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Clinical Trials on Alzheimer's Disease

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November 14-16, 2013 San Diego



European Alzheimer's Di



Alzheimer's Disease Cooperative Study UC San Diego



Under the auspices of :





Welcome

SCIENTIFIC COMMITTEE

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ORGANIZING COMMITTEE

Paul AISEN Jacques TOUCHON Bruno VELLAS Michael WEINER

CONGRESS SECRETARIAT

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

Dear Colleague,

We are proud to present our program for *the 6th annual conference Clinical Trials for Alzheimer's Disease CtaD 2013 in San Diego, CA – USA on November 14-16, 2013.*

This year the CtaD conference will relate experiences from international teams covering every stage of clinical trials in AD. From animal models to human trials, CtaD 2013 provides an opportunity to learn about the latest results in drug trials as well as important topics such as internet screening of cognition to recruit for clinical trials, designing drug trials taking into account neuropsychiatric symptoms of AD, Down syndrome and AD as well as ethical issues and methodological considerations.

Again this year CTAD is the perfect opportunity to exchange views with your peers on the difficulties and challenges of Alzheimer's disease and take home some hands-on therapeutic and methodological tools to improve and reinforce your AD research and clinical trial teams. UC San Diego School of Medicine reviewed and awarded CtaD 2013 with 18 AMA PRA Category 1 Credits[™] in compliance with ACCME essentials and Standards and CME policies and procedures.

We are very happy to welcome you to CTAD 2013 !

Paul Aisen, MD University of California San Diego (UCSD)

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Jacques Touchon, MD, PhD University Hospital of Montpellier, France

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Bruno Vellas, MD, PhD University Hospital of Toulouse, France



Michael Weiner, MD University of California San Francisco (UCSF)



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Paul S. Aisen M.D. is the Director of the Alzheimer's Disease Cooperative Study (ADCS) and Professor in the Department of Neurosciences at UCSD. He has been conducting therapeutic research on Alzheimer's disease for the past two decades. Dr. Aisen joined the faculty at Georgetown University in 1999 as Professor in the Departments of Neurology and Medicine and that year, he founded the Memory Disorders Program, a clinical and research program for Alzheimer's disease and related disorders. He continued basic research studies on therapeutic targets and biomarkers of AD and designed and directed multicenter therapeutic

trials. He became Vice Chair of the Department of Neurology at Georgetown in 2004. Following the tragic death of ADCS founder Leon Thal, M.D. in early 2007, Dr. Aisen relocated to UCSD to assume the position of Director of the ADCS and Professor of Neurosciences.



Jeffrey Cummings, MD, ScD, is Director of Cleveland Clinic Lou Ruvo Center for Brain Health and the Camille and Larry Ruvo Chair for Brain Health. Dr. Cummings' research and leadership in the field of Alzheimer's disease have been recognized with many awards, including the Henderson Award of the American Geriatrics Society, the Research Award of the John Douglas French Alzheimer's Research Foundation, and the Ronald and Nancy Reagan Research Award of the national Alzheimer's Association.

Dr. Cummings is the author of the Neuropsychiatric Inventory (NPI), the most commonly used tool for characterizing behavioral disturbances in dementia syndromes and for measuring the effect of therapies on neuropsychiatric symptoms in Alzheimer's disease and other dementias.



Serge Gauthier, MD, FRCPC - Dr. Gauthier is currently Professor in the Departments of Neurology & Neurosurgery, Psychiatry, Medicine, at McGill University, and Director of the Alzheimer Disease and Related Disorders Research Unit of the McGill Center for Studies in Aging, Douglas Hospital.

He did his medical training at Université de Montréal, Neurology training at McGill University, Research Fellowship at Prof. Theodore L. Sourkes laboratory, Allen Memorial Institute, Montreal. Clinical investigator and staff neurologist at the Montreal Neurological Hospital

and Institute (1976-1986), Director of the McGill Centre for Studies in Aging (1886-1996), Senior Scientist of the CIHR-Rx&D program (1997-2007).

Contributions to research include design and implementation of randomized clinical trials in order to establish the safety and efficacy of cholinesterase inhibitors, muscarinic agonists, and agents possibly modifying progression for Alzheimer's disease and vascular dementia. Special interests include consensus approach to the management of dementia in different stages, the ethics of research involving persons with dementia, and primary prevention strategies against cognitive decline and dementia.



David M. Holtzman, is the Andrew B. and Gretchen P. Jones Professor and Chairman of Neurology, Professor of Developmental Biology, Associate Director of the Alzheimer's Disease Research Center, and a member of the Hope Center for Neurological Disorders at the Washington University School of Medicine in St. Louis, MO - USA

His major interest is in understanding basic mechanisms underlying acute and chronic cell dysfunction in the CNS particularly as these mechanisms may relate to Alzheimer's disease (AD) and injury to the developing brain.

Keynote speakers



William C. Mobley is a Distinguished Professor and Chair of the Department of Neurosciences at UCSD. He also serves as Executive Director of UCSD's Down Syndrome Center for Research and Treatment.

Dr. Mobley has a distinguished record of academic achievement and is considered one of the most outstanding academic neurologists in the US. He has an international reputation for his research on degenerative disease of the central nervous system as well as being a leader in translational medicine, bridging clinical and basic science in various areas. More



Ronald C. Petersen, MD, PhD is the Director of the Mayo Alzheimer's Disease Research Center and has an interest in clinical research involving aging, mild cognitive impairment, dementia, Alzheimer's Disease, and neuroimaging. The Mayo Alzheimer's Disease Research Center is part of a network of 28 centers around the country sponsored by the National Institute on Aging. This center operates in Rochester, MN and Jacksonville, FL. In addition, Dr. Petersen has a National Institute on Aging funded registry on aging and dementia in Rochester. This is a longitudinal project on clinical, epidemiological, genetic, biomarker,

imaging, and neuropathological aspects of aging and very early cognitive impairment. His team is developing models for predicting a subsequent cognitive impairment in normal elderly persons. A great deal of his work has focused on mild cognitive impairment as an intermediate stage between normal aging and Alzheimer's disease. Recently, he has begun a project funded by the Mayo Foundation investigating various aspects of successful cognitive aging in the community. He also studies non-Alzheimer's disease dementias such as frontotemporal dementia, dementia with Lewy bodies and vascular dementia.



Dr. Eric Reiman is chief executive officer of Banner Research, executive director of Banner Alzheimer's Institute, clinical director of the Neurogenomics Division at the Translational Genomics Research Institute (TGen), professor of psychiatry at the University of Arizona, and director of the Arizona Alzheimer's Consortium. His research interests include brain imaging, genomics and their application to the study of normal and abnormal human behaviors; the early detection, tracking and study of Alzheimer's disease; and the accelerated evaluation of presymptomatic Alzheimer's disease treatments.

Dr. Reiman is internationally recognized for his contributions to the fields of brain imaging, the behavioral neurosciences and the presymptomatic study of Alzheimer's disease.

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Program at a glance

Thursday, November 14th

8.00 - 8.15 a.m California Ballroom ABC	WELCOME BY THE ORGANIZING COMMITTEE	
8.15 - 8.45 a.m	OPENING KEYNOTE	
California Ballroom ABC	Toward effective Alzheimer's therapy : progress and collaboration	
8.45 - 10.00 a.m	Symposium 1	
California Ballroom ABC	Clinical trials in early stage Alzheimer's di considerations	sease: Current methodological and regulatory
10.00 - 10.30 a.m	KEYNOTE	
California Ballroom ABC	When to Treat: Biomarkers in MCI and Pr	e-Clinical AD
	Coffee Break and poster sessions - San Diego Ba	llroom
11.00 - 12.45 p.m	PARALLEL SESSIONS	: ORAL COMMUNICATIONS
	DATA FROM CLINICAL TRIALS	IMAGING IN CLINICAL TRIALS ON AD
	California Ballroom AB	California Ballroom C
	Lunch Break and poster sessions - San Diego Ball	lroom
1.45 - 3.00 p.m	PARALLEL SESSIONS: ORAL COMMUNICATIONS	
	STUDY DESIGN FOR CLINICAL TRIALS	PRECLINICAL STUDIES IN ALZHEIMER'S DISEASE
	California Ballroom AB	California Ballroom C
3.00 - 3.45 p.m	PARALLEL SESSIONS: ORAL COMMUNICATIONS	
	COGNITIVE AND IMAGING ASSESSMENT FOR CLINICAL TRIALS	PET IMAGING OF TAU PATHOLOGY
	California Ballroom AB	California Ballroom C
	Coffee Break and poster sessions - San Diego Ba	liroom
4.15 - 4.45 p.m California Ballroom ABC	KEYNOTE The New Era in Alzheimer's Prevention Research	
4.45 - 6.00 p.m California Ballroom ABC	Symposium 2 Rethinking the Way to Conduct Drug Trials in Alzheimer 's disease	
6.30 p.m	Bus departure to the Welcome Reception	
7.00	Lobby of the Westin Gaslamp Quarter	
7.00 p.m	Welcome Reception at the Omni Hotel	

Friday, November 15th

8.30 - 9.00 a.m **KEYNOTE**

California Ballroom ABC AD and Down's syndrome

9.00 - 10.15 a.m Symposium 3

California Ballroom ABC Agitation and Aggression in AD: A New Target for Drug Development

	Coffee Break and poster sessions - San Diego Ballro	pom
10.45 - 12.15 p.m	PARALLEL SESSIONS: ORAL COMMUNICATIONS	
	COMPOSITE OUTCOMES FOR CLINICAL TRIALS	NEUROIMAGING PET FOR CLINICAL TRIALS
	California Ballroom AB	California Ballroom C
	Lunch Break and poster sessions - San Diego Ballro	om
1.15 - 3.15 p.m	PARALLEL SESSIONS: ORAL COMMUNICATIONS	
	TREATMENT ASSESSMENT FOR CLINICAL TRIALS	BIOMARKERS FOR CLINICAL TRIALS
	California Ballroom AB	California Ballroom C
	Coffee Break and poster sessions - San Diego Ballro	pom
3.45 - 4.15 p.m California Ballroom ABC	KEYNOTE Designing drug trials taking into account neuropsychiatric symptoms of AD	
4.15 - 5.30 p.m California Ballroom ABC	Symposium 4 Internet screening of cognition as a method for recruiting to clinical trials in prodromal Alzheimer's disease	
5.30 - 6.00 p.m California Ballroom ABC	KEYNOTE Ethical issues in AD prevention trials: gene	tics, biomarkers and treatment risk

