (1) Department of Biostatistics, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD USA

P1-8 EFFECTS OF POTENTIALLY SELECTIVE END OF FOLLOW-UP IN A POPULATION WITH LATE MILD COGNITIVE IMPAIRMENT USING A DISEASE SIMULATION

Anuraag Kansal, PhD (1), Ali Tafazzoli, PhD (1), Stanimira Krotneva, MSc (2), Rodrigo DosSantos, BA (1), Jack Ishak, PhD (2) (1) Evidera, Bethesda, MD, USA, (2) Evidera, Montreal, QC Canada

P1-9 SAMPLE SIZE CONSIDERATIONS FOR ASSESSING AGREEMENT AMONG MULTIPLE RATERS IN A STUDY WITH AMNESTIC MILD COGNITIVE IMPAIRMENT

Ying Zhang, PhD (1), James Kost, PhD (1), Michael Egan, MD (1) (1) Merck Sharp and Dohme, Upper Gwynedd, PA, USA

P1-10 THE INCREMENTAL VALIDITY OF SHORT-TERM PRACTICE EFFECTS IN DETERMINING AMYLOID POSITIVITY

Bonnie C.A. Dalley (1), Kayla R. Suhrie (1), Taylor J. Atkinson (1), Britney Beardmore (3), Kevin Horn (3), Kelli Rasmussen (3), Lance Burrell (3), Dustin B. Hammers (1,2), Norman L. Foster (1,2), Kevin Duff (1,2), John M. Hoffman (3)

(1) Center for Alzheimer's Care, Imaging and Research, Department of Neurology, University of Utah, (2) Center on Aging, University of Utah, (3) Center for Quantitative Cancer Imaging, Huntsman Cancer Institute

POSTER SESSION 1: Thursday, December 8

THEME 1: Clinical Trials Methodology (continued)

San Diego Ballroom - Lobby Level

P1-11 THE ALZHEIMER'S PREVENTION REGISTRY GENEMATCH PROGRAM

<u>Trisha Walsh</u> (1), David Gordon (1), Jason Karlawish (2), Angela Bradbury (2), Beth McCarty Wood (2), J. Scott Roberts (3), Scott Kim (4), Linda Patrick-Miller (5), Richard J. Caselli (6), Gary E. Marchant (7), Doris Zallen (8), Carolyn Langlois (1), Eric M. Reiman (1), Pierre N. Tariot (1), Jessica B. Langbaum (1*)

(1) Banner Alzheimer's Institute, Phoenix, AZ, (2) University of Pennsylvania, Philadelphia, PA, (3) University of Michigan, School of Public Health, Ann Arbor, MI, (4) National Institutes of Health, Bethesda, MD, (5) University of Chicago, Chicago, IL, (6) Mayo Clinic Arizona, Scottsdale, AZ, (7) Arizona State University, Tempe, AZ, (8) Virginia Tech University, Blacksburg, VA

P1-12 RISK-BENEFIT PREFERENCES FOR DELAYING THE ONSET OF ALZHEIMER'S DISEASE IN HEALTHY, ASYMPTOMATIC OLDER ADULTS

Rachael L. DiSantostefano, MS, PhD (1), Shelby D. Reed, PhD (2), Jui-Chen Yang, MEM (2), Bennett Levitan, MD, PhD (1), Johannes Streffer, MD (3), F. Reed Johnson, PhD (2)

(1) Janssen R&D, Titusville, NJ, USA, (2) Duke Clinical Research Institute, Duke University, Durham, NC, USA, (3) Janssen R&D, Beerse, Belgium

P1-13 ALZHEIMER'S DISEASE CLINICAL TRIALS: THE IMPACT OF DIGITAL TECHNOLOGIES

Amir Kalali, MD (1), Arshya Vahabzadeh, MD (2)

(1) Neuroscience Center of Excellence, Quintiles Inc, San Diego, CA, USA, (2) Harvard Medical School, Boston, MA, USA

P1-14 UTILIZING MOBILE CLINICAL TRIAL UNIT TO ENHANCE RECRUITMENT AND RETENTION IN CLINICAL TRIALS FOR ALZHEIMER'S DISEASE

Jill Smith, MA, CCRC; Amanda Smith, MD, <u>Dave Morgan</u>, PhD Byrd Alzheimer's Institute, University of South Florida, Tampa FL USA

P1-15 THE CHALLENGE OF EFFECTIVE MANAGEMENT FOR AN ACADEMIC INVESTIGATOR-INITIATED INTERNATIONAL MULTI-SITE CLINICAL RESEARCH IN JAPAN

Hisako Fujii, PhD (1), Hiroyuki Shimada, MD, PhD (1), Mikio Shoji, MD, PhD (2), Takeshi Ikeuchi, MD, PhD (3), Kazushi Suzuki, MD, PhD (4), Michio Senda, MD, PhD (5), Kenji Ishii, MD (6), Hiroshi Matsuda, MD, PhD (7), Atsushi Iwata, MD, PhD (4), Ryoko Ihara, MD, PhD (4,8), John Morris, MD (8), Randall Bateman, MD (8), Yuichi Kato, PhD (1), Hiroshi Mori, PhD (1), and The DIAN Study Group

(1) Osaka City University Graduate School of Medicine, Osaka, JAPAN, (2) Hirosaki University Graduate School of Medicine, Aomori, JAPAN, (3) Brain Research Institute, Niigata University, Niigata, JAPAN, (4) Graduate School of Medicine, University of Tokyo, Tokyo, JAPAN, (5) Institute of Biomedical Research and Innovation, Hyogo, JAPAN, (6) Tokyo Metropolitan Institute of Gerontology, Tokyo, JAPAN, (7) National Center of Neurology and Psychiatry, Tokyo, JAPAN, (8) Knight Alzheimer Disease Research Center, Washington University School of Medicine, MO, USA

P1-16 SIMAMCI: A RANDOMIZED CONTROLLED TRIAL OF SIMVASTATIN IN AMNESTIC MCI PATIENTS FOR THE PREVENTION OF CONVERSION TO ALZHEIMER'S DEMENTIA

Brigitte Haas, PhD, Arne Klostermann, Oliver Peters, MD, <u>Isabella Heuser</u>, MD, PhD Department of Psychiatry, Charité University Medicine Berlin, Berlin, Germany

P1-17 DESIGNING A CROSS-OVER RCT INVESTIGATING NABILONE AS A TREATMENT FOR AGITATION IN PATIENTS WITH MODERATE-TO-SEVERE AD

Myuri Ruthirakuhan, MSc, PhD(c) (1,2), Nathan Herrmann, MD (1,3,4), Celina Liu, BScH (1,2), Eleenor H Abraham, BAH (1), Paul Verhoeff, MD, PhD (4), Alex Kiss, PhD (1), Ana C Andreazza, PhD (2), Sandra Black, MD (1), Krista Lanctôt, PhD (1,2,3,4) (1) Hurvitz Brain Sciences Program, Sunnybrook Research Institute, Toronto, Canada, (2) Department of Pharmacology and Toxicology, University of Toronto, Canada, (3) Department of Psychiatry, Sunnybrook Health Sciences Centre, Toronto, Canada, (4) Department of Psychiatry, University of Toronto, Canada

P1-18 CHARACTERISTICS OF THE ALZHEIMER'S DISEASE (AD) COHORTS IN THE EUROPEAN MEDICAL INFORMATION FRAMEWORK (EMIF)

Stephanie Vos (1), Angelika Wientzek (2), Preciosa Coloma (2), Myriam Alexander (2), Nadia Foskett (2), Isabelle Bos (1), Sebastiaan Engelborghs (3), Pieter Jelle Visser (4), H. Michael Arrighi (5), José L Molinuevo (6), Alberto Lleó (7), Andy Simmons (8), Gerald Novak (9), Mark Forrest Gordon (10)

(1) Department of Psychiatry and Neuropsychology, School for Mental Health and Neuroscience, Maastricht University, Alzheimer Center Limburg, Maastricht, the Netherlands, (2) Real World Data Science, F. Hoffmann-La Roche, Basel, Switzerland, (3) Reference Center for Biological Markers of Dementia (BIODEM), University of Antwerp, Antwerp, Belgium, (4) Department of Neurology, Alzheimer Center, Neuroscience Campus, VU University Medical Center, Amsterdam, the Netherlands, (5) Janssen Research & Development, South San Francisco, CA, USA, (6) ICN Hospital Clinic i Universitari, IDIBAPS, Barcelona, Spain, (7) Neurology Department, Hospital de la Santa Creu i Sant Pau, Barcelona, Spain, (8) Kings College London, United Kingdom, (9) Janssen Pharmaceutical Research and Development, Titusville, NJ, USA, (10) Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT, USA

POSTER SESSION 1: Thursday, December 8

- P1-19 WHAT DOES IT MEAN TO BE TOLD YOU HAVE "ELEVATED AMYLOID"? RESULTS FROM THE SOKRATES STUDY Jessica Mozersky, PhD, Pamela Sankar, PhD, Kristin Harkins BA, Sara Hachey BS, <u>Jason Karlawish</u>, MD University of Pennsylvania, Penn Memory Center / Perelman School of Medicine / Department of Medical Ethics and Health Policy, Philadelphia, PA, USA
- P1-20
 PHASE 2 TRIAL OF PIROMELATINE FOR MILD ALZHEIMER'S DISEASE (The ReCOGNITION Trial)

 Amnon Katz, PhD (1), Anat Frydman, PhD (1), Tali Nir DVM (1), Lon S. Schneider, MD (2)

 (1) Neurim Pharmaceuticals (1991) Ltd, Tel-Aviv, Israel, (2) University of Southern California Keck School of Medicine, Los Angeles, CA, USA
- P1-21

 MULTI-MODAL BIOMARKER COMPOSITE FOR DISEASE PROGRESSION IN AD PREVENTION TRIALS

 John C.S. Breitner, MD, MPH, Jeannie M. Leoutsakos, PhD (2), Marilyn Albert PhD (3), PREVENT-AD Research Group (4),

 BIOCARD Research Group (3,5)

 (1) Department of Psychiatry, McGill University, Montreal, QC, Canada, (2) Department of Psychiatry, Johns Hopkins School of Medicine, Baltimore, MD, USA, (3) Department of Neurology, Johns Hopkins School of Medicine, Baltimore, MD, USA, (4) Douglas Hospital Research Centre, Montreal, QC, Canada, (5) Department of Biostatistics, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, USA
- P1-22 CHARACTERIZATION OF THE SCREENING POPULATION IN THE TOMMORROW STUDY

 Ferenc Martenyi, MD (1), Kathleen A. Welsh-Bohmer, PhD (2), Carl Chiang, PhD (3), Brenda L. Plassman, PhD (2), Patrick
 Harrigan, BChE (1), Janet O'Neil, MBA (1), Grant Runyan, PhD (1), Meredith Culp, BS (1), Ryan Walter, BS (1), Michael W. Lutz,
 PhD (2), Eric Lai, PhD (1), Ann M. Saunders, PhD (2), Stephen Haneline, MS,(3), David Yarnall, MS (3), Deborah Yarbrough,
 MS, MBA (1), Craig Metz, PhD (3), Daniel K. Burns, PhD (3), Allen D. Roses, MD (3) for the TOMMORROW Study Investigators
 (1) Takeda Development Center Americas, Inc., Deerfield, IL, USA, (2) Duke University Bryan ADRC, Durham, NC, USA, (3)
 Zinfandel Pharmaceuticals, Inc., Durham, NC, USA
- P1-23

 DESIGN OF PILOT STUDIES TO INFORM THE CONSTRUCTION OF COMPOSITE OUTCOME MEASURES

 Steven D. Edland, PhD (1,2), M. Colin Ard, PhD (1), Weiwei Li, MS (3), Lingjing Jiang MS (2)

 (1) Department of Neurosciences, University of California San Diego, La Jolla, CA, USA, (2) Division of Biostatistics, Department of Family Medicine and Public Health, University of California San Diego, La Jolla, CA, USA, (3) Department of Mathematics, University of California San Diego, La Jolla, CA, USA

THEME 3: Clinical Trials Imaging

San Diego Ballroom - Lobby Level

- P1-24 MICROSTRUCTURAL DAMAGE OF THE WHITE MATTER IN THE FRONTAL ASLANT TRACT ACCOUNTS FOR VISUO-SPATIAL PERFORMANCES IN PATIENTS WITH ALZHEIMER'S DISEASE

 Laura Serra PhD (1), Giulia Bechi Gabrielli (1), Elisa Tuzzi (1), Barbara Spanò MD, PhD (1), Camillo Marra MD (2), Carlo Caltagirone MD (3,4), Mara Cercignani PhD (5), Marco Bozzali MD (1)