Saturday, November 16th

8.00 - 8.30 a.m California Ballroom AB KEYNOTE

Novel immunotherapy approaches

8.30 - 10.00 a.m	PARALLEL SESSIONS	
	Symposium 5 Metabolic dysregulation in the Alzheimer brain: challenges and opportunities	ORAL COMMUNICATIONS 8.30 - 9.00 a.m BIOMARKERS FOR CLINICAL TRIALS 9.00 - 10.00 a.m
	California Ballroom AB	PRECLINICAL STUDIES IN AD California Ballroom C
	Coffee Break and poster sessions - San Diego Ballr	pom
10.30 - 11.45 a.m California Ballroom AB	Symposium 6 CSF biomarkers in clinical trials	

Thursday, November 14th

CTAD San Diego 2013 Program

8.00 a.m	California Ballroom ABC Welcome by the organizing committee and presentation of the CtaD Lifetime Achievement Award in Alzheimer's Disease Therapeutic Research, to Russell Katz MD, former Director, Division of Neurology Products, U.S. Food and Drug Administration Paul Aisen, Jacques Touchon, Bruno Vellas, Mike Weiner	
8.15 a.m	OPENING KEYNOTE - <i>California Ballroom ABC</i> Toward effective Alzheimer's therapy: progress and colla Paul Aisen, MD, <i>University of California at San Diego, USA</i>	boration
8.45 a.m	SYMPOSIUM 1 - California Ballroom ABC Clinical trials in early stage Alzheimer's disease: Current methodological and regulatory considerations Moderators: John Harrison PhD, <i>Metis Cognition Ltd, Kilmington Common, Wiltshire, UK</i>	
	 What are we trying to measure in preclinical and p Lon Schneider MD, MS. Keck School of Medicine of the 	
	 How can changes in cognitive function be measure Keith Wesnes PhD, Bracket Global, Goring UK & Swinds 	
	3. A regulatory perspective on therapeutic trials in ea Nicholas Kozauer MD, <i>Food and Drug Administration, S</i> .	
10.00 a.m	KEYNOTE - California Ballroom ABC Moderator : Bruno vellas When to treat: Biomarkers in MCI and pre-clinical AD Ronald C. Petersen, M.D., Ph.D, <i>Mayo Alzheimer's Disease Research Center, Mayo Clinic, Rochester, MN, USA</i>	
10.30 a.m	Coffee Break and poster sessions - San Diego Ballro	pom
	11.00 a.m - 12.45 p.m PARALLEL SESSIONS: ORAL COMMUNICATIONS	
11.00 - 12.45 p.m	California Ballroom AB DATA FROM CLINICAL TRIALS	California Ballroom C IMAGING IN CLINICAL TRIALS ON AD
	DATA FROM CLINICAL TRIALS - California Ballroom AB Moderators : Jeffrey Cummings, Serge Gauthier	
11.00 a.m	OC1 - Stereotactic gene delivery of NGF (via AAV2-NGF) in AD patients: Safe & effective targeting to degenerating cholinergic neurons Raymond T. Bartus, PhD (1.2), Tiffany L. Baumann, BS (1,3), Roy A.E. Bakay, MD (4), Jeffrey M. Ostrove, PhD (1), Joao Siffert, MD (1,5), Adam S. Fleisher, MD (6,7), Christopher D. Herzog, PhD (1), David Barba, MD (6), Mary Pay, APN (6), David P. Salmon, MD (6), Yaping Chu, MD (4), Jeffrey H. Kordower, PhD (4), Kathie Bishop, PhD (1.3), David Keator, PhD (8), Steven Potkin, MD (8), Michael S. Rafii, MD (6) (1) Ceregene, Inc., San Diego, CA, USA, (2) RTBioconsultants, Inc, San Diego, CA, USA, (3) Isis Pharmaceuticals, Carlsbad, CA, USA, (4) Department of Neurological Sciences, Rush University Medical Center, Chicago, IL, USA, (5)Avanir Pharmaceuticals, Alijo Viejo, CA, USA; (6) Department of Neurosciences, University of California, San Diego, CA, USA, (7) Banner Alzheimer's Institute, Phoenix, AZ, USA, (8) University of California, Invine, CA, USA	
11.15 a.m	OC2 - Improvements to attention and verbal episodic memory with memantine in Parkinson's disease dementia and dementia with Lewy bodies <u>Keith A. Wesnes</u> (1,2,3), Clive Ballard (5), Elisabet Londos (6) (1) Bracket Global, Goring on Thames, UK, (2) Department of Psychology, Northumbria University, Newcastle, UK, (3) Centre for Human Psychopharmacology, Swinburne University, Melbourne, Australia, (5) Wolfson Centre for Age Related Diseases, Institute of Psychiatry, King'sCollege London, London, UK, (6) Clinical Memory Research Unit, Department of Clinical Sciences, Malmö, Lund University, Sweden	
11.30 a.m	OC3 - Baseline memory problems associate with clinical impairments eight years later: centralized follow-up in the PREADVISE trial Richard Kryscio, PhD (1,2), <u>Erin Abner</u> , PhD (2), Allison Caban-Holt, PhD (2,3), Melissa Mathews, PhD (4), Frederick Schmitt, PhD (2,3,4,5) (1) Departments of Statistics and Biostatistics, University of Kentucky, Lexington, KY, USA, (2) Sanders-Brown Center on Aging, University of Kentucky, Lexington, KY, USA, (3) Department of Behavioral Sciences, University of Kentucky, Lexington, KY, USA, (4) Department of Neurology, University of Kentucky, Lexington, KY, USA, (5) Department of Psychiatry, University of Kentucky, Lexington, KY, USA	



Thursday, November 14th

DATA FROM CLINICAL TRIALS - California Ballroom AB

11.45 a.m

Yun-Fei Chen (1), Richard Mohs (1), Ying Ding (2), Paul Aisen (3), Ronald G. Thomas (3) (1) Eli Lilly and Company, USA, (2) University of Pittsburg, USA, (3) University of California, San Diego, USA 12.00 p.m OC5 - Mild versus moderate stage of Alzheimer's disease three-year outcomes of cholinesterase inhibitor therapy in a routine clinical setting Carina Wattmo, RN, BSc, PhD, Lennart Minthon, MD, PhD, Åsa K. Wallin, MD, PhD Clinical Memory Research Unit, Department of Clinical Sciences, Malmö, LundUniversity, Malmö, Sweden 12.15 p.m OC6 - The NIA ASPREE trial-aspirin in reducing events in the elderly Anne M. Murray, MD (1), Richard H Grimm, MD, PhD (2), Brenda Kirpach (2), John McNeil, MD, PhD (3), Robyn Woods, PhD, (3), Mark Nelson, MD, PhD (3), Elsdon Storey, MD (3), A.Tonkin, MD (3), Raj Shah, MD (4) (1) Department of Medicine and Geriatrics, Hennepin County Medical Center, Minneapolis, MN USA, (2) Berman Center for Clinical Trials, Minneapolis Medical Research Foundation and University of Minnesota, Minneapolis, MN, USA, (3) Monash University, Department of Epidemiology & Preventive Medicine, Melbourne, Australia, T.Lockett, Preventative Health National Research Flagship, Commonwealth Scientific and Industrial Research Organisation (CSIRO) Molecular and Health Technologies, North Ryde, NSW, Australia, (4) Rush Alzheimer's disease center, Chicago, IL. USA 12.30 p.m OC7 - A first-in-human study of BAN2401, a novel monoclonal antibody against amyloid-β protofibrils Veronika Logovinsky, MD, PhD (1), Robert Lai, MA, MB BChir, PhD, MRCP, FFPM (2), Kenan Gu, PhD (1), Yanke Yu, PhD (3), Chad J. Swanson, PhD (1), Andrew Satlin, MD (1) (1) Eisai Inc. Woodcliff Lake, NJ, USA, (2) Eisai Ltd. London, UK, (3) Eisai Inc. Andover, MA, USA IMAGING IN CLINICAL TRIALS ON AD - California Ballroom C Moderators : Mark Mintun, Joyce Suhy 11.15 a.m OC8 - Increasing role of imaging in Alzheimer disease trials: issues and risk management strategies Kohkan Shamsi MD. PhD Founder and Principal, RadMD, New York, NY, USA 11.30 a.m OC9 - Performance metrics for two large phase III Alzheimer's disease clinical trials; an MRI perspective Rahul Peethala, Joyce Suhy, Joonmi Oh Synarc Inc, Newark, NJ, USA 11.45 a.m OC10 - Effects of ELND005 (Scylloinositol) long term treatment on Amyloid related imaging abnormalities (ARIA) in Phase 2 AD studies Anton P. Porsteinsson (1), Christopher VanDyck (2), Matthias Kurth (3), Sheila O'Mahony (3), Aarti Verma (3), Gerald Crans (3), J. Patrick Kesslak (3), Susan Abushakra (3) (1) Department of Psychiatry, University of Rochester, (2) Department of Neurology, Yale University, (3) Elan Pharmaceuticals, Inc., Global Development, San Francisco CA 12.00 p.m OC11 - MRI findings in patients on placebo in phase 3 clinical trials of mild-moderate Alzheimer's disease Ketter, N, Brashear, HR, Miaux, Y, Purcell, DD, Barkhof, F,Gass, A, M, Morris, K, Guenzler, V, Arrighi, HM Janssen Alzheimer Immunotherapy R&D, LLC, South San Francisco, CA - USA 12.15 p.m OC12 - Preliminary analysis of baseline FDG PET in PET substudies of Phase 3 i.v. bapineuzumab trials in mild to moderate AD: Patterns and severity of regional brain hypometabolism and relationship to fibrillary amyloid burden

OC4 - Bayesian longitudinal modeling on placebo data from Alzheimer's disease clinical studies

 measured by 11C-PiB PET and clinical outcomes <u>Schmidt ME</u>, MD (1), Gregg K, PhD (1), Margolin R, MD (1), Lukic AS, PhD (2), Andrews RD, MS (2), Matthews DC, MS, MBA (2), Wernick MN, PHD (2), Strother SC, PHD (2), Brashear R, MD (1), Liu E, PhD (1) (1) Janssen Alzheimer Immunotherapy R&D, LLC, South San Francisco, CA, USA, (2) ADMdx, Chicago, IL, USA
 12.30 p.m OC13 - Longitudinal LEAP is equivalent to semi-automatic VBSI on ADNI data in terms of group separation <u>Katherine R. Gray</u>, PhD (1,2), Robin Wolz, PhD (1,2), Mark Austin, PhD (1), Daniel Rueckert, PhD (2), Kate McLeish, PhD (1), Derek Hill, PhD (1)

(1) IXICO Ltd, London, United Kingdom, (2) Department of Computing, Imperial College London, United Kingdom

12.45 p.m Lunch Break and poster sessions - San Diego Ballroom

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1.45 - 3.00 p.m	California Ballroom AB STUDY DESIGN FOR CLINICAL TRIALS	California Ballroom C PRECLINICAL STUDIES IN ALZHEIMER'S DISEASE
	STUDY DESIGN FOR CLINICAL TRIALS - C Moderators : Susan Abushakra, Lon Schneider	alifornia Ballroom AB
1.45 p.m	disease: An update <u>Allen D.Roses</u> , MD (1,2), Kathleen A.Welsh-Bohmer, PhD PhD (1,2), Michael W.Lutz, PhD (1,2), Craig A.Metz, PhI Stephen Brannan, MD (3), Kumar Budur, MD, MS (3)	to delay onset of mild cognitive impairment due to Alzheimer (2), Daniel K.Burns, PhD (1), Carl Chiang, PhD (1), Donna G.Crensha D (1), Ann M.Saunders, PhD (1,2), Deborah Yarbrough, MS, MBA (e Bryan ADRC, Durham, NC, USA, (3) Takeda Global Research&Developme
2.00 p.m	Aß42 <u>Keith A. Wesnes</u> PhD (1,2), Peter Annas PhD (3), Hans E (1) Bracket Global, Goring on Thames, UK, (2) Centre for Hum.	in Alzheimer's disease is linked to APOE ε4 status and CS Basun MD PhD (4), Kaj Blennow MD PhD (5) an Psychopharmacology, Swinburne University, Melbourne, Australia, (3) As AB, Sweden, (5) Neurochemistry Laboratory, Sahlgrenska University Hospit
2.15 p.m	signature <u>Duygu Tosun</u> , PhD (1), Peng Yu, PhD (2), Peter Castel Siemers, MD (2), Adam J Schwarz, PhD (2), Michael Wei	linical trial cohort using a structural MRI based shape variation luccio, MS (2), Yun-Fei Chen, PhD (2), Joyce Suhy, PhD (2), Eric ner, MD (1) of California San Francisco, CA, USA, (2) Eli Lilly and Company, Indianapolis,
2.30 p.m		enotypes and CSF Aβ levels on inclusion of patients armD PhD (2), <u>Jacques Hugon</u> MD PhD (1), Claire Paquet MD PhD(ment of Biochemistry Lariboisiere Hospital Paris, France
2.45 p.m	OC18 - A better way to measure the progress of pro John Breitner, MD, MPH McGill University Faculty of Medicine, Centre for Studies on Preve	
	PRECLINICAL STUDIES IN ALZHEIMER'S I Moderators : David Holtzman, Zaven Kachaturian	DISEASE - California Ballroom C
1.45 p.m	OC19 - New cellular models for drug discovery in A Jordan L.Holtzman, M.D.,Ph.D. (1,2,3) (1) Departments of Pharmacology, (2) Medicine, (3) and Division USA	Nzheimer's disease a of Environmental Health Sciences, University of Minnesota, Minneapolis, N
2.00 p.m	Moira Marizzoni, PhD (1), Edoardo Micotti, PhD (2), Ales (1,3), Sophie Dix, PhD (4), Christian Czech, PhD (5), La PhD (2), Giovanni Frisoni, MD (1), on behalf of the Pharm (1) Laboratory of Epidemiology and Neuroimaging, IRCCS Fatebe Pharmacological Research, Milano, Italy, (3) Biomedical Enginee	models of Alzheimer's disease: an in vivo diffusion study sandra Paladini, MS (2), Claudia Balducci, PhD (2), Anna Caroli, Pl urence Ozmen, PhD (5), Jill C.Richardson, PhD (6), Gianluigi Forlo naCog Consortium presented by Martina Bocchetta, MS nefratelli, Brescia, Italy, (2) Department of Neuroscience, Mario Negri Institute ring Department, Mario Negri Institute for Pharmacological Research, Bergar (, (5) CNS Research, Hoffmann-La Roche AG, Basel, CH, (6) GlaxoSmithKlii



Thursday, November 14th

PRECLINICAL STUDIES IN ALZHEIMER'S DISEASE - California Ballroom C

- 2.15 p.m OC21 A novel peptide derived from the Cdk5 regulator p35, crosses blood brain barrier and rescues phenotypes of Alzheimer's disease model mice Harish C. Pant, MD, PhD, CPR Division, NINDS, NIH, Bethesda, MD USA
- 2.30 p.m OC22 Does atorvastatin or telmisartan alter CSF memantine kinetics? A study in normal and STZ-induced rat model of Alzheimer <u>Omnia Nayel</u>, MD, PhD (1), Maha El-Tohamy, PhD (2), Wessam El Hadidy, MD, PhD (3) (1) Pharmacology department, Faculty of Medicine, King Saud University, Riyadh, KSA, (2) Chemistry department, Faculty of Science, King Saud University, Riyadh, KSA, (3) Pharmacology department, Medical Research Institute, Alexandria University, Alexandria, Egypt

2.45 p.m OC23 - MultiTEP platform based AD vaccine immunogenic in rabbits and monkeys Hayk Davtyan, PhD (1), Irina Petrushina, PhD (2), Claire F. Evans, PhD (3), Armine Hovakimyan (1), Arpine Davtyan (1), Drew Hannaman (3), David H.Cribbs, PhD (2,4), Anahit Ghochikyan, PhD (1), <u>Michael G.Agadjanyan</u>, PhD (1,2) (1) Department of Molecular Immunology, Institute for Molecular Medicine, Huntington Beach, CA, USA, (2) Institute for Memory Impairments and Neurological Disorders, University of California at Irvine, Irvine CA, USA, (3) Ichor Medical Systems, San Diego, CA, USA, (4) Department of Neurology, University of California at Irvine, Irvine, CA, USA

	3.00 p.m - 3.45 p.m PARALLEL SESSIONS: ORAL COMMUNICATIONS	
3.00 - 3.45 p.m	California Ballroom AB COGNITIVE AND IMAGING ASSESSMENT FOR CLINICAL TRIALS	California Ballroom C PET IMAGING OF TAU PATHOLOGY
	COGNITIVE AND IMAGING ASSESSMENT F Moderators : Michael Donohue, Lisa Mosconi	OR CLINICAL TRIALS - California Ballroom AB
3.00 p.m	trials <u>William R. Shankle</u> , MS, MD (1,4), Junko Hara, PhD (1,2),	inic, Newport Beach, CA, (3) Memory and Cognitive Disorders Program, Hoag
3.15 p.m	AD Therapeutic Trials Richard A Margolin MD (1), Randolph D Andrews MS (2), M (3), Reisa Sperling MD, MMSc (4), H Robert Brashear ME MS, MBA (2) for the Alzheimer's Disease Neuroimaging In (1) Janssen Alzheimer Immunotherapy LLC, South San Francisco, Warren Alpert Medical School of Brown University, Providence, R Hospital, Harvard Medical School, Boston, MA, USA; Center for	ve and Amyloid-negative ADNI MCI Subjects: Implications for Michael Ropacki PhD (1), Ana S Lukic PhD (2), Stephen Salloway MD D (1), Mark E Schmidt MD (6), Enchi Liu PhD (1), Dawn C Matthews itiative CA, USA; (2) ADM Diagnostics LLC, Chicago, IL, USA; (3) Butler Hospital, The I, USA; (4) Departments of Neurology and Radiology, Massachusetts General Alzheimer Research and Treatment, Department of Neurology, Brigham and ts, MA, USA; (6) Janssen Research and Development, Beerse, Belgium
3.30 p.m	trial implications <u>Paul Maruff</u> , PhD (1,2,6), Yen Ying Lim (2), Robert H.Pie C.Rowe (5,6) (1) CogState Ltd, (2) The Florey Institute of Neuroscience and Men	amyloid accumulation in preclinical and prodromal AD: Clinical trzak (3), Kathryn A.Ellis (4,6), Colin L.Masters (2,4,6), Christopher ntal Health, Parkville, Victoria, Australia, (3) Yale University Medical School, (4) Health, The University of Melbourne, Heidelberg, Victoria, Australia, (6) For the