 (1) Neuroimaging Laboratory, IRCCS Santa Lucia Foundation, Rome, (2) Institute of Neurology, Catholic University, Rome, (3) Department of Clinical and Behavioural Neurology, IRCCS Santa Lucia Foundation, Rome, (4) Department of Neuroscience, University of Rome 'Tor Vergata', Rome, (5) Brighton & Sussex Medical School, Clinical Imaging Sciences Centre, University of Sussex, Brighton, United Kingdom
- P1-25 EFFECTS OF PARTIAL VOLUME DIFFERENCES BETWEEN TIME POINTS ON LONGITUDINAL AMYLOID SUVR MEASUREMENTS

 Crossov Klein (1) Joël Schoorer (2) Florent Books (2) Mahul Sampet (4) Coppen Chan (1) Joves Subv (1)

Gregory Klein (1), Joël Schaerer (2), Florent Roche (2), Mehul Sampat (1), Gennan Chen (1), <u>Joyce Suhy</u> (1) (1) Bioclinica, Newark, CA, USA, (2) Bioclinica, Lyon, France

P1-26 IMPAIRMENT AND DECLINE ON THE COGSTATE BRIEF BATTERY IS RELATED TO AMYLOID AND HIPPOCAMPAL VOLUME IN VERY MILD DEMENTIA

Paul Maruff [1,2], Yen Ying Lim [2], Peter Snyder [3], Victor Villemagne [2,4], Chris Rowe [2,4] Colin Masters [2] [1] Cogstate Ltd New Haven, CT, USA, [2] Florey Institute for Neuroscience, Melbourne, Australia, [3] Lifespan Hospital, RI, USA, [4] Austin Health. Heidelberg, Australia

P1-27 TWO-POINT CORRELATION ANALYSIS OF ABNORMAL WHITE MATTER CHANGES AND THEIR ASSOCIATION TO AMYLOID PET RETENTION

Sepideh shokouhi, PhD (1), Hyeyon Kim (1), Harry E. Gwirtsman, MD (2) (1) Department of Radiology and Radiological Sciences, Vanderbilt University Medical Center, Nashville, TN, (2) Department of

- (1) Department of Radiology and Radiological Sciences, Vanderbilt University Medical Center, Nashville, TN, (2) Department of Psychiatry, Vanderbilt University Medical Center, Nashville, TN
- P1-28
 THE RELATIONSHIP BETWEEN VOLUMETRIC MRI MEASURES,APOE4 AND MMSE STATUS AT BASELINE IN SUBJECTS WITH MILD-TO-MODERATE ALZHEIMER'S DISEASE PARTICIPATING IN THE PHASE 2-3 EPOCH TRIAL OF VERUBECESTAT (MK-8931)

Cyrille Sur, PhD (1), Yi Mo, PhD (1), James Kost, PhD (1), Tiffini Voss, MD (1), Joyce Suhy, PhD (2), Luc Bracoud PhD (2), Joonmi Oh, PhD (2), David Michelson, MD (1), Michael Egan, MD (1) (1) Merck & Co., Inc., Kenilworth, NJ, USA, (2) Bioclinica, Newark, CA, USA

San Diego 2

Clinical Trials on Alzheimer's Disease

POSTER PRESENTATIONS

POSTER SESSION 1: Thursday, December 8

P1-29 INITIAL PH 1 TRIAL THAT WILL EVALUATE THE USE OF WHOLE BRAIN IRRADIATION IN THE TREATMENT OF PATIENTS WITH ALZHEIMER'S DEMENTIA (AD)

<u>James Fontanesi</u>, M.D.(1), Prakash Chinnaiyan, M.D.(1), Daniel Michael, M.D. Ph. D.(1,3), Alvaro Martinez, M.D.(2), Michael Maddens, M.D.(1), George Wilson, M.D. Ph.D.(1), Brian Marples, Ph.D.(1)

(1) William Beaumont Health Systems, Royal Oak, Michigan, (2) 21st Century Oncology, Farmington Hills, Michigan, (3) Michigan Head & Spine Institute, PC, Royal Oak, MI

P1-30 UNCOVERING THE RELATIONSHIP BETWEEN &-AMYLOID AND GLUCOSE METABOLISM

Felix Carbonell (1), <u>Donald G. McLaren</u> (1), Alex P. Zijdenbos (1), Barry J. Bedell (1,2)

(1) Biospective Inc., Montreal, Quebec, Canada, (2) McGill University, Montreal, Quebec, Canada

P1-31 ROBUSTNESS OF MRI-BASED VOLUMETRY FOR THE PREDICTION OF SHORT-TERM CONVERSION FROM MILD COGNITIVE IMPAIRMENT TO ALZHEIMER'S DEMENTIA

Oliver Peters, MD (1), Per Suppa (2,3), Brigitte Haas, PhD (1), Ralph Buchert, PhD (3), Lothar Spies, PhD (2), Isabella Heuser, MD. PhD (1)

(1) Department of Psychiatry, Charité, Berlin, Germany, (2) jung diagnostics GmbH, Hamburg, Germany, (3) Department of Nuclear Medicine, Charité Berlin, Germany

THEME 4: Clinical Trials: biomarkers including plasma

San Diego Ballroom - Lobby Level

P1-32 A NOVEL CONFORMATIONAL, PHOSPHO-THREONINE 231 SPECIFIC ASSAY FOR CSF PROTEIN TAU

Ann De Vos, PhD (1), Dirk Jacobs, Eng (1), Lien Van den Abbeele, MSc (1), Erik Stoops, Eng (1), Kimberley Mauroo, BSc (1), Maria Bjerke, PhD (2), Sebastiaan Engelborghs, MD, PhD (2,3), Hugo Vanderstichele, PhD(1), Eugeen Vanmechelen, PhD (1) (1) ADx NeuroSciences NV, Technologiepark 4, 9052 Ghent, Belgium, (2) Reference Center for Biological Markers of Dementia (BIODEM), Institute Born-Bunge, University of Antwerp, Antwerp, Belgium, (3) Department of Neurology and Memory Clinic, Hospital Network Antwerp (ZNA) Middelheim and Hoge Beuken, Antwerp, Belgium

P1-33 CT1812, A DRUG CANDIDATE FOR ALZHEIMER'S DISEASE, ACHIEVES PREDICTED THERAPEUTIC CONCENTRATIONS AFTER MULTIPLE DOSING IN HEALTHY HUMAN VOLUNTEERS

Susan Catalano, PhD (1), Michael Grundman, MD, MPH (1,2), Lon S Schneider, MD, MS (3), Steven DeKosky, MD (4), Jason D Lickliter, MBBS, PhD (5), Roger Morgan, MD (6), Michelle Higgin, PhD (1), Julie Pribyl (1), Kelsie Mozzoni (1), Nicholas J Izzo, PhD (1), Hank Safferstein, PhD (1)

(1) Cognition Therapeutics Inc., Pittsburgh, PA, USA, (2) Global R&D Partners, LLC, San Diego, California, (3) Keck School of Medicine of USC, Los Angeles, CA, USA, (4) McKnight Brain Institute, University of Florida, Gainesville, FL, USA, (5) Nucleus Network, Melbourne, Victoria, Australia, (6) MedSurgPl, LLC Raleigh, North Carolina, USA

P1-34 CIRCULATING BRAIN-ENRICHED MICRORNAS AS BIOMARKERS FOR ALZHEIMER'S DISEASE CLINICAL TRIALS

<u>Kira S. Sheinerman (1)</u>, Vladimir G. Tsivinsky (1), Jon B. Toledo (2), Jennifer McBride (2), Elizabeth Grant (3), Anne M. Fagan (3), John Q. Trojanowski (2), Samuil R. Umansky (1)

(1) DiamiR, LLC, Monmouth Junction, NJ, USA, (2) Center for Neurodegenerative Disease and Department of Pathology & Laboratory Medicine, University of Pennsylvania, Philadelphia, PA, USA, (3) Department of Neurology, Washington University School of Medicine, St. Louis, MO, USA

POSTER SESSION 1: Thursday, December 8

D1_25 MRI AND EEG BIOMARKERS TO TRACK DISEASE PROGRESSION IN AMCI PATIENTS WITH AD PATHOLOGY

Moira Marizzoni, PhD (1), Samantha Galluzzi, MD (1), Clarissa Ferrari, PhD (1), Jorge Jovicich, PhD (2), Flavio Nobili, MD (3), Jean-Philippe Ranjeva, MD (4), David Bartrés-Faz, MD (5), Ute Fiedler, MD (6), Peter Schönknech, MD (7), Pierre Payoux, MD (8,9), Alberto Beltramello, MD (10), Massimo Caulo, PhD (11), Andrea Soricelli, MD (12,13), Lucilla Parnetti, MD (14), Magda Tsolaki, MD (15), Paolo Maria Rossini, MD (16,17), Pieter Jelle Visser, MD (18), Federica Fusco, PhD (19), Diego Albani, PhD (19), Gianluigi Forloni, PhD (19), Regis Bordet, MD (20), Jill Richardson, MD, PhD (21,22), Cecilia Estrella, PhD (23), Nicola Marzano, PhD (24), Claudio del Percio, PhD (24), Susanna Cordone, PhD (24), Claudio Babiloni, PhD (24), Olivier Blin, MD (25), Giovanni Battista Frisoni, MD (1,26); on behalf of the PharmaCog Consortium (1) Laboratory of Neuroimaging and Alzheimer's Epidemiology, IRCCS Istituto Centro San Giovanni di Dio Fatebenefratelli, Brescia, Italy; (2) Center for Mind/Brain Sciences, University of Trento, Trento, Italy; (3) Department of Neuroscience, Ophthalmology, Genetics and Mother-Child Health (DINOGMI), University of Genoa, Genoa, Italy; (4) CIC-UPCET, CHU La Timone, AP-HM, UMR CNRS-Universite de la Mediterranee, Marseille, France; (5) Department of Psychiatry and Clinical Psychobiology, Universitat de Barcelona and IDIBAPS, Barcelona, Spain; (6) LVR-Clinic for Psychiatry and Psychotherapy, Institutes and Clinics of the University Duisburg-Essen, Essen, Germany; (7) University Hospital Leipzig, Leipzig, Germany; (8) INSERM, Imagerie cérébrale et handicaps neurologiques, UMR 825, Toulouse, France; (9) Université de Toulouse, UPS, Imagerie cérébrale et handicaps neurologiques, UMR 825, CHU Purpan, Place du Dr Baylac, Toulouse France; (10) Department of Neuroradiology, General Hospital, Verona, Italy; (11) University "G. d'Annunzio" of Chieti, Chieti, Italy; (12) IRCCS SDN, Naples, Italy; (13) University of Naples Parthenope, Naples, Italy; (14) Section of Neurology, Centre for Memory Disturbances, University of Perugia, Perugia, Italy; (15) 3rd Department of Neurology, Aristotle University of Thessaloniki, Thessaloniki, Greece; (16) Dept. Geriatrics, Neuroscience & Orthopaedics, Catholic University, Policlinic Gemelli, Rome, Italy; (17) IRCSS S.Raffaele Pisana, Rome, Italy, (18) Alzheimer Center and Department of Neurology, VU University Medical Center, Amsterdam, Netherlands: (19) Neuroscience Department, IRCCS Istituto di Ricerche Farmacologiche «Mario Negri», Milano, Italy: (20) Department of Pharmacology, EA1046, University of Lille Nord de France, Lille, France; (21) Neurosciences Therapeutic Area, U.K., United Kingdom; (22) GSK R&D, China-UK, U.K., United Kingdom; (23) AlzProtect, Loos, France; (24) Sapienza University of Rome, Rome, Italy; (25) Pharmacology, Assistance Publique-Hôpitaux de Marseille, Aix-Marseille University-CNRS UMR 7289, Marseille, France; (26) Memory Clinic and LANVIE - Laboratory of Neuroimaging of Aging, University Hospitals and University of Geneva, Geneva, Switzerland

P1-36 STRATIFICATION OF MCI AND COGNITIVELY NORMAL INDIVIDUALS USING POLYGENIC SCORING: EVALUATION OF A NOVEL SNP (SINGLE NUCLEOTIDE POLYMORPHISM) ARRAY IN RISK ASSESSMENT

Maryam Shoai PhD (1); Richard Pither, PhD (3); Lakshmi Radhakrishnan MSc (7); Geoff Scopes PhD (7); Valentina Escott-Price, PhD (5); Simon M Laws PhD (4); Julie Davis, MSc (3); Harald Hampel, MD, PhD (2); Rik Vandenberghe (6); Isabelle Cleynen (6); Claire Bloor PhD (7); Greg Davidson PhD (8); John Hardy, PhD, DSc (1)

(1) UCL Institute of Neurology, London, United Kingdom, (2) AXA Research Fund & UPMC Chair, Paris, France, (3) Cytox Ltd, UK, Oxford, United Kingdom, (4) Edith Cowan University, and Cooperative Research Centre (CRC) for Mental Health, Perth, Australia, (5) Cardiff University, Cardiff, United Kingdom, (6) Katholiele Universiteit Leuven, Leuven, Belgium, (7) Affymetrix (Thermo Fisher Scientific) UK and USA, (8) Ledcourt Associates, UK