Thursday, November 14th

	PET IMAGING OF TAU PATHOLOGY - California Ballroom C
3.00 p.m	OC27 - PET imaging of tau pathology in patients with Alzheimer's disease using18F-THK5117 <u>Nobuyuki Okamura</u> (1), Shozo Furumoto (2), Ryuichi Harada (1), Katsutoshi Furukawa (3), Aiko Ishiki (3), Naoki Tomita (3), Ren Iwata (2), Manabu Tashiro (2), Kazuhiko Yanai (1,2), Hiroyuki Arai (3), Yukitsuka Kudo (4) (1) Department of Pharmacology, Tohoku University School of Medicine, Sendai, Japan, (2) Cyclotron and Radioisotope Center, Tohoku University, Sendai, Japan, (3) Department of Geriatrics and Gerontology, Institute of Development, Aging and Cancer, Tohoku University, Sendai, Japan, (4) Clinical Research, Innovation and Education Center, Tohoku University Hospital, Sendai, Japan
3.15 p.m	OC28 - Tau PET, amyloid PET and cognitive performance Keith A Johnson, M.D., J. Alex Becker, Ph.D., Dorene Rentz, Psy.D., Aaron Schultz, Ph.D., Marlie Philiossaint, Jonathan Alverio, Kelly Judge, Neil Vasdev, Ph.D., Thomas Brady, M.D., Bradley Hyman, M.D., Ph.D., Reisa A. Sperling, M.D Massachusetts General Hospital, Harvard Medical School, Boston, MA, USA
3.30 p.m	OC29 - Preliminary Analysis of PET Scans using the Tau Imaging Tracer [F-18]-T807 (AV-1451) in Alzheimer's
	Disease <u>Mark Mintun</u> (1), Abhinay Joshi (1), Sergey Shcherbinin (2), Adam J. Schwarz (2), Ming Lu (1), Michael Pontecorvo (1), Michael Devous (1), Daniel Skovronsky (1), Hartmuth Kolb (1) (1) Avid Radiopharmaceuticals, Inc., Philadelphia, PA, (2) Eli Lilly & Co, Indianapolis, IN
3.45 p.m	Coffee Break and poster sessions - San Diego Ballroom
4.15 p.m	KEYNOTE - California Ballroom ABC Moderator : Mike Weiner The New Era in Alzheimer's Prevention Research Eric Reiman MD - Executive Director, Banner Alzheimer's Institute, Phoenix, AZ - USA
4.45 p.m	SYMPOSIUM 2 - California Ballroom ABC Rethinking the way to conduct drug trials in Alzheimer's disease Moderators: Bruno Vellas (<i>Toulouse</i>), Jeffrey Cummings (<i>Las Vegas</i>), Michael Weiner (<i>San-Francisco</i>), Jacques Touchon (<i>Montpellier</i>)
	1. A historical analysis of AD drug trials from 2000 to 2013 Valérie Legrand, PharmD, <i>ICON, Paris, France</i>
	2. Changes needed and consequences conducting drug trials from symptomatic to disease-modifying trials Julien Delrieu, MD <i>Toulouse Alzheimer's Disease Research Clinical Center, Gérontopôle, Toulouse, France</i>
	3. New models of clinical trials for Alzheimer's disease Jeffrey Cummings, MD Cleveland Clinic Lou Ruvo Center for Brain Health, Las Vegas Nevada, Cleveland, Ohio and
	Weston, Florida 4. Center for drug trials on AD, today limits and perspectives
	Pierre-Jean Ousset, MD, CenGeps Alzheimer Drug Trial Network, Gerontopole, Toulouse France
	5. Using the Internet for recruiting, assessing, and monitoring subjects in AD prevention trials: The Brain Initiative
	Mike Weiner, MD, University of California at San Francisco, UCSF
6.30 p.m	Bus departure to the Welcome Reception - Lobby of the Westin Gaslamp
7.00 p.m	Welcome Reception at the Omni San Diego Hotel



Friday, November 15th

8.30 a.m	KEYNOTE - <i>California Ballroom ABC</i> Moderator : Paul Aisen AD and Down's syndrome William Mobley, <i>Professor and Chair, Department of Neuro</i>	sciences, University of California at San Diego, CA – USA
9.00 a.m	Agitation and aggression in AD: a new target for drug development Susan Abushakra MD (1), Sandrine Andrieu MD (2), Gene Kinney PhD (3), David Sultzer MD (4), Anton P. Porsteinss (5), Constantine Lyketsos MD (6)	
		v of Toulouse, France, (3) Prothena Biosciences, San Francisco A, (5) University of Rochester, Rochester, NY, (6) Johns Hopkins
10.15 a.m	Coffee Break and poster sessions - San Diego E	Ballroom
	10.45 a.m - 12.15 p.m PARALLEI	SESSIONS: ORAL COMMUNICATIONS
10.45 - 12.15 p.m	California Ballroom AB COMPOSITE OUTCOMES FOR CLINICAL TRIALS	California Ballroom C NEUROIMAGING PET FOR CLINICAL TRIALS
	COMPOSITE OUTCOMES FOR CLINICAL TR Moderators : John Harrison, Suzanne Hendrix	IALS - California Ballroom AB
10.45 a.m	OC30 - An empirical model of the natural progression of clinical measures of Alzheimer disease Suzanne Hendrix, PhD, Stephanie Stanworth, MS, Noel Ellison, MS Pentara Corporation, Salt Lake City, UT, USA	
11.00 a.m	OC31 - Composites v2.0: newer measures + earlier population = improved composite <u>Michael T. Ropacki</u> , PhD (1,2), Suzanne B.Hendrix, PhD (3), Daniel Ryon Seichepine, PhD (4), Robert Stern, PhD (4) (1) Janssen Research & Development, LLC, San Francisco, CA,USA, (2) Neurology Department, Loma Linda University, (3) Pentara Corporation, Salt Lake City, UT, USA, (4) Alzheimer's Disease Center, Boston University School of Medicine, Boston, MA, USA	
11.15 a.m	disease <u>M. Colin Ard,</u> PhD (1), Steven D. Edland, PhD (1,2)	trials in mild cognitive impairment and pre-clinical Alzheimer's eventive Medicine Division of Biostatistics, University of California, San Diego,
11.30 a.m	due to AD Bruce Albala, PhD (1), Paul Maruff, PhD (3), Judith Jaeger,	s a screening tool for clinical trials in MCI and mild dementia PhD (4), Michelle Gee, PhD (5), Andrew Satlin, MD (1) ne, Australia, (4) Cog State Inc., New Haven, CT, USA, (5) Eisai Ltd., Hatfield,
11.45 a.m	sensitivity to donepezil Judith Jaeger (1,2,3), Adina Soaita (1), Joanne Gale (1), Kr	nal neuropsychological tests of memory: factors influencing istin Hannesdottir (4) Medicine, Bronx, NY,USA, (3) University of Manchester, UK, (4) AstraZeneca
12.00 p.m	OC34bis - The INSIGHT study: Conceptual consider <u>Bruno Dubois</u> , MD, PhD (1), Harald Hampel, MD, PhD (2) (1) Department of Neurology, Salpêtrière Hospital, Paris, France, (University, Munich, Germany	rations on the preclinical states of AD (2) Department of Psychiatry, Alzheimer Memorial Center, Ludwig-Maximilian

Friday, November 15th

	NEUROIMAGING PET FOR CLINICAL TRIAL Moderators : Dorene Rentz, Stephen Salloway	S - California Ballroom C
10.45 a.m	patients <u>Lisa Mosconi</u> , PhD (1,2,3), Randolph D Andrews, MS (1 Strother (1,4,5), Enchi Liu (7), Richard Margolin (7), Mark I Neuroimaging Initiative (1) ADM Diagnostics, Chicago, IL USA, (2) Abiant Inc., Grayslake, I New York, NY, USA, (4) Predictek Inc., Chicago, IL USA, (5) Illin	roves prediction of cognitive change in Normals, MCI and AD I,2), Ana S Lukic, PhD (1,4), Miles N Wernick (1,4,5), Stephen C E Schmidt (8), Dawn C Matthews (1,2), and the Alzheimer's Disease IL USA, (3) Department of Psychiatry, New York University School of Medicine, ois Institute of Technology, Chicago, IL USA, (6) Rotman Research Institute, rapy, South San Francisco, CA USA, (8) Janssen Research and Development,
11.00 a.m	ADNI study: preliminary data <u>Martina Bocchetta, MS</u> , on behalf of the PharmaCog Conse	of mild cognitive impairment patients in WP5 Pharmacog/E- ortium CS Istituto Centro San Giovanni di Dio Fatebenefratelli, Brescia, Italy
11.15 a.m	OC37 - Validation of the EADC-ADNI harmonized results <u>Martina Bocchetta, MS</u> for the EADC-ADNI group for the H IRCCS S.Giovanni di Dio-Fatebenefratelli, Brescia, Italy	protocol for manual hippocampal segmentation: preliminary armonization of the Harmonized Protocol
11.30 a.m	OC38 - ETNA3, a clinical randomized study assessin Hélène Amieva, PhD (1,2), <u>Jean-François Dartigues</u> , MD, F (1) INSERM U897 Epidemiology and Biostatistics Unit, Bordeaux, F	
11.45 a.m	OC39 - Novel cognitive outcomes for preclinical Alzheimer's disease prevention trials <u>Dorene M. Rentz</u> , PsyD (1), Adrian Schembri, DPsych (2), David Salmon, PhD (4), Michael Donohue, PhD (4), Paul Maruff, PhD (2), Paul Aisen, MD (4), Reisa A. Sperling, MD (1) (1) Departments of Neurology, Massachusetts General Hospital and Brigham and Women'sHospital, Boston, MA, (2) CogState Ltd, Melbourne, Australia, (3) University of California Irvine, Irvine, CA, (4) University of Californiaat San Diego, San Diego, CA	
12.00 p.m	 OC40 - A dose-response relationship between computerized cognitive training and global cognition in older adults Amit Lampit, Mag (FH) (1), Hariharan Hallock, MA (1), Rebecca Moss, MA (1), Sindy Kwok, PGDipPsych (1), Michael Rosser, BA, (2), Matthew Lukjanenko, PGDipPsych (1), Alana Kohn, PGDipPsych (1), Sharon Naismith, DPsych (Neuro) (3), Henry Brodaty, MBBS, DSc, FRANZCP (4), Michael Valenzuela, PhD, MBBS (Hons) (1) (1) Regenerative Neuroscience Group, Brain and Mind Research Institute, University of Sydney, Australia, (2) School of Psychology, University of New South Wales, Sydney, Australia, (3) Clinical Research Unit, Brain and Mind Research Institute, University of Medicine, University of New South Wales, Sydney, Australia, (3) Clinical Research Unit, Brain and Mind Research Institute, University of Medicine, University of New South Wales, Sydney, Australia, (3) Clinical Research Unit, Brain and Mind Research Institute, University of Medicine, University of New South Wales, Sydney, Australia, (3) Clinical Research Unit, Brain and Mind Research Institute, University of Medicine, University of New South Wales, Sydney, Australia, (3) Clinical Research Unit, Brain and Mind Research Institute, University of Medicine, University of New South Wales, Sydney, Australia 	
12.15 p.m	Lunch Break and poster sessions - San Diego B	
1.15 - 3.15 p.m	1.15 p.m - 3.15 p.m PARALLEL California Ballroom AB TREATMENT ASSESSMENT FOR CLINICAL TRIALS	SESSIONS: ORAL COMMUNICATIONS California Ballroom C BIOMARKERS FOR CLINICAL TRIALS
1.15 p.m	 TREATMENT ASSESSMENT FOR CLINICAL TRIALS - California Ballroom AB Moderators : Steve Ferris, Anton Porsteinsson OC41 - The API Colombia study: A prevention study in ADAD that will pave the way for prevention studies in sporadic AD Paul R (1), Ayutyanont N (2), Hendrix S (3), Langbaum JB (2), Friesenhahn (1), Cho W (1), Ward M (1), Ho C (1), Tariot P (2), Reiman E (2), Lopera F (4) (1) Genentech, South San Francisco, CA, USA, (2) Banner Alzheimer's Institute, Phoenix, AZ, USA, (3) Pentara Corporation, Salt Lake City, UT, USA, (4) Grupo de Neurociencias de Antioquia, Universidad de Antioquia, Medellín, Colombia 	