P1-37 LTP-LIKE CORTICAL PLASTICITY IS DISRUPTED IN ALZHEIMER'S DISEASE PATIENTS INDEPENDENTLY FROM AGE OF ONSET

Francesco Di Lorenzo MD (1,2), Viviana Ponzo B.Sc.,(1) Sonia Bonnì PhD,(1) Caterina Motta, (1,2), Marco Bozzali MD PhD,(1), Carlo Caltagirone MD,(1,2) Alessandro Martorana MD PhD,(2) Giacomo Koch MD PhD (1,4)

(1) Non Invasive Brain Stimulation Unit/Department of Behavioural and Clinical Neurology, Santa Lucia Foundation IRCCS, Via Ardeatina 354, 00179, Rome, Italy, (2) Department of Systems Medicine, University of Rome Tor Vergata, Viale Oxford 81, 00133, Rome, Italy

P1-38 APOE4 BLOOD MARKER ASSAY. A NEW NON-GENETIC METHOD TO EVALUATE ALZHEIMER'S DISEASE RISK USING CLINICAL CHEMISTRY PLATFORMS

Sergio Veiga, PhD (1), Andrés Rodríguez-Martín (1), Olga Calero, PhD (2), Luis García-Albert, PhD (3), Almudena Pérez (4), Sergi Gassó, PhD (4), Miguel Calero, PhD (5)

(1) Biocross S.L., Valladolid, Spain, (2) CIBERNED and Chronic Disease Programme, Instituto de Salud Carlos III. Madrid, Spain, (3) Chronic Disease Programme, Instituto de Salud Carlos III. Madrid, Spain, (4) Pragmatic Diagnostics S.L., Bellaterra (Cerdanyola del Vallès), Barcelona, Spain, (5) Chronic Disease Programme, CIBERNED, and CIEN Foundation-Queen Sofia Foundation, Instituto de Salud Carlos III. Madrid, Spain

P1-39 [18F]MK-6240 A NOVEL NEUROFIBRILLARY TANGLES PET TRACER: DISCOVERY AND CLINICAL EVALUATION

Cyrille Sur, PhD (1), Idriss Bennacef, PhD (1), Zhizhen Zeng, PhD (1), Talakad Lohith, PhD (1), Patricia J Miller (1), Cristian A Salinas, PhD (1), Brett M Connolly, PhD (1), Liza T Gantert (1), Hyking D Haley (1), Holahan A Marie (1), Stacey S O'Malley (1), Mona L Purcell (1), Kerry Riffel, PhD (1), Paul J Coleman, PhD (2), Jing Li, PhD (2), Jaume Balsells-Padros, PhD (2), Aileen Soriano (3), Aimie M Ogawa (3), Serena Xu (3), Zhang Xiaoping (3), Joseph Della Rocca (2), Joel B. Schachter, PhD (4), David Hesk (5), Schenk J David (5), Arie Struyk, MD, PhD (6), Cyrille Sur, PhD (1), Sofie Celen, PhD (7), Kim Serdons, PhD (7), Guy Bormans, PhD (7), Mathieu Vandenbulcke, MD, PhD (7), Rik Vandenberghe, MD, PhD (7), Jan De Hoon, MD (7), Michel Koole, MD (7), Koen Van Laere, PhD, MD (7), Walji Abbas, PhD (2), Hosteller Eric, PhD (1), Jeffrey Evelhoch, PhD (1)

(1) Merck & Co. / Translational Biomarkers, West Point, PA, USA, (2) Merck & Co. / Chemistry, West Point, PA, USA, (3) Merck & Co. / Pharmacology, Kenilworth, NJ, USA, (4) Merck Research Laboratories, West Point, PA, USA, (5) Merck & Co. / Chemistry, Rahway, NJ, USA, (6) Merck & Co. / Translational Pharmacology, North Wales, PA, USA, (7) KU Leuven, Leuven, Belgium

Clinical Trials on Alzheimer's Disease

POSTER PRESENTATIONS

POSTER SESSION 1: Thursday, December 8

THEME 4: Clinical Trials: biomarkers including plasma (continued)

San Diego Ballroom - Lobby Level

P1-40 TAU PATHOLOGY MEASURED BY 18F-AV1451 POSITRON EMISSION TOMOGRAPHY AND CEREBROSPINAL FLUID BIOMARKERS IN ALZHEIMER'S DISEASE

Niklas Mattsson, MD, PhD (1,2,3), Michael Schöll, PhD (1), Ruben Smith, MD, PhD (3), Olof Strandberg, PhD (1), Sebastian Palmqvist, MD, PhD (1,2,3), Philip Insel (1,4,5), Henrik Zetterberg, MD, PhD (6,7), Kaj Blennow, MD, PhD (6), Thomas Olsson, MD, PhD (8), Douglas Hägerström, MD, PhD (9), Jonas Jögi, MD, PhD (10), Lennart Minthon, MD, PhD (1,2), Oskar Hansson, MD, PhD (1,2)

(1) Clinical Memory Research Unit, Faculty of Medicine, Lund University, Lund, Sweden, (2) Memory Clinic, Skåne University Hospital, Sweden, (3) Department of Neurology, Skåne University Hospital, Sweden, (4) Center for Imaging of Neurodegenerative Diseases, Department of Veterans Affairs Medical Center, San Francisco, CA, USA, (5) Department of Radiology and Biomedical Imaging, University of California, San Francisco, CA, USA, (6) Clinical Neurochemistry Laboratory, University of Gothenburg, Gothenburg, Sweden, (7) UCL, London, UK, (8) Department of Radiation physics, Skåne University Hospital, Lund, Sweden, (9) Department of Clinical Neurophysiology, Skåne University Hospital, Lund, Sweden, (10) Department of Clinical Physiology and Nuclear Medicine, Skåne University Hospital, Lund, Sweden

P1-41

LUMIPULSE G ß-AMYLOID 1-42: KEY PERFORMANCES OF A FULLY AUTOMATED CHEMILUMINESCENT IMMUNOASSAY
Martine Dauwe (1), Filip Dekeyser (1), Tinne Dumont (1), Roger Moonen (1), Els Huyck (1), Manu Vandijck (1), John Lawson (2),
Zivjena Vucetic (2), Johan Gobom (3), Kaj Blennow (3), Vesna Kostanjevecki (1), Geert Jannes (1)
(1) Fujirebio Europe N.V., Ghent, Belgium, (2) Fujirebio Diagnostics Inc., Malvern, PA, USA, (3) Institute of Neuroscience and
Physiology, University of Gothenburg, Gothenburg, Sweden

P1-42 CSF MARKERS OF INFLAMMATION RELATE TO AD BIOMARKERS AND COGNITIVE PERFORMANCE IN HEALTHY ELDERLY AT RISK FOR AD

Pierre-François Meyer, MSc (1), Anne Labonté, BSc (1), Judes Poirier, PhD (1,2), John Breitner, MD, MPH (1,2), and the PREVENT-AD research Group

(1) Centre for Studies on Prevention of AD, Douglas Mental Health University Institute, Montreal, QC, Canada, (2) McGill University Faculty of Medicine, Montreal, QC, Canada

P1-43 AN ELECTROENCEPHALOGRAPHIC MARKER OF CHOLINERGIC ACTIVITY IN THE LIVING HUMAN BRAIN WITH APPLICATION TO ALZHEIMER'S

Magnus Johannsson (1), Jon Snaedal (2), Gisli Holmar Johannesson (1), Thorkell Eli Gudmundsson (2), Ivar Meyvantsson (1), Kristinn Johnsen (1)

(1) Mentis Cura ehf, Reykjavík, Iceland, (2) Memory Clinic, Geriatric Department, National University Hospital, Landakot, Revkiavík, Iceland

P1-44 PERFORMANCE CHARACTERISTICS OF CANDIDATE CSF BIOMARKERS OF METABOLIC, INFLAMMATORY, AND VASCULAR CONTRIBUTIONS TO ALZHEIMER'S DISEASE

Aaron M. Koenig MD (1), Bianca Trombetta BA (2), Steven E. Arnold MD (2)

(1) Department of Psychiatry, Massachusetts General Hospital, Boston, MA, USA, (2) Department of Neurology, Massachusetts General Hospital, Boston, MA, USA

P1-45 COGNITIVE AND FUNCTIONAL CHANGES ASSOCIATED WITH Aß PATHOLOGY AND THE PROGRESSION TO MILD COGNITIVE IMPAIRMENT

Philip S. Insel, MS (1,2,3), Michael C. Donohue, PhD (4), R. Scott Mackin, PhD (2,5), Paul S. Aisen, MD (4), Oskar Hansson, MD, PhD (1,6), Michael W. Weiner, MD (2,3), Niklas Mattsson, MD, PhD, (1,6,7) and the Alzheimer's Disease Neuroimaging Initiative

(1)Clinical Memory Research Unit, Faculty of Medicine, Lund University, Lund, Sweden, (2) Center for Imaging of Neurodegenerative Diseases, Department of Veterans Affairs Medical Center, San Francisco, CA, USA, (3) Department of Radiology and Biomedical Imaging, University of California, San Francisco, CA, USA, (4) Department of Neurology, Keck School of Medicine, University of Southern California, Los Angeles, CA, USA, (5) Department of Psychiatry, University of California, San Francisco, CA, USA, (6) Memory Clinic, Skåne University Hospital, Sweden 7Department of Neurology, Skåne University Hospital, Sweden

THEME 5: Clinical trials: cognitive and functional endpoints

San Diego Ballroom - Lobby Level

- P1-46 STRATEGIC MEMORY ALZHEIMERS REHABILITATION TRAINING (SMART): COGNITIVE PROTECTION AND INTERVENTION FOR AMNESTIC-TYPE MILD COGNITIVE IMPAIRMENT (MCI)

 John W. DenBoer, Ph.D, SMART Brain Aging, Inc.
- P1-47 STRATEGIC MEMORY ALZHEIMERS REHABILITATION TRAINING (SMART) MEMORY PROGRAM: TEMPORARY IMPROVEMENT FOR MCI/VCI VIA SYSTEMATIC NOVEL COGNITIVE EXERCISE

 John W. DenBoer, Ph.D., SMART Brain Aging, Inc.

POSTER SESSION 1: Thursday, December 8

THEME 5: Clinical trials: cognitive and functional endpoints (continued)

San Diego Ballroom - Lobby Level

P1-48 NEURAL PREDICTORS OF COGNITIVE IMPROVEMENT BY THE MEMORY TRAINING BASED ON METAMEMORY CONCEPT IN OLDER ADULTS

Jun-Young Lee MD, PhD, (1) Soowon Park, PhD (2), Seung-Ho Ryu, MD, PhD (3), Jung-Hae Youn, PhD (4), Jong-Min Lee (5), PhD (5)

(1) Department of Psychiatry, Seoul National University College of Medicine & SMG-SNU Boramae Medical Center, Seoul, Republic of Korea, (2) Department of Education, Sejong University, Seoul, Republic of Korea, (3) Department of Psychiatry, School of Medicine, Konkuk University, Konkuk University Medical Center, Seoul, Republic of Korea, (4) Yongmoon Graduate School of Counseling Psychology, Seoul, Republic of Korea, (5) Department of Biomedical Engineering, Hanyang University, Seoul, South Korea

P1-49 EXPANDING ON THE COGNITIVE FUNCTION INSTRUMENT FOR USE IN SECONDARY PREVENTION TRIALS

Rebecca E, Amariglio PhD (1,2,3), Dylan R. Kirn MPH (2), Rachel F. Buckley PhD (2,3,4,5), Elizabeth C. Mormino PhD (2,3), Dorene M. Rentz PsyD (1,2,3), Reisa A. Sperling MD (1,2,3)

(1) Department of Neurology, Brigham and Women's Hospital, Boston, MA, USA, (2) Department of Neurology, Massachusetts General Hospital, Boston, MA, USA, (3) Harvard Medical School, Boston, MA USA, (4) Florey Institutes of Neuroscience and Mental Health, Melbourne, Australia, (5) Melbourne School of Psychological Science, University of Melbourne, Australia

P1-50 BIAS AND EQUIVALENCE IN CROSS-CULTURAL ITEM EQUIVALENCE OF THE ALZHEIMER'S DISEASE ASSESSMENT SCALE – COGNITION (ADAS-COG)

Anzalee Khan (1,2), Ioan Stroescu (1), Alexandra Atkins (1), Rich Keefe (1,3) (1) NeuroCog Trials, (2) Nathan S. Kline Institute for Psychiatric Research, (3) Duke University

POSTER SESSION 2: Friday, December 9

THEME 2: Clinical Trials results

San Diego Ballroom - Lobby Level

P2-1 A NOVEL SNP GENOTYPING ARRAY FOR ALZHEIMER'S DISEASE DETECTION AT THE PRECLINICAL STATE Harald Hampel, MD, MSc, PhD (1,2); Maryam Shoai, PhD (3); Lakshmi Radhakrishnan, MSc (7); Richard Pither, PhD (4); Geoff Scopes, PhD (7); Marie-Claude Potier, PhD (1); Valentina Escott-Price, PhD (6); Simon M Laws, PhD (5); Simone Lista, PhD (2,8); Julie Davis, MSc (4); Claire Bloor, PhD (7); Bruno Dubois, MD, PhD (1); John Hardy, PhD, DSc (3) (1) Université Pierre et Marie Curie, Paris, France; (2) AXA Research Fund and UPMC Chair, Paris (3) UCL Institute of Neurology, London, United Kingdom; (4) Cytox Ltd, UK, Oxford, United Kingdom; (5) Edith Cowan University, and Cooperative Research Centre (CRC) for Mental Health, Perth, Australia; (6) Cardiff University, Cardiff, United Kingdom; (7) Affymetrix UK and USA; (8) IHU-A-ICM — Paris Institute of Translational Neurosciences, Paris, France. The study is supported by the IHU-A-ICM, the Memento cohort, the Fondation Plan-Alzheimer, Pfizer and Amyvid/Lilly.

P2-2 A CLINICAL PRECISION MEDICINE APPROACH REDUCES ALZHEIMER'S, DEMENTIA AND VASCULAR RISK AND IMPROVES COGNITION: RESULTS FROM THE ALZHEIMER'S PREVENTION CLINIC PATIENT REGISTRY AT WEILL CORNELL MEDICINE AND NEWYORK-PRESBYTERIAN

Richard S. Isaacson, MD, (1), Robert Krikorian, PhD, (2), Katherine Hackett, BA,(1), Chiashin Shih, PhD,(1), Mu Ji Hwang, (3), Jaclyn L. Chen, BS, (1), Josefina Meléndez-Cabrero, PhD, (4), Randy Cohen, MD, MS, (5), Mary Montgomery, RD, (6) Jessica Shum, BA,(1), Matthew W. Schelke, BA, (1), Roberta Marongiu, PhD, (1), Jeannette Hogg, RD,(1), Robert Kachko, ND,(7), Cara Berkowitz, BA,(1), Emily Caesar, BS,(1), Alon Seifan, MD, MS,(8)

(1) Weill Cornell Medicine, New York, NY, USA, (2) University of Cincinnati College of Medicine, Cincinnati, OH, USA, (3) Weill Cornell Medicine – Qatar, Doha, QATAR, (4) Alzheimer's Prevention Clinic and Research Center, San Juan PR, USA, (5) Mount Sinai St. Luke's, New York, NY, USA, (6) NewYork-Presbyterian Hospital, New York, NY, USA, (7) Inner Source Health, New York, NY, USA, (8) Nova Southeastern University, FL, USA

P2-3 PREDICTING RESPONSE TO A SIX MONTH TREATMENT WITH GALANTAMINE IN PATIENTS WITH MILD TO MODERATE ALZHEIMER'S DISEASE BASED ON A SINGLE DOSE PHARMACOLOGICAL CHALLENGE

Anne Catrien Baakman, MD(1), Laura Camps Cardenal, BSc(1), Carmen Gavan, MD(2), Ovidiu Bajenaru, MD, PhD(2), Marieke de Kam, MSc(1), Evelien Lemstra, MD, PhD(3), Philip Scheltens, MD, PhD(3), Adam Cohen, MD, PhD(1), Joop van Gerven, MD, PhD(1), Geert Jan Groeneveld, MD, PhD(1)

(1) Centre for Human Drug Research, Leiden, The Netherlands, (2) University Emergency Hospital, Department of Neurology, Bucharest, Romania, (3) Alzheimer Centre, VU University Medical Center, Amsterdam, The Netherlands

POSTER SESSION 2: Friday, December 9

(1) Alzheon, Inc., Framingham, MA, USA

P2-4 CLINICAL EXPERIENCE WITH A NOVEL AMYLOID-BETA PEPTIDE VACCINE FOR IMMUNOTHERAPY OF MILD ALZHEIMER'S DISEASE

P. N. Wang, MD(1*), M. J. Chiu, MD, PhD(2*), C. C. Huang, MD(3), C. C. Chang, MD(4), P.A. Frohna, MD, PhD(5), Y. T. Tseng, DVM(5,6), S. Lynn, PhD(6), X. D. Fang, PhD(7), C. L. Finstad, PhD(7), C. C. Yu, MD, PhD(5,6), C. Y. Wang, PhD(5,6,7) (1) Department of Neurology, Taipei Veterans General Hospital, Taipei, Taiwan; (2) Department of Neurology, National Taiwan University Hospital, Taipei, Taiwan; (3) Department of Neurology, Linkou Chang Gung Memorial Hospital, Taoyuan, Taiwan; (4) Department of Neurology, Kaohsiung Chang Gung Memorial Hospital, Kaohsiung, Taiwan; (5) United Neuroscience, Inc., Hauppauge, NY, USA; (6) UBI Asia, HsinChu, Taiwan; (7) United Biomedical, Inc., Hauppauge, NY, USA *These two authors have equal contribution to this study

P2-5 INTEPIRDINE (RVT-101), A 5-HT6 RECEPTOR ANTAGONIST, AS AN ADJUNCT TO DONEPEZIL IN MILD-TO-MODERATE ALZHEIMER'S DISEASE: EFFICACY ON ACTIVITIES OF DAILY LIVING DOMAINS

<u>Ilise Lombardo</u>, MD (1), Geetha Ramaswamy, MD (1), Lawrence Friedhoff, MD, PhD, FACP (1) (1) Axovant Sciences, Inc., New York, NY, USA

- P2-6

 THE EFFICACY OF INTEPIRDINE (RVT-101), A 5-HT6 RECEPTOR ANTAGONIST, AS AN ADJUNCT TO DONEPEZIL IN ADULTS WITH MILD-TO-MODERATE ALZHEIMER'S DISEASE: COMPLETER ANALYSIS OF A PHASE 2B STUDY

 Geetha Ramaswamy, MD(1), Ilise Lombardo, MD(1), Jason T. Olin, PhD(1), Stephen C. Piscitelli, PharmD(2), Lawrence Friedhoff, MD, PhD, FACP(1)

 (1) Axovant Sciences, Inc., New York, NY, USA, (2) Roivant Sciences, Inc., New York, NY, USA
- P2-7 COMBINED NEURAL AND MESENCHYMAL STEM CELL THERAPY FOR PATIENTS WITH DEMENTIA: PRELIMINARY RESULTS OF A SAFETY PHASE I STUDY

Alexei Lukashev, PhD (1), Daniyar Djumaniyazov, MD, PhD (2), Yury Prokopenko, MD (2), Sakhipzhamal Idrhissova, MD, PhD (2), Abay Baigenzhin, MD, PhD (2), Tristan Bolmont, PhD (1)

(1) Stemedica International SA, Lausanne, Switzerland, (2) National Medical Scientific Center, Astana, Kazakhstan

- P2-8

 CRENEZUMAB EXPOSURE-RESPONSE ACROSS AD ENDPOINTS SUPPORTS A HIGHER DOSE FOR PHASE 3

 Dan Polhamus PhD (2), James Rogers PhD (2), Robert Paul MD (1), Smita Kshirsagar PhD (1), Srikumar Sahasranaman PhD (1), Jin Y Jin PhD (1), Angelica L Quartino PhD (1)

 (1) Genentech, San Francisco, CA, USA, (2) Metrum Research Group, Tariffville, CT, USA
- P2-9 PHARMACOKINETICS, PHARMACODYNAMICS, SAFETY, AND TOLERABILITY OF THE NEW EXPLORATORY ALZHEIMER'S DRUG PIROMELATINE

 Moshe Laudon, PhD1 Amnon Katz, PhD1, Anat Frydman, PhD1, Nava Zisapel PhD1

 (1) Neurim Pharmaceuticals (1991) Ltd, Tel-Aviv, Israel
- P2-10 PHASE 1 PROGRAM OF ALZ-801, A NOVEL PRO-DRUG OF TRAMIPROSATE WITH IMPROVED TOLERABILITY: SUPPORTS BRIDGING TO UPCOMING PHASE 3 PROGRAM

 J.A. Hey (1), M. Versavel (1), S. Abushakra (1), A. Power (1), P.L. Kaplan (1), M. Tolar (1)
- P2-11

 RIVASTIGMINE AND CITALOPRAM TREATMENT FOR ALZHEIMER'S DISEASE IN EVERY DAY CLINICAL PRACTICE
 Magda Tsolaki, MD,PhD (1), Krishna Prasad Pathak, PhD (2), Eleni Verikouki MS (3), Paschalis Devranis, MD (4), Chaido
 Zachou Messini MS (5), Konstantinos Lysitsas MS (6), Tara Gaire. Msc, RN (7)
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 - (1) Macedonia of University, Thessaloniki, Greece, (2) Department of Neurology, Aristotle University of Thessaloniki, Greece, (3) Eleni Verikouki, Aristotle University of Thessaloniki, Greece, (4) Paschalis Devranis, Aristotle University of Thessaloniki, Greece, (6) Konstantinos Lysitsas. Aristotle University of Thessaloniki, Greece, (7) Star Hospital, Lalitpur, Nepal
- P2-12 PHARMACOKINETICS, PHARMACODYNAMICS, SAFETY, AND TOLERABILITY OF THE NEW EXPLORATORY ALZHEIMER'S DRUG PIROMELATINE

Moshe Laudon, PhD (1), <u>Amnon Katz</u>, PhD (1), Anat Frydman, PhD (1), Nava Zisapel PhD (1) (1) Neurim Pharmaceuticals (1991) Ltd, Tel-Aviv, Israel

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THEME 2: Clinical Trials results (continued)

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P2-13 MK7622, A POSITIVE ALLOSTERIC MODULATOR OF THE M1 ACETYLCHOLINE RECEPTOR, DOES NOT IMPROVE SYMPTOMS IN ALZHEIMER'S DISEASE: A RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED PROOF OF CONCEPT TRIAL

<u>Tiffini Voss</u>, MD (1); Jerry Li, PhD (1); Jeffrey Cummings, MD (2); Rachelle Doody, MD, PhD (3); Martin Farlow (4), MD; Christopher Assaid, PhD (1); Samar Froman (1); Heather Leibensperger (1); Linda Snow-Adami (1); Kerry Budd McMahon (1); Michael Egan, MD: David Michelson, MD (1)

(1) Merck & Co. Inc., Kenilworth, NJ, USA, (2) Cleveland Clinic Lou Ruvo Center for Brain Health, Las Vegas, NV, USA, (3) Baylor College of Medicine, Houston, TX, USA, (4) Indiana University School of Medicine, Indianapolis, IN, USA

P2-14 OPTIMAL ERYTHROCYTE OMEGA-3 FATTY ACID COMPOSITION CUT-OFF FOR PREDICTING COGNITIVE DECLINE AND/OR TREATMENT RESPONSE TO SUPPLEMENTATION: DATA FROM THE MAPT TRIAL

Nicola Coley (1), Mike Donohue (2), Rema Raman (2), Paul Aisen (2), Bruno Vellas (3), Sandrine Andrieu (2) (1) UMR1027, Toulouse University, UPS, INSERM, CHU Toulouse, Department of Epidemiology and Public Health, Toulouse, France, (2) Alzheimer's Therapeutic Research Institute, University of Southern California, San Diego, CA, USA, (3) UMR1027, Toulouse University, UPS, INSERM, CHU Toulouse, Gerontopole, Department of Geriatric Medicine, Toulouse, France

THEME 5: Clinical trials: cognitive and functional endpoints

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P2-15 DIGITAL BIOMARKERS FOR CLINICAL TRIAL USE IN PRE-SYMPTOMATIC TO SYMPTOMATIC ALZHEIMER'S DISEASE AND RELATED DEMENTIAS - BUILDING THE REGULATORY SCIENCE ROADMAP

Stephen P. Arneric, PhD (1), Daniel R. Karlin, MD (2), Maurizio F. Facheris, MD (3), Jesse M. Cedarbaum, MD (4), Mark Forrest Gordon, MD (5), Enrique Avilés (1), Derek L. Hill, PhD (6), Lynn D. Hudson, PhD (1), Volker D. Kern, PhD (1), Klaus Romero, MS, MD (1), Jane Rhodes, MBA, PhD (4), George Vrandenburg (7), Penny A. Dacks, PhD (8), Jeffrey A. Kaye, MD (9) (1) Critical Path Institute, Tucson, AZ, USA, (2) Pfizer, Boston, MA, USA, (3) AbbVie, North Chicago, IL, USA, (4) Biogen, Cambridge, MA, USA, (5) Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT, USA, (6) IXICO, London, United Kingdom, (7) USAgainstAlzheimer's, Washington, DC, USA, (8) Alzheimer's Drug Discovery Foundation, New York, NY, USA, (9) Oregon Health Science University, Portland, OR, USA