Friday, November **15**th

TREATMENT ASSESSMENT FOR CLINICAL TRIALS - California Ballroom AB

- 1.30 p.m OC42 - A phase 2 study to investigate the effects of SAR110894 on cognition, daily function, apathy and sleep in mild to moderate Alzheimer's disease patients Jeanne Stemmelin (1), Stéphane Kirkesseli (1), Renata Martincova (1), Raphael Bejuit (1), Valérie Corp-dit-Genti (1), Gilmour Morrison (2), Blandine Nembo (1), Christine Fauveau (1), Hervé Bester (1), Agnès Menut (1), Sophie Claudel (1), John Alam (1) (1) Sanofi Research and Development, Chilly Mazarin, France, (2) Covance, Alnwick, UK
- 1.45 p.m **OC43 - CANCELLED**

2.00 p.m OC44 - A novel active immunization against C-terminal region of Aβ enters clinical trial phase I Pedro Pesini, PhD, Manuel Sarasa, PhD Araclon Biotech Ltd. Zaragoza. Spain

2.15 p.m OC45 - Anti-amyloid-β therapy of Alzheimer disease (AD) patients by omega-3 supplementation: Recovery of innate immunity Milan Fiala, M.D (1), Verna Porter, M.D (2), Marc Dubourdeau, Ph.D (3) (1) Surgery Department, UCLA, Los Angeles, CA, USA, (2) Neurology Department, UCLA, Los Angeles, CA, USA, (3) Ambiotis SAS, Toulouse, France ind Research Institute, University of Sydney, Sydney, Australia

2.30 p.m OC46 - Safety and efficacy of ORM-12741 on cognitive and behavioral symptoms in patients with Alzheimer's disease: A randomized, double-blind, placebo-controlled, parallel group, multicenter, proof-of-concept 12 week study K. Wesnes (1), J.O. Rinne (2,3), J. Hänninen (4), M. Murphy (5), H. Riordan (5), J. Rouru (4), and the ALPO Study Group (1) Bracket Global, Goring-on-Thames, UK, (2) Turku PET Centre, (3) Turku University Central Hospital, Turku, Finland, (4) Orion Pharma, Turku, Finland, (5) World Wide Clinical Trials, King of Prussia, PA, USA

- 2.45 p.m OC47 - Intravenous Bapineuzumab in mild to moderate Alzheimer's disease: Results from two double-blind, placebo-controlled phase 3 trials Prisca Lucas, PharmD, PhD (1), David Li, PhD (2), Kasia Lobello, MD (2), Enchi Liu, PhD (3), H Robert Brashear, MD (3), Scot Styren, PhD (4), on behalf of the study 3133K1-3000/3001 Investigators (1) Pfizer PGRD, Paris, France, (2) Pfizer Inc, Collegeville, PA, USA, (3) Janssen Alzheimer Immunotherapy Research & Development, LLC, South San Francisco, CA, USA, (4)Pfizer, Inc, Groton, CT, USA
- 3.00 p.m OC48 - Relationship between cognitive and functional progression in patients with mild Alzheimer's disease Hong Liu-Seifert, PhD (1), Eric Siemers, MD (1), Karen Sundell, BS (1), Karen Price, PhD (1), Baoguang Han, PhD (1), Shannon Gardell, PhD (2) (1) Lilly Research Laboratories, Lilly Corporate Center, Indianapolis, IN, USA, (2) inVentiv Health Clinical, Somerset, NJ, USA

BIOMARKERS FOR CLINICAL TRIALS - California Ballroom C Moderators : Cristina Sampaio, Scott Turner

1.15 p.m OC49 - Detection of ligand bound to β Amyloid in the lenses of for Alzheimer's disease diagnosis Charles Kerbage, PhD (1), Carl H. Sadowsky, MD (2), Pierre N. Tariot, MD (3), Marc Agronin, MD (4), Gustavo Alva, MD (5),1*, Dennis Nilan (1), Anne Cameron, PhD (1), Gerald D. Cagle, PhD (1) (1) Cognoptix, Inc., Acton, MA, USA, (2) Premiere Research Institute and Nova Southeastern University, West Palm Beach, FL, USA, (3) Banner Alzheimer's Institute, Phoenix, AZ, USA, (4) Miami Jewish Health Systems, Miami, FL, USA, (5) ATP Clinical Research Inc. Costa Mesa, CA, USA OC50 - Prediction of cognitive and functional decline in patients with mild cognitive impairment by multiple brain 1.30 p.m volumes automatically extracted from structural MRI Robin Wolz, PhD (1,2), Peng Yu, PhD (3), Adam J.Schwarz, PhD (3), Kate McLeish, PhD (1), Daniel Rueckert, PhD (1,2), Derek Hill, PhD (1)

(1) IXICO Ltd, London, UK, (2) Imperial College London, London, UK, (3) Elli Lilly and Company, Indianapolis IN, USA

Friday, November 15th

	BIOMARKERS FOR CLINICAL TRIALS - California Ballroom C
1.45 p.m	OC51 - Resting-state functional MRI standardization for multi-center clinical trials <u>David Scott</u> , PhD (1), Ping-Chun Chiao, PhD (2), Jeff Sevigny, MD (2), Joyce Suhy, PhD (1) (1) Synarc, Inc, Newark, CA, USA, (2) Biogen Idec, Inc Weston, MA, USA
1.45 p.m 2.00 p.m	OC52 - Event related potentials: a cognitive biomarker for diagnosis of early-stage Alzheimer disease <u>Marco Cecchi</u> , PhD (1), Shauna Burkholder, MS (1), Sarah Berg, PhD (1), Carl Sadowsky, MD (2), Paul Solomon, PhD (3), P.Murali Doraiswamy, MBBS (4), Charles Smith, MD (5), Gregory Jicha, MD, PhD (5), Steven Arnold, MD (6), Bradley Folley, PhD (7), David Casey, MD (8), Andrew E.Budson, MD (9) (1) Neuronetrix, KY, USA, (2) Premiere Research Institute, FL, USA, (3) The Memory Clinic, VT, USA, (4) Psychiatry Department, Duke University, NC, USA, (5) Neurology Department, University of Kentucky, KY, USA, (6) Psychiatry Department, University of Pennsylvania, PA, USA, (7) Norton Neuroscience, Norton Healthcare, KY, USA, (8) Psychiatry Department, University of Louisville, KY, USA, (9) Boston Center for Memory, MA, USA
2.15 p.m 2.30 p.m 2.45 p.m 3.00 p.m	OC53 - In contrast to lower brain glucose uptake, brain ketone uptake is unchanged in mild Alzheimer's disease: A dual tracer PET study comparing 18F-FDG and 11Cacetoacetate <u>Alexandre Castellano, PhD (1)</u> , Scott Nugent (1), Melanie Fortier (1), Nancy Paquet (2), Christian Bocti (1), Martin Lepage (3), Eric Turcotte (3), Tamas Fulop (1), Stephen Cunnane (1) (1) Research Center on Aging, CSSS-IUGS, (2) Clinical Research Center, (3) Sherbrooke Molecular Imaging Center, Université de Sherbrooke, Sherbrooke, Québec, Canada
2.30 p.m	OC54 - A panel of ten plasma lipids identifies antecedent memory impairment in older adults <u>Massimo S. Fiandaca</u> Departments of Neurology and Neuroscience, Georgetown University Medical Center, Washington, DC, USA
2.45 p.m	OC 55 - The Aβ oligomer count in CSF is a biomarker for Alzheimer's disease Lei Wang-Dietrich, PhD (1), Susanne Aileen Funke, PhD (1), Eva Birkmann, PhD (1,2), <u>Dieter Willbold</u> , PhD (1,2) (1) Research Centre Juelich, Juelich, Germany, (2) Heinrich-Heine-University, Duesseldorf, Germany
3.00 p.m	OC56 - Reconstruction of entire chronological changes of multiple biomarkers in Alzheimer's disease from ADNI data by modeling: Significance of classification by Amyloid beta in CSF <u>Akihiro Hisaka</u> , PhD (1), Takaa kilshida, MS (2), Masashi Honma, MS (2), Kazutoshi Yokozuka, MS (3), Hidefumi Kasai, MS (3), Takashi Moritoyo, MD, PhD (4), Yoshihiro Arakawa, PhD (5), Takeshi Watsubo, MD, PhD (6), Hiroshi Suzuki, PhD (2) (1) Pharmacology and Pharmacokinetics, The University of Tokyo Hospital, Tokyo, Japan, (2) Department of Pharmacy, The University of Tokyo Hospital, Tokyo, Japan
3.15 p.m	Coffee Break and poster sessions - San Diego Ballroom