- P2-16

 EARLY- VERSUS LATE-ONSET ALZHEIMER'S DISEASE—DIFFERENCES IN FUNCTIONAL IMPAIRMENT
 Carina Wattmo, RN, BSc, PhD (1), Åsa K. Wallin, MD, PhD (1)
 (1) Clinical Memory Research Unit, Department of Clinical Sciences, Malmö, Lund University, Malmö, Sweden
- P2-17

 NEUROPHYSIOLOGICAL EFFECT OF PXT864 IN MILD ALZHEIMER'S DISEASE PATIENTS

 Karim Bennys (1), Peter Schmitt (2), Audrey Gabelle (1), Daniel Cohen (2), JacquesTouchon (1)

 (1) Memory Research Resource Center for Alzheimer's disease, University Hospital Montpellier, France, Montpellier, France, (2)

 Pharnext SAS, Issy les Moulineaux, France, Paris, France
- P2-18 BIASED ESTIMATES OF COGNITIVE DECLINE RESULTING FROM VIOLATIONS OF MEASUREMENT INVARIANCE CAN BE EXPECTED, TESTED AND CORRECTED

<u>Luca Kleineidam</u>, MSc (1,2), Wolfgang Maier, MD (1,2), Michael Wagner, PhD (1,2) (1) University of Bonn, Department of Psychiatry and Psychotherapy, Bonn, Germany, (2) DZNE, German Center for Neurodegenerative Diseases, Bonn, Germany

P2-19 OLFACTORY IDENTIFICATION ABILITY CORRELATES WITH CSF TOTAL-TAU/Aß1-42 IN NORMAL ELDERLY AT RISK OF AD

Marie-Elyse Lafaille-Magnan (1,2), Judes Poirier (1,2), Anne Labonté (1), David Fontaine (1), John Breitner (1,2), PREVENT-AD Research Group

(1) Centre for Studies on Prevention of AD, Douglas Mental Health University Institute; (2) McGill University, Faculty of Medicine, Montreal, QC, Canada

P2-20 ATYPICAL PRESENTATIONS OF ALZHEIMER'S DISEASE (AD) AND THEIR EFFECT ON DISEASE PROGRESSION AND SURVIVAL

Ajay Sood MD, PhD (1), Eveleen Darby (2) MS, Wenyaw Chan, PhD (3), Vallory Pavlik, PhD (2), Massman PJ, PhD (4), Rachelle Doody, MD, PhD (2)

(1) AMITA Health, Alexian Brothers Medical Center, Elk Grove Village, IL, USA, (2) Department of Neurology and Alzheimer's Disease and Memory Disorders Center, Baylor College of Medicine, Houston, TX USA, (3) Department of Biostatistics, University of Texas Health Science Center at Houston, Houston, TX, USA, (4) Department of Psychology, University of Houston, TX USA

P2-21 DETECTION OF NEURODEVELOPMENTAL DIVERSITY IN AN ALZHEIMER PREVENTION COHORT USING A SELF-REPORT SCALE

Alon Seifan, MD, MS, (1), Richard S. Isaacson, MD, (2), Katherine Hackett, BA, (2) Chiashin Shih, PhD, (2) Jaclyn L. Chen, BS, (2), Jessica Shum, BA, (2) Matthew W. Schelke, BA, (2), Robert Krikorian, PhD, (3), Eve LoCastro, MS, (4), Gloria Chiang, MD, (4), Linda Heier, MD, (4)

(1) Compass Health Systems / Nova Southeastern University, FL, USA, (2) Weill Cornell Medicine, New York, NY, USA, (3) University of Cincinnati College of Medicine, Cincinnati, OH, USA, (4) Weill Cornell Medicine, Department of Radiology, Imaging Data Evaluation & Analytics Lab

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P2-22 VALUE OF PERFORMANCE-BASED OUTCOME ASSESSMENTS OF FUNCTION IN EARLY ALZHEIMER'S DISEASE CLINICAL TRIALS

Chris J Edgar PhD (1); Meaghan Krohe PhD (2); Stephen Joel Coons PhD (3); on behalf of the Patient-Reported Outcome (PRO) Consortium's Cognition Working Group

(1) Roche Products Ltd, Welwyn, UK, (2) Adelphi Values, Boston, MA, USA, (3) Patient-Reported Outcome Consortium, Critical Path Institute, Tucson, AZ, USA

P2-23 INTELLIGENT CLINICAL INTERVIEWS FOR ALZHEIMER'S DISEASE: HOW THE ADDITION OF AUDIO REVIEWS TO ECOA SCALE ADMINISTRATION RESULTS IN IMPROVED DATA QUALITY

Todd M. Solomon, PhD, Jessica Meyer, BA and David S. Miller, MD, MA Bracket, Wayne, PA, USA

P2-24 COULD OBJECTIVE MEASURES OF ACTIVITY AND THE STANDARDISATION OF ENDPOINTS HELP CLARIFY THE VALUE AND IMPACT OF EXERCISE IN PATIENTS WITH AD?

Marie Mc Carthy, Bill Byrom, Willie Muehlhausen ICON PLC, Dublin Ireland

THEME 6: Cognitive Assessments and clinical trials

San Diego Ballroom - Lobby Level

P2-25 WASURE-NAVI-TO FOR A BETTER DEMENTIA AND MCI PATIENT CARE

Atsushi Iwata, MD, PhD (1), Mamoru Yanagimachi (2), Hitomi Sunaga R.Ph.(3), Toji Miyagawa MD, PhD (1), Tatsuo Mano, MD, PhD (1), Kazushi Suzuki MD, PhD (1), Yasuhiko Nakamoto R.Ph.(3), Takafumi Watanabe, Rami Suzuki PhD (2), Shoji Tsuji MD, PhD (1)

(1) Department of Neurology, The University of Tokyo, Tokyo, Japan, (2) Eisai Co, Ltd, Tokyo, Japan, (3) Cocokara fine Healthcare, Yokohama, Kanagawa, Japan

P2-26 OLFACTORY DEFICITS IN MCI AS PREDICTOR OF IMPROVED COGNITION ON DONEPEZIL: A PRELIMINARY STUDY D.P. Devanand, MD (1,2), Gregory Pelton, MD (1), Cody Lentz, BS (1), Evan Chunga, BA (1), Karen Bell, MD (2), Jennifer Scodes, MS (3), Adam Ciarleglio, PhD (3)

(1) Division of Geriatric Psychiatry, Department of Psychiatry, New York State Psychiatric Institute and Columbia University Medical Center, (2) Department of Neurology and Taub Institute for Research on Alzheimer's disease, Columbia University Medical Center, (3) Division of Biostatistics, Department of Psychiatry, Columbia University Medical Center

P2-27 STABILITY OF BAYESIAN COGNITIVE PROCESS PARAMETERS ACROSS WORDLIST MEMORY TASKS AND STUDY POPULATIONS

William R. Shankle, MS, MD(1,2,3), Junko Hara, PhD(1), Dennis Fortier, MS(1), William H. Batchelder, PhD(2), Gregory E. Alexander, MS(2), Ronald C. Petersen, MD, PhD(4)

(1) Medical Care Corporation, Newport Beach, CA, USA, (2) Dept. of Cognitive Sciences, University of California at Irvine, Irvine, CA, USA, (3) Hoag Neuroscience Institute, Hoag Memorial Hospital, Newport Beach, CA, USA, (4) Mayo Clinic, Rochester, MN, USA

P2-28 REPETITIVE TMS OF THE DEFAULT MODE NETWORK: A RANDOMIZED, DOUBLE-BLINDED, CROSS-OVER STUDY TRIAL IN MCI PATIENTS

Giacomo Koch (1), Sonia Bonnì (1), Silvia Picazio (1), Francesco Di Lorenzo (1), Viviana Ponzo (1), Maria Concetta Pellicciari (1), Elias Casula (1), Laura Serra (2), Matteo Mancini (2), Carlo Caltagirone (1), Alessandro Martorana (3), Marco Bozzali (2) (1) Non-Invasive Brain Stimulation Unit, Santa Lucia Foundation IRCCS, Rome, Italy, (2) Neuroimaging Laboratory, Santa Lucia Foundation, Rome, Italy, (3) Memory Clinic, Department of Neuroscience, Policlinico Tor Vergata, Rome, Italy

P2-29 COGNITIVE COMPOSITES FOR MILD COGNITIVE IMPAIRMENT (MCI): UTILITY OF THE REPEATABLE BATTERY FOR THE ASSESSMENT OF NEUROPSYCHOLOGICAL STATUS (RBANS)

Noel Ellison, MS, Suzanne Hendrix, PhD (1) (1) Pentara Corporation, Salt Lake City, USA

P2-30 COMPARING RATER PERFORMANCE WITH AUDIO-RECORDED VS. MOCK ADMINISTRATIONS OF COGNITIVE ASSESSMENTS IN AN ALZHEIMER'S DISEASE CLINICAL TRIAL

Gladys Valdez, PhD(1), Macarena García-Valdecasas Colell, MA(1), Magda Perez, PhD(1), Stephen Sainati, MD(2), Manny Lazaro, MD(2), Stephen Brannan, MD(2), Dana Hilt, MD(2)

(1) inVentiv Health, Cary, NC, USA, (2) Forum Pharmaceuticals, Waltham, MA, USA

P2-31 PSYCHOMETRIC PROPERTIES OF COGNITIVE ENDPOINTS FROM THE CANTAB NEUROPSYCHOLOGICAL BATTERY IN A PRODROMAL ALZHEIMER'S DISEASE POPULATION

Rosemary Abbott, PhD(1), Chris Edgar, PhD(2), Francesca Cormack, PhD(1), Robert Lasser, MD, MBA(3), Elizabeth Ashford, BSc(2), Kenton Zavitz, PhD(1)

(1) Cambridge Cognition, Cambridge, UK, (2) Roche Products Limited, Welwyn Garden City, UK, (3) F. Hoffmann-La Roche Ltd, Basel, Switzerland

POSTER SESSION 2: Friday, December 9

THEME 6: Cognitive Assessments and clinical trials (continued)

San Diego Ballroom - Lobby Level

P2-32 COMBINING THE INFORMATION FROM MULTIPLE EPISODIC MEMORY TESTS TO OPERATIONALIZE THE DIAGNOSIS OF MILD COGNITIVE IMPAIRMENT

G Novak MF(1), DS Keller PhD(2), MF Gordon MD(3), L Ford MD(1), A Lleó MD(4), JL Molinuevo MD PhD(5) (1) Janssen R&D, Titusville, NJ, USA, (2) Pfizer, Cambridge, MA, USA, (3) Boehringer-Ingelheim, Ridgefield, CT, USA, (4) Hospital de la Santa Creu i Sant Pau, Barcelona, Spain, (5) ICN Hospital Clinic i Universitari, IDIBAPS, Barcelona, Spain

P2-33 VIRGIL PLATFORM HELPS IMPROVE SITE PERFORMANCE AND SIGNAL DETECTION IN AD TRIALS Christopher Randolph, PhD(1,2), Selam Negash, PhD(1), Doug Osman, PhD(1), Peter Sorantin, PhD(1) (1) MedAvante, Inc., Hamilton, NJ, USA, (2) Loyola University Medical Center, Maywood, IL, USA

P2-34 A COMPARISON OF AUDIO AND MANUAL REVIEW OF RATER PERFORMANCE IN AN ALZHEIMER'S DISEASE CENTRAL RATING REVIEW PROGRAM

Stephen M. Meyer, MA (1), <u>Dawn Sikich</u> (1), Elisa S. Conrad, MA (1), Magdalena Perez, PhD (1), Stephen M. Sainati, MD, PhD (2), E. Manny Lazaro (2), Stephen Brannan, MD (2), Dana Hilt, MD (2) (1) inVentiv Health Rater Training Services, Cary, NC, USA, (2) FORUM Pharmaceuticals, Waltham, MA, USA

P2-35 IMPACT OF THE BDNF VAL66MET POLYMORPHISM ON LONG TERM MEMORY IN SUBJECTS WITH AGE-ASSOCIATED MEMORY IMPAIRMENT (AAMI)

Rebecca Crean, PhD (1), Philip Perera, MD (1), Jamie Reiter, PhD (1), Donald Connor, PhD (2), Gary Kay, PhD (3), Keith Wesnes, PhD (4), David Carpenter, PhD (1)

(1) Dart NeuroScience, San Diego, CA, USA, (2) Contractor, San Diego, CA, USA, (3) Cognitive Research Corporation, St. Petersburg, FL, USA, (4) Wesnes Cognition LTD, Streatley on Thames, England, UK

THEME 11: New therapies and clinical trials

San Diego Ballroom - Lobby Level

P2-36 POTENTIAL OF PROTEOSTASIS-DIRECTED THERAPIES FOR ALZHEIMER'S DISEASE (AD) John Alam MD (1.2)