Friday, November 15th

3.45 p.m	KEYNOTE - California Ballroom ABC Moderator : Jacques Touchon Designing drug trials taking into account neuropsychiatric symptoms of AD Jeffrey Cummings, MD- Cleveland Clinic Lou Ruvo Center for Brain Health, Las Vegas, NV – USA
4.15 p.m	 SYMPOSIUM 4 - California Ballroom ABC Internet screening of cognition as a method for recruiting to clinical trials in prodromal Alzheimer's disease Moderators: John Harrison, PhD, <i>Metis Cognition, Wiltshire, UK</i> Scientific foundation of internet based cognitive screening for recognition of prodromal Alzheimer's disease <u>Paul Maruff</u> PhD (1), Judy Jaeger, PhD (1), Yen Ying Lim, PhD (2), Ara Khachaturian, PhD (3) (1) CogState Ltd, (2) Florey Institute of Neuroscience and Mental Health, Melbourne Australia, (3) PAD2020: The Campaign to Prevent Alzheimer's disease by 2020. Washington, DC. USA Does internet screening of cognition deliver appropriate subjects for trials of prodromal AD? A perspective from industry <u>Bruce Albala</u>, PhD (1), Michelle Gee, PhD (1) Andrew Satlin, MD (1) (1) <i>Eisai, Woodcliffe Lake, NJ, USA</i> Can internet based cognitive screening deliver appropriate patients to clinical research units for trials in prodromal AD? <u>Larry Ereshefsky</u>, PharmD <i>PAREXEL International, and California Clinical Trials Medical Group, Glendale, CA, USA</i>
5.30 p.m	KEYNOTE - California Ballroom ABC Moderator : Mathieu Ceccaldi Ethical issues in AD prevention trials: genetics, biomarkers and treatment risk Serge Gauthier, MD, FRCPC, McGill Center for Studies in Aging, Douglas Mental Health Research Institute, Montreal, Canada

KEYNOTE - California Ballroom AB

Novel immunotherapy approaches

Moderator : Paul Aisen

Saturday, November 16th

David Holtzman, MD - Professor and Chairman of Neurology, Associate Director of the Alzheimer's Disease Research Center,

CIAD San Diego 2013 Program 600.01 - 00.3 Program 8.30 - 10.00 - 00.3 Program 8.30 a.m

	Washington University in St. Louis, MO – USA	
	0.20 c m 40.00 c m	
8.30 - 10.00 a.m	California Ballroom AB 8.30 - 9.45 a.m SYMPOSIUM 5 Metabolic dysregulation in the Alzheimer brain: challenges and opportunities	PARALLEL SESSIONS California Ballroom C ORAL COMMUNICATIONS 8.30 - 9.00 a.m BIOMARKERS FOR CLINICAL TRIALS 9.00 - 10.00 a.m PRECLINICAL STUDIES IN AD
8.30 a.m	 MD, PhD1, Eric Reiman, MD, PhD2 (1) Research Center on Aging and Department of Medicine, 0 (2) Banner Alzheimer's Institute, Phoenix, AZ, USA 3. Dietary intervention to ameliorate neurocognitive de Robert Krikorian, PhD 	ages and opportunities ease brain in the elderly and in early Alzheimer's disease 2, MSc1, Kewei Chen, PhD2, Eric Turcotte, MD, PhD1, TamasFulop, <i>University of Sherbrooke, Sherbrooke, Quebec, Canada</i>
8.30 a.m	PhD (4), Susan M. Landau, PhD (5), Cindee M. Madison, I Reiman, MD (4), William J. Jagust, MD (5), Giovanni B. Friso (1) Laboratory of Epidemiology and Neuroimaging -IRCCS S. Giovann Department, IRCCS Istituto di Ricerche Farmacologiche Mario Negr Cambridge, UK, (4) Department of Decision Science, Bocconi Universi	neasures for clinical trials in MCI Vade, PhD (3,4), Kewei Chen, PhD (4), Napatkamon Ayutyanont, MS (5), Cathleen Haense, MD (6), Karl Herholz, MD (7), Eric M.
8.45 a.m	OC58 - Factors that influence use of plasma Amyloid & <u>Robert Rissman</u> , Michael Donohue, Setareh Moghadam, Chu Department of Neurosciences, University of California San Diego, San	ing-Kai Sun, Steven Edland, Paul Aisen



Saturday, November 16th

	PRECLINICAL STUDIES IN AD - California Ballroom C Moderators : Ron Petersen, Jacques Touchon
9.00 a.m	OC59 - Dissecting the anatomy of computerised cognitive training: systematic review and meta-analysis of RCTs in older adults <u>Amit Lampit</u> , Mag(FH), Hariharan Hallock, MA, Michael Valenzuela, PhD, MBBS(Hons) Regenerative Neuroscience Group, Brain and Mind Research Institute, University of Sydney, Sydney, Australia
9.15 a.m	OC60 - A centrally active ACE inhibitor promotes signs of hippocampal neuroregeneration in the Tg2576 model of Alzheimer's disease <u>Andreas Langer</u> , PhD, Said AbdAlla, PhD, Xuebin Fu, MSc, Ursula Quitterer, PhD Molecular Pharmacology Unit, Swiss Federal Institute of Technology, Zurich, Switzerland
9.30 a.m	OC61 - The anti-amyloid chaperone BRICHOS efficiently prevents amyloid β-peptide CNS toxicity in Drosophila melanogaster Erik Hermansson, PhDstud (1), Bengt Winblad, MD, PhD (1), <u>Jan Johansson</u> , MD, PhD (1,2,3), Jenny Presto, PhD (1) (1) KI Alzheimer Disease Research Centre, Dept NVS, Karolinska Institutet, Stockholm, Sweden, (2) Department of Anatomy, Physiology and Biochemistry, Swedish University
9.45 a.m	OC62 - Presenilin/γ-secretase function to cleave pathological Aβ42/43 <u>Masayasu Okochi</u> , MD, Shinji Tagami, MD, Kanta Yanagida, PhD, Yasuo Ihara, MD Osaka University, Osaka, Japan
10.00 a.m	Coffee Break and poster sessions - San Diego Ballroom
10.00 a.m 10.30 a.m	Coffee Break and poster sessions - San Diego Ballroom SYMPOSIUM 6 - California Ballroom AB Clinical trials in early stage Alzheimer's disease: CSF biomarkers symposium Moderator : Jacques Touchon, MD, PhD, Montpellier University Hospital, Memory Center and INSERM U1061, Montpellier, France
	SYMPOSIUM 6 - California Ballroom AB Clinical trials in early stage Alzheimer's disease: CSF biomarkers symposium Moderator : Jacques Touchon, MD, PhD, <i>Montpellier University Hospital, Memory Center and INSERM U1061, Montpellier,</i>
	 SYMPOSIUM 6 - California Ballroom AB Clinical trials in early stage Alzheimer's disease: CSF biomarkers symposium Moderator : Jacques Touchon, MD, PhD, Montpellier University Hospital, Memory Center and INSERM U1061, Montpellier, France 1. Brain amyloid-beta peptides dynamics in Alzheimer's disease Randall Bateman, MD, PhD

Themes

THEME: CLINICAL TRIALS METHODOLOGY P1 to P11	p. 19
THEME: CLINICAL TRIALS RESULTS P12 to P18	p. 20
THEME: CLINICAL TRIALS: IMAGING P19 to P31	p. 21
THEME: CLINICAL TRIALS BIOMARKERS P32 to P44	p. 23
THEME: CLINICAL TRIALS: COGNITIVE ENDPOINTS P45 to P47	p. 24
THEME: CLINICAL TRIALS: COGNITIVE ASSESSMENTS P48 to P54	p. 25
THEME: HEALTH ECONOMICS AND CLINICAL TRIALS P55 to P56	p. 25
THEME: EPIDEMIOLOGY AND CLINICAL TRIALS P57 to P58	p. 26
THEME: ANIMAL MODELS AND CLINICAL TRIALS P59 to P64	p. 26
THEME: NEW THERAPIES AND CLINICAL TRIALS P65 to P76	p. 27

THEME: CLINICAL TRIALS METHODOLOGY

P1	THERAPEUTIC STRATEGIES TO PREVENT ALZHEIMER'S DISEASE PATHOGENESIS USING FLUORESCENT CONJUGATED POLYMER Parameswar K. Iyer, PhD, B. Muthuraj, MSc, Atul K.Dwivedi, PhD, Sameer Hussain,MSc Department of Chemistry, Indian Institute of Technology, Guwahati, Assam – INDIA
P2	CHOOSING ALZHEIMER'S DISEASE PREVENTION TRIAL POPULATIONS Joshua D. Grill, PhD (1), Sarah Monsell (2) (1) Mary Easton Center for Alzheimer's Disease Research, Department of Neurology, UCLA, Los Angeles, CA, (2) National Alzheimer's Coordinating Center, University of Washington, Seattle, WA
P3	DOES STUDY PARTNER TYPE IMPACT THE RATE OF ALZHEIMER'S DISEASE PROGRESSION? Joshua D. Grill, PhD (1), Yan Zhou, PhD (1), Jason Karlawish, MD (3), David Elashoff, PhD (1,2) (1) Mary S. Easton Center for Alzheimer's Disease Research, Department of Neurology, David Geffen School of Medicine at UCLA, Los Angeles, CA, (2) Department of Medicine, David Geffen School of Medicine at UCLA, Los Angeles, CA, (3) University of Pennsylvania, Perelman School of Medicine, Departments of Medicine, and Medical Ethics and Health Policy, Penn Memory Center, Philadelphia, PA
P4	SELECTING ACCEPTABLE CAREGIVER INFORMANTS FOR AD CLINICAL TRIALS : IS MORE CARE NEEDED ? Priscilla Samuelson, RN and <u>David S. Miller</u> , MD, MA Bracket, Wayne, PA, USA
P5	PREDICTORS OF PLACEBO RESPONSE IN SUBJECTS WITH MILD-TO-MODERATE ALZHEIMER'S DISEASE: FINDINGS FROM 12-WEEK, PHASE 2A CLINICAL TRIALS Teresa Buracchio, MD,Andreas Meier, MD, Ferenc Martenyi, MD, Qi Tang, PhD, Laura Gault, MD, PhD AbbVie Inc.North Chicago, IL, USA
P6	SUBJECTS WITH MILD-TO-MODERATE ALZHEIMER'S DISEASE EXHIBIT EVIDENCE OF PRACTICE EFFECTS ON REPEATED MEASURES OF THE ALZHEIMER'S DISEASE ASSESSMENT SCALE-COGNITIVE SUBSCALE AND THE MINI-MENTAL STATUS EXAMINATION Andreas Meier, MD, Teresa Buracchio, MD, Ferenc Martenyi, MD, Qi Tang, PhD, Laura Gault, MD, PhD AbbVie Inc., North Chicago, IL, USA
P7	 PRACTICAL EXPERIENCE OF CONSENSUS DETERMINATION IN A GLOBAL, PHASE 2 ALZHEIMER'S DISEASE CLINICAL TRIAL (CN156-018) Matthew Gabel, PhD (1), Vladimir Coric, MD (2), Robert Berman, MD (2), Jesse Cedarbaum, MD (2), Howard Chertkow, MD (3), Rajan Duara, MD (4), Stephen Kaplita, PhD (2), Christine Moore, PhD (5), Norman Foster, MD (6) (1) Department of Political Science, Washington University, St. Louis, MO, USA, (2) Neuroscience Global Clinical Research, Bristol-Myers Squibb, Wallingford, CT USA (3) Lady Davis Institute, Sir Mortimer B. Davis Jewish General Hospital, Montreal, PQ CA, (4) Department of Neurology, McGill University School of Medicine, Montreal, Quebec CA, (5) Wien Center for Alzheimer's Disease and Memory Disorders, Mt. Sinai Medical Center, Miami Beach, FL USA, (6) InVentiv Health Clinical, Cary, NC USA, (7) Center for Alzheimer's Care, Imaging, and Research and Department of Neurology, University of Utah, Salt Lake City, UT USA
P 8	OPTIMIZING THE ANALYSIS OF PHASE 2 AND PHASE 3 CLINICAL TRIALS IN ALZHEIMER'S DISEASE Stephanie Stanworth, MS, Noel Ellison, MS, Leah Garriott, MS, Suzanne Hendrix, PhD Pentara Corporation, Salt Lake City, UT – USA
P9	ADCS ELECTRONIC DATA CAPTURE (EDC) - SMART ELECTRONIC CASE REPORT FORM (ECRF) FRAMEWORK Gustavo A. Jimenez-Maggiora, MBA, Ronald G. Thomas, PhD, Jia-shing So, BS, Stefania Bruschi, MS, Hongmei Qiu, BS, Phuoc Hong, BA, Paul S. Aisen, MD Neurosciences department, University of California at San Diego, La Jolla, CA, USA
P10	DOSE SELECTION FOR ELND005 (SCYLLO-INOSITOL) IN NEUROPSYCHIATRIC CLINICAL TRIALS: USE OF MODELING AND SIMULATIONS (M&S) OF POPULATION PHARMACOKINETIC MODEL TO ESTIMATE TARGET DRUG EXPOSURES Earvin Liang, PhD (1), Michelle Green, PhD (2), Matthias Kurth, MD, PhD (1), J Patrick Kesslak, PhD (1), Susan Abushakra, MD (1) (1) Elan Pharmaceuticals, Inc., San Mateo, CA, USA, (2) Pharsight, a Cartara Corporation, Sunnyvale, CA, USA