(1) EIP Pharma LLC, Cambridge, MA, USA, (2) Alliance for Aging Research, Washington, DC, USA

P2-37 AMYLOID-6 OLIGOMER MAY INDUCE NEURONAL IMPAIRMENT VIA DISRUPTING STRUCTURE AND LACTATE TRANSPORT OF OLIGODENDROCYTES

Zhongxiang Yao, MD, PhD (1), Mao Zhang, MS (1), Ziyi Ma, BS (2), Haochen Qin, BS (3), Jie Zhang, MS (1) (1) Department of Physiology, Third Military Medical University, Chongqing, China, (2) Battalion 14 of Cadet Brigade, Third Military Medical University, Chongqing, China, (3) Battalion 10 of Cadet Brigade, Third Military Medical University, Chongqing, China

P2-38 DECONVOLUTION OF NASAL ABSORPTION OF RIVASTIGMINE IN HUMANS AND FUTURE CLINICAL DEVELOPMENT Timothy Morgan, PhD Lachesis Biosciences Pty Ltd, Warrnambool, VIC, AU

P2-39 SYNTHESIS AND BIOLOGICAL EVALUATION OF SOME NOVEL N-METHYLENEBENZENAMINE DERIVATIVES AS SELECTIVE ACETYLCHOLINESTERASE INHIBITORS TO IMPROVE LEARNING AND MEMORY

<u>Sushant Kumar Shrivastava</u>, M.Pharm, Ph.D.(1), Pavan Srivastava, M.Pharm (1), TVR Upendra, M.Pharm (1), Prabhash Nath Tripathi, M.S.(Pharm) (1)

(1) Department of Pharmaceutics, Indian Institute of Technology (Banaras Hindu University), Varanasi - India

P2-40 STUDY DESIGN AND RECRUITMENT IN TWO PHASE II PROOF-OF-CONCEPT CLINICAL TRIALS OF THE PDE9 INHIBITOR BI 409306 IN EARLY ALZHEIMER'S DISEASE

Glen Wunderlich, PhD(1), Claus Thamer, MD(2), Michael Roehrle(2), Miguel Garcia Jr., MS(3), Lutz Froelich, MD(4), Bruno Dubois, MD(5)

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P2-41 THE INFLUENCE OF A SHORT COGNITIVE AND MOBILITY TRAINING PROGRAM ON COGNITIVE PERFORMANCE AMONG THE "YOUNG-OLD" AND THE "OLD-OLD"

Carine Federspiel, MD(1,2,3), Elisabeth Bourkel, PhD(1), Jean-Paul Steinmetz, PhD(1,3)

(1) Centre for memory and mobility, Luxembourg, (2) Association Luxembourg Alzheimer, Luxembourg, (3) ZithaSenior, Research&Development, Luxembourg

San Diego

Clinical Trials on Alzheimer's Disease

POSTER PRESENTATIONS

POSTER SESSION 2: Friday, December 9

P2-42 PHARMACOKINETICS OF SINGLE DOSES OF BI 425809 IN CHINESE SUBJECTS: A DOUBLE-BLIND PLACEBO-CONTROLLED TRIAL IN HEALTHY VOLUNTEERS

Yasuhiro Tsuda (1), Regina Park, BPharm (2), Hiroyuki Ugai (3), Michael Desch, PhD (4), Sophia Goetz, Dipl. Math.(4), Christina Schlecker, MD (5), Armin Schultz, MD, PhD (6), Karl-Heinz Liesenfeld (4), Sven Wind, PhD (4), Sun-Young A. Yum, MD (2,a), Glen Wunderlich, PhD (7), Jae-Gook Shin, MD, PhD (8)

(1) Nippon Boehringer Ingelheim Co. Ltd, Kobe, Japan, (2) Boehringer Ingelheim Corporation Ltd, Seoul, South Korea, (3) Nippon Boehringer Ingelheim Co. Ltd, Tokyo, Japan, (4) Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach an der Riss, Germany, (5) Boehringer Ingelheim Pharma GmbH & Co. KG, Ingelheim am Rhein, Germany, (6) CRS Clinical Research Services, Mannheim GmbH, Mannheim, Germany, (7) Boehringer Ingelheim (Canada) Ltd, Burlington, ON, Canada, (8) Inje University Busan Paik Hospital, Busan, Korea, (a) At the time of study

P2-43 PHASE 3 EFFICACY, SAFETY, AND TOLERABILITY STUDIES OF AVP-786 (DEUTERATED (D6)-DEXTROMETHORPHAN HYDROBROMIDE PLUS QUINIDINE SULFATE) FOR THE TREATMENT OF AGITATION IN ALZHEIMER'S DISEASE (NCT02442765, NCT02442778, NCT02446132)

<u>Jeffrey Cummings</u>, MD, ScD (1); Sanjay Dubé, MD (2,5); Paul Shin, MS (2); Thomas Megerian, MD, PhD (2); Stacy Wu, MD (2); Uyen Nguyen, BS (2); Constantine Lyketsos, MD, MHS (6)

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P2-44 PHASE 1 PROGRAM OF ALZ-801, A NOVEL PRO-DRUG OF TRAMIPROSATE WITH IMPROVED PHARMACOKINETIC PROPERTIES: BIOEQUIVALENCE STUDIES PROVIDE BRIDGING TO UPCOMING PHASE 3 PROGRAM

<u>J.A. Hey</u> (1), S. Abushakra (1), A. Power (1), J.Y. Yu (1), P.L. Kaplan (1), M. Versavel (1), M. Tolar (1) (1) Alzheon, Inc., Framingham, MA, USA

POSTER SESSION 3: Saturday, December 10

THEME 4: Clinical trials biomarkers including Plasma

San Diego Ballroom - Lobby Level

P3-1 EVALUATION OF CROSS-SECTIONAL TAU BURDEN AND PRELIMINARY LONGITUDINAL CHANGES IN ALZHEIMER'S DISEASE SUBJECTS USING [18F]GTP1 (GENENTECH TAU PROBE 1)

Sandra Sanabria Bohorquez, PhD(1), Thomas Bengtsson, PhD(2), Jan Marik, PhD(3), Olivier Barret, PhD(4), Gilles Tamagnan, PhD(4), David Alagille, PhD(4), Gai Ayalon, PhD(5), Mike Ward, PhD(6), Danna Jennings, MD(4), John P. Seibyl, MD(4), Ken Marek, MD(4), Geoffrey A. Kerchner, MD PhD(6), Robby M Weimer, PhD(3)

(1) Clinical Imaging Group, (2) Biostats, (3) Department of Biomedical Imaging, (5) Department of Neuroscience, and (6) Early Clinical Development, Genentech, Inc., 1 DNA Way, South San Francisco, CA 94080, USA, (4) Molecular NeuroImaging LLC, 60 Temple Street, New Haven, CT, 06510, USA

P3-2 CLUSTERIN IS A POTENTIAL BIOMARKER FOR LATE ONSET ALZHEIMER'S DISEASE

Jordan L. Holtzman, M.D., Ph.D, Environmental Health Sciences, University of Minnesota, Minnapolis, MN

POSTER SESSION 3: Saturday, December 10

THEME 6: Cognitive Assessments and Clinical Trials

San Diego Ballroom - Lobby Level

- P3-3 IMPACT OF DIABETES ON CAREGIVER STRESS IN PATIENTS WITH AD: DATA FROM THE ICTUS STUDY Jun Li, West China Hospital, Sichuan University, Chengdu, CN
- P3-4 IMPROVED DETECTION OF TREATMENT EFFECTS IN SEVERE ALZHEIMER'S DISEASE: A QUANTITATIVELY-DERIVED SIB-BASED COMPOSITE SCALE

Alireza Atri, MD, PhD (1,2), Suzanne Hendrix, PhD (3), Noel Ellison, MD (3), Mary Clare Kane, PhD (4), John Edwards, MD, MBA (5), George Grossberg, MD (6)

(1) Ray Dolby Brain Health Center, California Pacific Medical Center, San Francisco, CA, USA, (2) Center for Brain/Mind Medicine, Department of Neurology, Brigham and Women's Hospital and Harvard Medical School, Boston, MA, (3) Pentara Corporation, Salt Lake City, UT, USA, (4) Prescott Medical Communications Group, Chicago, IL, USA, (5) Allergan, Jersey City, NJ, USA, (6) Saint Louis University, Saint Louis, MO, USA

- P3-5

 NEUROPSYCHOLOGICAL TESTS VALIDATED BY CSF-BIOMARKERS TO DISTINGUISH BETWEEN COGNITIVE DEFICITS DUE TO OR INDEPENDENT FROM AD IN PATIENTS PRESENTING WITH DEPRESSIVE SYMPTOMS
 Oliver Peters, MD, Felix Menne, Manuel Fuentes, Brigitte Haas, PhD, Isabella Heuser, MD, PhD
 Department of Psychiatry, Charité University Medicine Berlin, Berlin, Germany
- P3-6

 PRACTICE EFFECTS IN ALZHEIMER'S DISEASE PREVENTION TRIALS: PROOF OF CONCEPT FOR A COGNITIVE TEST RUN-IN

 Diane M. Jacobs, PhD (1), M. Colin Ard, PhD (1), Steven D. Edland, PhD (1,2)

(1) Shiley-Marcos Alzheimer's Disease Research Center, Department of Neurosciences, University of California, San Diego, CA, USA, (2) Division of Biostatistics, Department of Family Medicine & Public Health, University of California, San Diego, CA, USA

- P3-7

 IMPROVING COGNITIVE SCREENING ACCURACY AND EFFICIENCY FOR MINIMALLY IMPAIRED INDIVIDUALS

 William Souillard-Mandar (1), Randall Davis, PhD (1,2), Rhoda Au, PhD (3), Dana L. Penney, PhD (1,4)

 (1) Digital Cognition Technologies, Inc, Waltham, MA, USA, (2) MIT Computer Science And Artificial Intelligence Laboratory,
 Cambridge, MA, USA, (3) Boston University Schools of Medicine and Public Health, Boston, MA, USA, (4) Lahey Hospital and
 Medical Center, Burlington, MA, USA
- P3-8 VALIDATION OF AN AUTOMATED SCORING METHOD FOR WEB CAMERA EYE TRACKING ON A VISUAL PAIRED COMPARISON TASK

Nicholas T. Bott, PsyD (1,2), Alex Lange, MS (2), Robert Cosgriff, MS (2), Paul Clopton, MS (3), Beth Buffalo, PhD (2,4), Dorene M. Rentz, PsyD (5,6,7), Stuart Zola, PhD (2,8)

(1) Department of Medicine, Stanford University School of Medicine, Stanford, CA, USA, (2) Neurotrack Technologies, Inc., Redwood City, California, USA, (3) University of California San Diego School of Medicine, San Diego, California, USA, (4) University of Washington, Seattle, Washington, USA, (5) Massachusetts General Hospital, Boston, Massachusetts, USA, (6) Harvard Medical School, Boston, Massachusetts, USA, (7) Brigham and Women's Hospital, Boston, Massachusetts, USA, (8) Emory University Office of the Provost, Atlanta, Georgia, USA

THEME 7: Behavioral disorders and clinical trials

San Diego Ballroom - Lobby Level

P3-9 ASSOCIATION OF SUBSYNDROMAL SYMPTOMS OF DEPRESSION WITH COGNITIVE DECLINE AND CORTICAL ATROPHY IN INDIVIDUALS WITH MILD COGNITIVE IMPAIRMENT

R. Scott Mackin, Ph.D.(1,2), Philip S. Insel, MS (2), Craig Nelson, MD (1), Mitzi M. Gonzales, Ph.D. (1,3), Duygu Tosun, Ph.D.(2,4), Niklas Mattsson, MD, Ph.D. (5,6), Susanne G. Mueller, MD (2,4), Simona Sacuiu, MD, Ph.D.(7), David Bickford, BA (1), Michael W. Weiner, MD (1,2,4,8), and the Alzheimer's Disease Neuroimaging Initiative

(1) Department of Psychiatry, University of California, San Francisco, CA, USA, (2) Center for Imaging of Neurodegenerative Diseases, Veterans Administration Medical Center, San Francisco, CA, USA, (3) Department of Mental Health, VA Northern California Health Care System, Martinez, CA, USA, (4) Department of Radiology, University of California, San Francisco, CA, USA, (5) Clinical Memory Research Unit, Faculty of Medicine, Lund University, Lund, Sweden, (6) Department of Neurology, Skane University Hospital, Lund, Sweden, (7) Institute of Neuroscience and Physiology, Sahlgrenska Academy, University of Gothenburg, Sweden, (8) Department of Medicine, University of California, San Francisco, CA, USA

P3-10 CHANGES IN NEUROPSYCHIATRIC SYMPTOMS OVER 3 YEARS BETWEEN EARLY -VERSUS LATE-ONSET AMNESTIC MILD COGNITIVE IMPAIRMENT

Geon Ha Kim (*a), Jong-Won Kim (*b), Youngshin Yoon (c), Kyoung-Gyu Choi (a), Seong Hye, Choi (d), Jee Hyang Jeong (a) (a) Department of Neurology, Ewha Womans University Mokdong Hospital, Ewha Womans University School of Medicine, Seoul, Korea, (b) Department of Emergency Medicine, School of medicine, Konkuk University, Konkuk University Medical Center, Seoul, Republic of Korea, (c) Department of Neurology, Seoul Metropolitan Seonam Hospital, Seoul, Korea, (d) Department of Neurology, Inha University Hospital, Inha University School of Medicine, Incheon, Korea

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POSTER SESSION 3: Saturday, December 10

P3-11 USING ENVIRONMENTAL LIGHT THERAPY TO IMPROVE SLEEP AND NEUROPSYCHIATRIC SYMPTOMS IN DEMENTIA Sébastien Gonfrier, MD(3), Sawsan Al Rifai, MD(1), Linda Benattar, MD(2), Laurence Merlin, MD(2), Philippe Zawieja, PhD(2), Olivier Guerin, MD, PhD(3)

(1) EHPAD Les Pastoureaux, Valenton, France, (2) ORPEA group, Puteaux, France, (3) CHU Nice, France

THEME 9: Epidemiology and clinical trials

San Diego Ballroom - Lobby Leve

P3-12 OPERATIONALIZING THE IWG2 AND NIA-AA DIAGNOSTIC CRITERIA IN SIX EUROPEAN COHORTS

W Tang (1), <u>G Novak</u> (2), MF Gordon (1), S Engelborghs (3), Stephanie J. B. Vos (4), A Lleó (5), JL Molinuevo (6), Giovanni B Frisoni (7), Pieter Jelle Visser (4,8)

(1) Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT, USA, (2) Janssen Pharmaceutical Research and Development, Titusville, NJ, USA, (3) University of Antwerp, Antwerp, Belgium, (4) Maastricht University, Maastricht, the Netherlands, (5) Hospital de la Santa Creu i Sant Pau, Barcelona, Spain, (6) ICN Hospital Clinic i Universitari, IDIBAPS, Barcelona, Spain, (7) University Hospitals and University of Geneva, Switzerland, and IRCCS Fatabenefratelli, Brescia, Italy, (8) VU University Medical Center, Amsterdam, the Netherlands

P3-13 AMYLOID PATHOLOGY IN THE PROGRESSION TO MILD COGNITIVE IMPAIRMENT

Philip Insel, MS (1,2,3), Oskar HanssonMD, PhD (1,5), R. Scott Mackin, PhD (2,4), Michael Weiner, MD (2,3), Niklas Mattsson, MD, PhD (1,5,6), for the Alzheimer's Disease Neuroimaging Inititative (7)

(1) Clinical Memory Research Unit, Faculty of Medicine, Lund University, Lund, Sweden, (2) Center for Imaging of Neurodegenerative Diseases, Department of Veterans Affairs Medical Center, San Francisco, CA, USA, (3) Department of Radiology and Biomedical Imaging, University of California, San Francisco, CA, USA, (4) Department of Psychiatry, University of California, San Francisco, CA, USA, (5) Memory Clinic, Skåne University Hospital, Sweden, (6) Department of Neurology, Skåne University Hospital, Sweden

P3-14 UTILIZING ADMINISTRATIVE CLAIMS DATA TO IDENTIFY SEVERITY IN PATIENTS WITH ALZHEIMER'S DISEASE: CHALLENGES AND OPPORTUNITIES

Fanta W Purayidathil, PhD, MPH(1), Sarah Cadarette, MS(2), Amanda Forys, MSPH(2), Trent McLaughlin BSc(Pharm), PhD(2), Manasee Shah, MPH(2), Myrlene Sanon Aigbogun, MPH(3)

(1) Health Economics and Outcomes Research, Avanir Pharmaceuticals, Inc., (2) Health Economics and Outcomes Research, Xcenda, (3) Health Economics and Outcomes Research, Otsuka Pharmaceutical Development & Commercialization, Inc.

THEME 10: Animal model and clinical trials

San Diego Ballroom - Lobby Level

P3-15 AMELIORATION OF GASTRO-INTESTINAL MICROBIOTA FOLLOWING STEM CELL TREATMENT IN A MOUSE MODEL OF CEREBRAL ABETA AMYLOIDOSIS

Tristan Bolmont, PhD (1,2), Taoufiq Harach (2), Alexei Lukashev, PhD (1), Nikolai Tankovich, MD, PhD (3)

(1) Stemedica International, Lausanne, Switzerland, (2) Ecole Polytechnique Federale de Lausanne, Lausanne, Switzerland, (3) Stemedica Cell Technologies, San Diego, CA, USA

P3-16 BI 425809, A NOVEL GLYT1 INHIBITOR, INCREASES GLYCINE LEVELS IN CEREBROSPINAL FLUID (CSF): RESULTS FROM PRECLINICAL AND CLINICAL TRANSLATIONAL PROOF-OF-MECHANISM STUDIES

Holger Rosenbrock, PhD (1), Viktoria Moschetti, MD (2), Oliver Kleiner, PhD (1), Michael Desch, PhD (1), Christina Schlecker, MD (2), Sophia Goetz, Dipl. Math.(1), Karl-Heinz Liesenfeld (1), Sun-Young A. Yum, MD (3,a), Gwenaelle Fillon, PhD (1), Glen Wunderlich, PhD (4), Sven Wind, PhD (1)

(1) Boehringer Ingelheim Pharma GmbH & Co. KG, Biberach an der Riss, Germany, (2) Boehringer Ingelheim Pharma GmbH & Co. KG, Ingelheim am Rhein, Germany, (3) Boehringer Ingelheim Corporation Ltd, Seoul, South Korea, (4) Boehringer Ingelheim (Canada) Ltd, Burlington, ON, Canada, aAt the time of study

P3-17 REVERSIBLE AND SPECIES-SPECIFIC DEPIGMENTATION EFFECTS OF AZD3293 ARE RELATED TO BACE2 INHIBITION AND CONFINED TO SKIN AND HAIR

Gvido Cebers, MD, PhD (1); Magnus Soderberg, MD, PhD (2); Evan W. Ingersoll, PhD (1); Robert C. Alexander, MD (1*); Samantha Budd Haeberlein, PhD (1*); Alan R. Kugler PhD (1*); Bassem Attalla, BS (3); Thyphaine Lejeune, DVM, DECVP (3); Stefan Platz, DVM, PhD (2); Clay W. Scott, PhD (4)

(1) Neuroscience iMed, AstraZeneca, Cambridge, MA, USA, (2) Drug Safety and Metabolism, AstraZeneca, Cambridge, UK, (3) Charles River Laboratories, Montreal ULC, Sonneville site, Canada, (4) Drug Safety and Metabolism, AstraZeneca, Waltham, USA * No longer an AstraZeneca employee

P3-18 APP GENE DOSE MEDIATED NEURODEGENERATION IN MOUSE MODELS OF DOWN SYNDROME

Mariko Sawa, PhD (1), Cassia Overk, PhD (1), Eliezer Masliah, MD (1), Ann Becker (1), Xu Chen, PhD (1), Chengbiao, Wu, PhD (1), William Mobley, MD, PhD (1)

(1) Department of Neurosciences, University of California San Diego, San Diego, CA, USA

POSTER SESSION 3: Saturday, December 10

P3-19 TRANSLATIONAL APPROACH TO NEURODEGENERATIVE DISEASES: A SMALL PEPTIDE DERIVED FROM NEURONAL CELL CYCLE KINASE (CDK5) PREVENTS NEURODEGENERATION Harish C. Pant, Chief, Cytoskeletal Protein Regulation Section, National Institute of Neurological Disorders and Stroke, National Institutes of Health, Bethesda, MD, USA PRECLINICAL STUDIES OF SAK3, A T-TYPE CALCIUM CHANNEL STIMULATOR IN APP23 MICE AND RATS Kohji Fukunaga PhD, Hisanao Izumi, Yasuharu Shinoda, Yasushi Yabuki PhD Department of Pharmacology, Graduate School of Pharmaceutical Sciences, Tohoku University, Sendai, Japan

THEME 11: New therapies and clinical trials

San Diego Ballroom - Lobby Level

San Diego Ballroom - Lobby Level

P3-21 SUVN-502: A PURE 5-HT6 ANTAGONIST FIRST-IN-CLASS TRIPLE COMBINATION PHASE-2 POC STUDY. A PROMISING THERAPEUTIC STRATEGY FOR SYMPTOMATIC TREATMENT OF AD

Ramakrishna Nirogi, PhD(1), Koteshwara Mudigonda, PhD(1), Devender Reddy Ajjala, PhD(1), Vijay Benade MS(1), Renny Abraham, PhD(1), Ramasastry Kambhampati, PhD(1), Anil Shinde, PhD(1), Venkat Jasti MS(1) (1) Discovery Research, Suven Life Sciences Ltd, Hyderabad, India

P3-22 SUVN-G3031: A POTENT AND SELECTIVE H3 RECEPTOR INVERSE AGONIST - SAFETY, TOLERABILITY AND PHARMACOKINETICS IN HEALTHY ADULT MEN

Ramakrishna Nirogi, PhD(1), Koteshwara Mudigonda, PhD(1), Nageswararao Muddana, MS(1), Rajesh Kumar Boggavarapu, MS(1), Ranjith Kumar Ponnamaneni MS(1), Pradeep Jayarajan, PhD(1), Anil Shinde PhD(1), Venkat Jasti MS(1) (1) Discovery Research, Suven Life Sciences Ltd, Hyderabad, India

P3-23 SUVN-D4010: A POTENT AND SELECTIVE 5-HT4 RECEPTOR PARTIAL AGONIST - SAFETY, TOLERABILITY AND PHARMACOKINETICS IN HEALTHY ADULT MEN

Ramakrishna Nirogi, PhD(1), Koteshwara Mudigonda, PhD(1), Gopinadh Bhyrapuneni, PhD(1), Veera Raghava Chowdary Palacharla, MS(1), Rajesh Kumar Boggavarapu, MS(1), Devender Reddy Ajjala, PhD(1), Abdul Rasheed Mohammed, PhD(1), Venkat Jasti MS(1)

(1) Discovery Research, Suven Life Sciences Ltd, Hyderabad, India

P3-24 A RANDOMIZED DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY TO TEST THE EFFICACY AND SAFETY OF S 47445 IN PATIENTS SUFFERING FROM ALZHEIMER'S DISEASE AT MILD TO MODERATE STAGE WITH DEPRESSIVE SYMPTOMS

Pueyo Maria, MD, PhD(1), Bernard Katy, PhD(1), Bretin Sylvie, PharmD, PhD(1), Gouttefangeas Sylvie, MD(1), Picarel-Blanchot Françoise. PhD(1)

Pôle Innovation Thérapeutique Neuropsychiatrie, Institut de Recherches Internationales Servier, Suresnes, France

- P3-25 THROMBIN: A VASCULAR-DERIVED NEUROTOXIN AND NOVEL TARGET FOR AD THERAPY
 Paula Grammas, PhD, George, Anne Ryan
 Institute for Neuroscience, University of Rhode Island, Kingston, RI, USA
- P3-26 MULTIPLE ASCENDING DOSE STUDY WITH A PRODRUG OF GALANTAMINE: EVIDENCE OF DIMINISHED SIDE EFFECTS

 D.G. Kay PhD(1) E t'Hart PhD(2) C. Bakker MD (2) J. van der Aart Msc (2) G.J. Groeneveld MD PhD(2) A. Maelicke PhD (1.3)

D.G. Kay PhD(1), E t'Hart PhD(2), C. Bakker MD (2), J. van der Aart Msc (2), G.J. Groeneveld MD PhD(2), A. Maelicke PhD (1,3) (1) Neurodyn Cognition Inc., Charlottetown, PE, Canada, (2) Centre for Human Drug Research (CHDR), Leiden, the Netherlands, (3) Galantos Pharma, Nieder-Olm, Germany

- P3-27
 NO DOSE ADJUSTMENT REQUIRED FOR E2609, A NOVEL BACE1 INHIBITOR, FOR JAPANESE SUBJECTS, BASED ON PHARMACODYNAMIC AND PHARMACOKINETIC COMPARISONS WITH WHITE COHORTS

 Robert Lai, MA, MB BChir, PhD(1), Bruce Albala, PhD(2), Peter Boyd, MSc(1), June Kaplow, PhD(2), Satish Dayal, BSc, Min-Kun Chang, PhD(2), Nozomi Hayata, MSc(3), Kenya Nakai, MSc(3), Sanae Yasuda, PhD(3), Bhaskar Rege, BPharm, PhD(2)

 (1) Eisai Co. Ltd., London, UK, (2) Eisai Inc., Woodcliff Lake, NJ, USA 3. Eisai Co. Ltd., Japan
- P3-28