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RETROSPECTIVE REVIEW OF SAFETY AND TOLERABILITY OF CONTINUOUS CEREBROSPINAL FLUID (CSF) COLLECTIONS DURING PHASE 1 PHARMACOKINETIC/PHARMACODYNAMIC STUDIES IN HEALTHY VOLUNTEERS AND PATIENTS

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Giovanni B. Frisoni, MD (1), Claudio Babiloni, PhD (2), Amalia C. Bruni, MD (3), Elio Scarpini, MD (4), Sandro Sorbi, MD (5), Fabrizio Tagliavini, MD (6), Martina Bocchetta, MS (1), Michela Pievani, PhD (1), Alessandro Padovani, MD, PhD (7) (1) LENITEM (Laboratory of Epidemiology, Neuroimaging and Telemedicine) IRCCS – S. Giovanni di Dio – Fatebenefratelli Brescia, Italy, (2) Università di Roma "La Sapienza", Roma, Italy, (3) Centro Regionale di Neurogenetica, Lamezia Terme, Italy, (4) IRCCS Ospedale Policlinico, Milano, Italy, (5) Università di Firenze, Firenze, Italy, (6) IRCCS Fondazione Istituto Neurologico Carlo Besta, Milano, Italy, (7) Università di Brescia, Brescia, Italy

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P27 LONGITUDINAL VOLUMETRIC CHANGES IN STUDY CN156-018, AS COMPARED TO ADNI-1

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P28 THE IMPACT OF THE WHITE MATTER HYPERINTENSITIES TO THE COGNITIVE FUNCTION IN THE PATIENTS WITH BEHAVIORAL VARIANT FRONTOTEMPORAL DEMENTIA

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P29 PROPOSITION OF T1-AXIAL VISUAL RATING SCALE FOR MEDIAL TEMPORAL ATROPHY FOR CLINICAL TRIALS OF ALZHEIMER'S DISEASE

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P30 AMYLOID PET SCREENING FOR ENROLLMENT INTO AD CLINICAL TRIALS: AN EFFECTIVE ENRICHMENT STRATEGY IN A PHASE 1B CLINICAL TRIAL

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P31 AMYLOID AND APOE4 INTERACT TO INFLUENCE COGNITIVE DECLINE OVER A SHORT FOLLOW UP PERIOD IN AGING

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ZHU Ai-gin, ZHONG Xing, LI Gou-feng, Li Ying-lan, Liao Bao-xia, Peng Hai, CHU Yi-de Institute of Geriatrics, Qinghai Provincial Hospital, Xining, China

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IMPACT OF THE FRENCH "NATIONAL PLAN FOR ALZHEIMER 2008-2012" ON THE USE OF CSF BIOMARKERS: THE **P36 PLM STUDY**

Audrey Gabelle (1,2), Julien Dumurgier (3), Olivier Vercruysse (4), Claire Paquet (3,5), Stéphanie Bombois (4), Jean-Louis Laplanche (6), KatellPeoc'h (6), Susanna Schraen (7), Luc Buée (7), Florence Pasquier (4), Jacques Hugon (3,5), Jacques Touchon (1,8), Sylvain Lehmann (2)

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IMMUNIZATION AGAINST AB40 INDUCES AN INCREASE OF AB40 PLASMA LEVELS WHEREAS LEVELS OF AB42 **P37 REMAINED UNCHANGED**

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EFFECTS OF AZD1446 (A NEURONAL NICOTINIC RECEPTOR AGONIST) **P38** THE ON QUANTIFIED ELECTROENCEPHALOGRAPHY (QEEG) IN PATIENTS WITH MILD-TO-MODERATE ALZHEIMER'S DISEASE. QUANTITATIVE MEASUREMENTS USING A QEEG CHOLINERGIC INDEX

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P39 PHARMACOLOGICAL REVERSAL OF AZD1446 AND DONEPEZIL AFTER SCOPOLAMINE INJECTIONS TO HEALTHY VOLUNTEERS, QUANTITATIVE MEASUREMENTS USING A QEEG CHOLINERGIC INDEX

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P40 EXPERIMENTAL DESIGN, CALIBRATION, AND STATISTICAL ANALYSIS OF BLOOD PLASMA BIOASSAYS

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P41 OLFACTORY IDENTIFICATION DEFICITS PREDICT RESPONSE TO CHOLINESTERASE INHIBITORS IN PATIENTS WITH MILD COGNITIVE IMPAIRMENT

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P42 A NOVEL GLYCAN BIOMARKER IN ALZHEIMER DISEASE

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P43 PLASMA BIOMARKERS ASSOCIATED WITH THE APOLIPOPROTEIN E (APOE) GENOTYPE AND AMYLOID-BETA IMAGING

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P44 NEW MODELING METHOD FOR ESTIMATION OF ENTIRE CHRONOLOGICAL CHANGES OF MULTIPLE BIOMARKERS FROM FRAGMENTED INFORMATION

Takaaki Ishida, MS (1), Akihiro Hisaka, PhD (2), Masashi Honma, MS (1), Kazutoshi Yokozuka, MS (3), Hidefumi Kasai, MS (3), Takashi Moritoyo, MD, PhD (4), Yoshihiro Arakawa, PhD (5), Takeshi Iwatsubo, MD, PhD (6), Hiroshi Suzuki, PhD (1) (1) Department of Pharmacy, The University of Tokyo Hospital, Tokyo, Japan, (2) Pharmacology and Pharmacokinetics, The University of Tokyo Hospital, Tokyo, Japan, (3) Bell Medical Solutions Inc. Tokyo, Japan, (4) Unit for Early and Exploratory Clinical Department, The University of Tokyo Hospital, Tokyo, Japan, (5) Clinical Research Support Center, The University of Tokyo Hospital, Tokyo, Japan, (6) Neuroscience, Faculty of Medicine, The University of Tokyo, Tokyo, Japan

THEME: CLINICAL TRIALS: COGNITIVE ENDPOINTS

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Renné Alegria, PhD (1,2), Cleide Rosana Prisco (3), Cassio MC Bottino (2), MD, PhD, Maria Inês Nogueira, PhD (1) Neuroscience and Behavior, Institute of Psychology, University of São Paulo, SP, Brazil, (2) PROTER- Old Age Research Group, Institute of Psychiatry, School of Medicine, University of Sao Paulo, SP, Brazil, (3) Institute of Biomedical Sciences, University of São Paulo, SP, Brazil

P46 CREATING A COMPOSITE SCORE : METHODOLOGY COMPARISON Noel Ellison, MS, Suzanne Hendrix, PhD, Stephanie Stanworth, MS, Leah Garriott, MS *Pentara Corporation, Salt Lake City, UT - USA*