 DOSE-RELATED REDUCTIONS OF CSF AMYLOID B (1-X) BY E2609, A NOVEL BACE INHIBITOR IN PATIENTS WITH MILD COGNITIVE IMPAIRMENT DUE TO ALZHEIMER'S DISEASE (AD) AND MILD-MODERATE AD DEMENTIA

 Oneeb Majid, PhD(1), Michelle Gee, PhD(1), Bruce Albala, PhD(2), Robert Lai, MA, MB BChir, PhD(1), Satish Dayal, BSc(1), June Kaplow, PhD(2), Ziad Hussein, PhD(1), Jim Ferry, PhD(2), Bhaskar Rege, BPharm, PhD(2)

 (1) Eisai Co. Ltd., London, UK, (2) Eisai Inc., Woodcliff Lake, NJ, USA
- P3-29 ADVANCING THERAPEUTICS FOR NEUROINFLAMMATION IN ALZHEIMER'S DISEASE: CLINICAL DEVELOPMENT CONSIDERATIONS

Richard Margolin MD(1), Lon Schneider MD, MS(2), Gary Cutter PhD(3), John Breitner MD, MPH(4), Gary Landreth PhD(5), Daniel Chain PhD(1)

(1) CereSpir, Inc., New York, NY, USA, (2) Keck USC School of Medicine, Los Angeles, CA, USA, (3) University of Alabama, Birmingham School of Public Health, Birmingham, AL, USA, (4) Douglas Mental Health University Institute - Research Centre, McGill University, Montreal, PQ, Canada, (5) Case Western Reserve University, School of Medicine, Cleveland, OH, USA

Clinical Trials on Alzheimer's Disease

POSTER PRESENTATIONS

POSTER SESSION 3: Saturday, December 10

THEME 12: Clinical trials: recruitment and pre-screening

San Diego Ballroom - Lobby Level

P3-30 PATIENT SELECTION FOR CNS CLINICAL TRIALS: FINDINGS FROM A 23,800-PATIENT ELIGIBILITY REVIEW DATABASE AND SUB-ANALYSIS OF ALZHEIMER DISEASE TRIALS

Robin C. Hilsabeck, PhD (1), Jennifer Murphy, PhD (1), Nadia Yakovleva, MD (1), Claire K. Reinhold (1), Katya Miloslavich (1), Jeffrey Holleran (1), Kari R. Nations, PhD (1)

INC Research, Austin, TX, USA

- P3-31 EVALUATING CORRELATIONS BETWEEN RECRUITMENT RATES AND SITE RATINGS QUALITY Miller, D (1), Wang, X (1), Allen, S (1), Gratkowski, H (1), Feaster, T (1), Butler, A (1) (1) Bracket, Wayne, PA, USA
- P3-32 RECRUITMENT PRACTICES FOR ENABLING RAPID PRECLINICAL ALZHEIMER'S DISEASE CLINICAL TRIALS ENROLLMENT: EXPERIENCE FROM THE TOMMORROW STUDY

Kathleen A. Welsh-Bohmer, PhD(1), Stephen Haneline,MS,(2) Brenda L. Plassman, PhD(1), Heather R. Romero, PhD(1), Kathleen M. Hayden, PhD,(1) Meredith Culp, BS3 Ryan Walter, BS(3) Patrick Harrigan, BChE,(3) Daniel K. Burns, PhD(1), Ferenc Martenyi, MD(3), Oksana Makeeva, PhD,(4) Allen D. Roses, MD(1,2) for the TOMMORROW investigators (1) Duke University Bryan ADRC, Durham, NC, USA, (2) Zinfandel Pharmaceuticals, Inc., Durham, NC, USA, (3) Takeda Global Research & Development Center, Inc., Deerfield, IL, USA; (4) Nebbiolo, LLC | Center for Clinical Trials, Tomsk, Russia

- P3-33

 COMPUTERISED TESTING: APPLICATIONS IN RECRUITMENT AND MONITORING OF PATIENTS IN CLINICAL TRIALS

 Francesca Cormack PhD(1), Nick Taptiklis(1), Jack Curtis(2), Rosemary Abbott PhD(1), Jennifer H Barnett PhD(1,3)

 (1) Cambridge Cognition, Cambridge, UK, (2) Department of Physiology Development & Neuroscience, University of Cambridge, UK, (3) Department of Psychiatry, University of Cambridge, UK
- P3-34

 RETHINKING INSTITUTIONAL REVIEW BOARD SUBMISSIONS FOR ONLINE CLINICAL TRIAL RECRUITMENT

 Shannon Finley, MA(1), Derek Flenniken(1), Aaron Ulbricht(1), Monica Camacho(1), Juliet Fockler(1), R Scott Mackin PhD(1,2),
 Rachel L Nosheny PhD (1,3), Diana Truran(1), Michael W Weiner MD(1,3)

 (1) Center for Imaging of Neurodegenerative Diseases, San Francisco Veteran's Administration Medical Center, San Francisco,
 CA, USA, (2) UCSF Department of Psychiatry, San Francisco, CA, USA, (3) UCSF Department of Radiology and Biomedical Imaging, San Francisco, CA, USA
- P3-35 THE BRAIN HEALTH REGISTRY CAREGIVER AND STUDY PARTNER PORTAL TO FACILITATE ALZHEIMER'S CLINICAL TRIALS

Nosheny RL (1,3), Flenniken D(1), Camacho M(1), Ulbricht A, Fockler J(1), Insel PS(1,3), Mackin RS PhD(1,2), Truran D(1), Finley S(1), Mckenzie K(1), Weiner MW, (1,3)

(1) Center for Imaging of Neurodegenerative Diseases, San Francisco Veteran's Administration Medical Center, San Francisco, CA, (2) UCSF Department of Psychiatry, San Francisco, CA, (3) UCSF Department of Radiology and Biomedical Imaging, San Francisco, CA

THEME 13: Others

San Diego Ballroom - Lobby Level

P3-36
REPRESENTATIVENESS OF WESTERN EUROPEAN CLINICAL TRIAL POPULATIONS IN MILD ALZHEIMER'S DISEASE DEMENTIA – A COMPARISON OF 18-MONTH OUTCOMES WITH REAL- WORLD DATA FROM THE GERAS OBSERVATIONAL STUDY

Antje Tockhorn-Heidenreich (1), Mark Belger (1), Grazia Dell'Agnello (2), Kristin Kahle Wrobleski (3,4), Gopalan Sethuraman (3), David Henley (3,4), Ann Hake (3,4), Joel Raskin (3), Catherine Reed (1)

(1) Eli Lilly and Company Limited, Windlesham, UK, (2) Eli Lilly Italia, Sesto Fiorentino, Italy, (3) Eli Lilly and Company, Indianapolis, USA, (4) Indiana University School of Medicine, Indianapolis, USA

P3-37 SERUM PROTEINS MEDIATE DEPRESSION'S ASSOCIATION WITH DEMENTIA

Donald R. Royall, MD (1-4), Safa Al-Rubaye (1), Ram Bishnoi (1), Raymond F. Palmer, PhD (3)

(1) Department of Psychiatry, The University of Texas Health Science Center at San Antonio (UTHSCSA), San Antonio, Texas, USA, (2) Department of Medicine, UTHSCSA, San Antonio, Texas, USA, (3) Department of Family & Community Medicine. UTHSCSA, San Antonio, Texas, USA, (4) South Texas Veterans Health Administration Geriatric Research Education and Clinical Center (GRECC), San Antonio, Texas, USA

P3-38 A NEW PARTNERSHIP TO CREATE A NATIONAL IRB FOR CLINICAL TRIALS IN DEMENTING ILLNESS

David S. Knopman, MD (1), Eli T. S. Alford, MS (2), Rebecca A. Ballard, JD, MA, CIP (3), Kaitlin E. Tate, BA (2), Ara S. Khachaturian, Ph.D.(4)

(1) Department of Neurology, Mayo Clinic, Rochester, Minnesota, USA, (2) Schulman IRB, Research Triangle Park, North Carolina, USA, (3) Schulman IRB, Cincinnati, Ohio, USA, (4) National Biomedical Research Ethics Council, Las Vegas, Nevada, USA

POSTER SESSION 3: Saturday, December 10

THEME 13: Others (continued)

San Diego Ballroom - Lobby Level

- P3-39
 LONGITUDINAL ANALYSIS OF [18F]THK5351 TAU PET IMAGES IN PATIENTS WITH ALZHEIMER'S DISEASE
 Nobuyuki Okamura, MD, PhD(1) Ryuichi Harada, PhD(2,3), Aiko Ishiki, MD, PhD(2), Katsutoshi Furukawa, MD, PhD(1,2),
 Shozo Furumoto, PhD(4), Manabu Tashiro, MD, PhD(4), Kazuhiko Yanai, MD, PhD(3,4), Hiroyuki Arai, MD, PhD(2), Yukitsuka
 Kudo, PhD(2)
 - (1) Faculty of Medicine, Tohoku Medical and Pharmaceutical University, Sendai, Japan, (2) Institute of Development, Aging and Cancer, Tohoku University, Sendai, Japan, (3) Department of Pharmacology, Tohoku University School of Medicine, Sendai, Japan, (4) Cyclotron and Radioisotope Center, Tohoku University, Sendai, Japan
- P3-40
 THE USE OF CONVERSATION ANALYSIS FOR INTERACTIONAL DESIGN WITHIN A LIVING LAB FRAMEWORK
 Giovanni Carletti, PhD(1); Pierre Wargnier PhD(2); Samuel Benveniste(2), Pierre Jouvelot(2), Anne-Sophie Rigaud(3)
 (1) LIAS Institut Marcel Mauss, CNRS-EHESS, France, (2) MINES ParisTech, PSL Research University, France,
 (3) Broca Hospital, Assistance Publique Hôpitaux de Paris, France
- P3-41 ELABORATION OF A TOOL AIMING TO IDENTIFY SUBJECTS AT RISKS OF FRAILTY AND TO EVALUATE THE IMPACT OF PREVENTION MEASURES

Michel Noguès, PHD(1), Valérie Bruguière, MA(1), Justine Millot-Keurinck, MSc(1), Gabrielle Onorato, MSc(1), Sébastien Teissier (2), Jacques Touchon, MD, PHD(3), Jean-Claude Reuzeau, MA(1)

(1) Caisse Assurance Retraite et Santé Au Travail (Carsat) Languedoc-Roussillon, Montpellier, France (2) Resilient Innovation, Montpellier, France (3) University of Montpellier, France

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San Diego

General information

Conference Venue

Marriott Marquis San Diego Marina 333 West Harbor Drive San Diego, California 92101 USA



Practical details:

<u>Pre-registration</u> - Marina Foyer - Level 3 Wednesday, December 7th 2 - 6 pm To avoid the rush at the registration desk on Thursday morning we recommend you come pick up your badge and attendee's bag the day before.

Registration desk opening hours:

The registration desk is located in the Marina Foyer - Level 3.

- Thursday, December 8th 6:30 am 6:30 pm
- Friday, December 9th 6:30 am 6:15 pm
- Saturday, December 10th 7:00 am 12:30 pm

Meeting Room: Marina Ballroom DEFG - Level 3

Coffee Breaks, Lunches and Poster Sessions:

in the San Diego Ballroom - Lobby Level of the Hotel

Please note that only attendees who purchased lunches can access the poster sessions area during lunchtime. This year 3 different poster sessions are presented during the event:

- POSTER SESSION 1 : Thursday, December 8th
 P1-1 to P1-50
- POSTER SESSION 2 : Friday, December 9th
 P2-1 to P2-44
- POSTER SESSION 3 : Saturday, December 10th
 P3-1 to P3-41

Welcome Reception

Thursday, December 8th From 7:45 pm to 10:45 pm

CTAD 2016 and the USC Alzheimer's Therapeutic Research Institute welcome you to San Diego!

Come join us for a cocktail reception the evening of December 8th on the Coronado Terrace at the Marriot Marquis. This beautiful outdoor venue overlooking the water, showcases breathtaking views of San Diego Bay and Coronado Island. Spend time meeting other attendees while enjoying great food and drinks!

The Coronado Terrace is located on the 4th Floor of the South Tower at the Marriott Marquis San Diego.



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San Diego 42



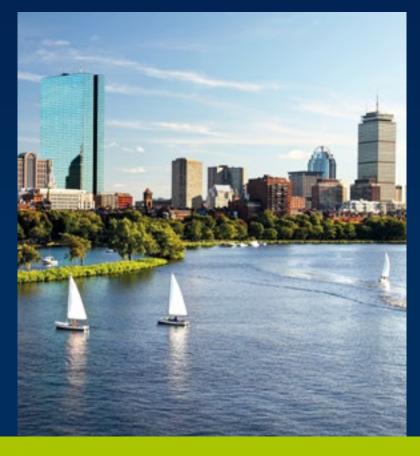


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