San Diego

THEME: CLINICAL TRIALS: COGNITIVE ENDPOINTS

- LONG-TERM NEUROPSYCHIATRIC SYMPTOM INTENSITY IN ALZHEIMER'S DISEASE IS PREDICTABLE VIA SHORT-P47 TERM SYMPTOM SEVERITY AS MEASURED BY SYMPTOMGUIDE™ SCORE Kenneth Rockwood, MD, PhD (1,2), Arnold Mitnitski, PhD (1,2), Matthew Richard, BSc (1), Matthias Kurth, MD, PhD (3), J Patrick Kesslak, PhD (3), Susan Abushakra, MD (3) (1) DGI Clinical Inc., Halifax, NS, Canada, (2) Division of Geriatric Medicine, Dalhousie University, Halifax, NS, Canada, (3) Elan Pharmaceuticals, San Francisco, CA USA
- THEME: CLINICAL TRIALS: COGNITIVE ASSESSMENTS
- MODELING OF ADAS-COG PLACEBO RESPONSE IN ASIAN AND CAUCASIAN PATIENTS WITH ALZHEIMER'S **P48** DISEASE An Hye Kim, MD (1), Kyoungsoo Lim, MD, PhD (1), Jae Yong Chung, MD, PhD (2) (1) Department of Clinical Pharmacology and Therapeutics, Seoul National University College of Medicine and Hospital, Seongnam, Korea, (2) Department of Clinical Pharmacology and Therapeutics, Seoul National University College of Medicine and Bundang Hospital, Seongnam, Korea LONG-TERM EFFECT OF CURRENT ALZHEIMER'S MEDICATIONS ON COGNITIVE FUNCTION AMONG CHINESE P49 ALZHEIMER'S DISEASE PATIENTS: A THREE YEAR PROSPECTIVE STUDY Chu LW (1), Kwan F (1), Yik PY (1), Song YQ (2) (1) Division of Geriatric Medicine, Department of Medicine, Queen Mary Hospital, The University of Hong Kong, (2) Department of Biochemistry, The University of Hong Kong EFFICIENT SCREENING FOR MILD COGNITIVE IMPAIRMENT DUE TO AD FOR CLINICAL TRIAL ENROLLMENT **P50** Stephen W. Hurt, PhD (1), Bruce Albala, PhD (2), Paul Maruff, PhD (3) (1) Psychiatry Department, Weill Cornell Medical College, White Plains, New York USA, (2) Eisai Inc., Woodcliff Lake, New Jersey, USA, (3) CogState, New Haven, Connecticut, USA THE GOTHENBURG MCI STUDY: THE NEUROPSYCHOLOGICAL PROFILES OF INCIPIENT AD AND VASCULAR **P51 COGNITIVE DISORDER DIFFER** Arto Nordlund, PhD, Maria Bierke, PhD, Mattias Göthlin, MSc, Carl Eckerström, MD, PhD, Anders Wallin, MD, PhD Institute of Neuroscience and Physiology, Sahlgrenska Academy at University of Gothenburg, Molndal, Sweden EFFECTS OF BIOMARKERS ON COGNITIVE DOMAINS IN ALZHEIMER'S DISEASE **P52** Opler M (1,3), Yavorsky C (1,2), <u>Rothman B</u> (1), Lucic L (1,4), Khan A (1,5) (1) ProPhase, LLC, (2) CROnos CCS, (3) New York University School of Medicine, (4) Pratt Institute, (5) Nathan S. Kline Institute for Psychiatric Research DIFFERENTIAL ITEM FUNCTIONING AND THE ALZHEIMER'S DISEASE ASSESSMENT SCALE-COGNITIVE (ADAS-COG) **P53** AMONG PATIENTS WITH ALZHEIMER'S DISEASE Yavorsky C (1,2), Khan A (1,5), Opler M (1,3), Lucic, L (1,4), Rothman, B (1) (1) ProPhase, LLC, (2) CROnos CCS, (3) New York University School of Medicine, (4) Pratt Institute, (5) Nathan S. Kline Institute for Psychiatric Research ALTERATIONS IN VASCULAR FUNCTION IN ALZHEIMER'S DISEASE AND ACROSS THE ADULT LIFESPAN **P54** Sarah Catchlove, PhDc, Andrew Pipingas, PhD, Helen Macpherson, PhD Centre for Human Psychopharmacology, Swinburne University of Technology, Hawthorn, VIC, Australia THEME: HEALTH ECONOMICS AND CLINICAL TRIALS LIVING ALONE IN ALZHEIMER'S DISEASE—THE INFLUENCE OF FUNCTIONAL IMPAIRMENT **P55** Carina Wattmo, RN, BSc, PhD, Lennart Minthon, MD, PhD, Åsa K. Wallin, MD, PhD Clinical Memory Research Unit, Department of Clinical Sciences, Malmö, Lund University, Malmö, Sweden

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Clinical

CANCELLED **P56**

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Kasem Akhras (1), Baoguo Jiang (1), Beenish S. Manzoor (2), <u>Shawn Yu</u> (1), Jiao Yang (1) (1) Takeda Pharmaceuticals International, Inc., Deerfield, IL, USA, (2) University of Illinois at Chicago, College of Pharmacy, Chicago, IL, USA

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Sandrine Andrieu (1,2,3,4), Nicola Coley (1,2,4), Miia Kivipelto (5,6,7), Francesca Mangialasche (5), Tiia Ngandu (7), Yannick Meiller (8), Juliette Guillemont (1,2,8), Abraham van de Groep (9), Eric P. Moll van Charante (10), Carol Brayne (11), Hilkka Soininen (6,12), Willem A van Gool (13), Edo Richard (13) for the HATICE consortium

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Aruna Sharma, MD (1), Dafin F Muresanu, MD, PhD (2), Rudy J Castellani, MD, Ph D (3), Mark A Smith, MD, Ph D (4), Hari S Sharma, MD, Ph D, Dr Med Sci (5)

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Jin Chu, Domenico Pratico

Temple University, Philadelphia PA, USA

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Vicki Poole Hoffmann, PharmD, Michael Case, MSc, Ann Marie Hake, MD1 Neuroscience, Eli Lilly and Company, Indianapolis, IN, USA

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Human Photosynthesis Study Center, Aguascalientes, Mexico

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Xiangjian Luo, PhD, Zheng Yin, Dongbing Gao, Xiaofeng Xia, Stephen TC Wong Department Systems Medicine and Bioengineering, The Methodist Hospital Research Institute, Houston, TX - USA

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Gonzalo A. Farías, MD, PhD (1,2), Leonardo Guzmán (1), George Perry, PhD (3), Ricardo B. Maccioni, PhD (1) (1) International Center for Biomedicine (ICC), Avda Vitacura 3568, Vitacura, Santiago, Chile, (2) Department of Neurology and Neurosurgery, Faculty of Medicine, Universidad de Chile, Santiago, Chile, (3) College of Sciences, University of Texas, San Antonio, TX, USA

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Department of Psychiatry, Osaka University Graduate School of Medicine, Osaka, Japan

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Dehua Chui (1), Ting Zhou (1), Tao Zhang (1), Hecheng Wang (1), Yawei Tong (1), Yan Yu (1), Pengfei To (2) (1) Neuroscience Research Institute & Department of Neurology, Third Hospital, Peking University, China, (2) The State Key Laboratory of Natural and Biomimetic Drugs, Health Science Center, Peking University, China

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THEME: NEW THERAPIES AND CLINICAL TRIALS

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WHY AMYLOID THERAPY WON'T CURE ALZHEIMER'S DISEASE AND IS A WASTE OF TIME AND PUBLIC FUNDS? Alexei Koudinov, MD, PhD, DrSci (1,2,3), Natalia Shishkova, MD, PhD, DrSci (1,2), Temirbolat Berezov, MD, PhD, DrSci (1,2) (1) Biochemistry, TT Berezov Laboratory, Russian People Friendship University, (2) Orekhovich Institute of Biomedical Chemistry, Moscow, Russia, (3) Neurobiology of Lipids, Rehovot, Israel

P75 FYN KINASE INHIBITION BY SARACATINIB FOR THE TREATMENT OF ALZHEIMER'S DISEASE: RATIONALE, PRECLINICAL SUPPORT AND PHASE 1B TRIAL DESIGN Haakon B. Nygaard, MD, PhD (1,2), Ji Won Um, PhD (1), Adam C. Kaufman, BS (1), Christopher van Dyck, MD (3), Stephen

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Mathieu Ceccaldi, MD,PhD (1), Pierre Jouanny, MD (2), Olivier Guerin, MD (3), Alain Bredin, MD (4), Jean Jacques Pere, MD (5), Isabelle Bourdeix, PhD (5)

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General Information

Congress Venue

Westin Gaslamp Quarter 910 Broadway Circle San Diego, California 92101



Practical details:

Registration desk opening hours:

- Thursday, November 14th
 7:00 am 6 pm
- Friday, November 15th 7:30 am - 5:30 pm
- Saturday, November 16th
 7:30 am 12:30 pm

CME credits:

Please come see us at the Management desk to obtain your CME certificate. Remember to fill out the overall evaluation and daily evaluations (both in your attendee bag) to obtain your certificate in order to abide by CME guidelines.

Welcome Reception Thursday, November 14

Hosted by the Alzheimer's Disease Cooperative Study (ADCS) at the University of California San Diego, CtaD 2013 welcomes you to an evening of networking and relaxation at the Omni Hotel San Diego where from its Palm Terrace you will take in the extraordinary views of the San Diego Bay, the downtown skyline and the Gaslamp Quarter.

Buses will depart at 6:30 pm from the Westin Gaslamp and return attendees directly to the hotel afterwards.

Omni San Diego Hotel 675 L Street San Diego, California 92101



OUR LOCAL PARTNER

The Alzheimer's Disease Cooperative Study (ADCS) was formed in 1991 as a cooperative agreement between the National Institute on Aging (NIA) and the University of California, San Diego. The ADCS is a major initiative for Alzheimer's disease (AD) clinical studies in the Federal government, addressing treatments for both cognitive and behavioral symptoms. This is part of the NIA Division of Neuroscience's effort to facilitate the discovery, development and testing of new drugs for the treatment of AD and also is part of the Alzheimer's Disease Prevention Initiative.

More at <u>www.adcs.org</u>

Continuing Medical Education

This UCSD School of Medicine accreditation and its designated number of CME credits are recognized by all the national authorities of the countries of the European Union. Individual physicians are awarded the designated number of corresponding European credits by the European Accreditation Council for Continuing Medical Education EACCME.

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In order to claim your credits for this event, please fill out the overall and daily evaluations in your attendee bags. Certificates will be available at the Conference Management desk at the end of the event.

Course Description

Alzheimer's disease is one of the most important health challenges facing aging populations worldwide. The development of the next generation of Alzheimer's disease drugs is becoming essential to face up to this challenge. New pathways have been identified with biomarkers, facilitating novel trial designs for studies of tau-based therapies and other diseasemodifying drugs including immunotherapy.

However, methodological challenges continue to slow the development of specific new drug candidates. One of the objectives of the conference is to identify these hurdles and find ways to address them by bringing together world leaders in AD drug development to discuss solutions to the difficulties that have slowed the pace of progress, with a particular focus on clinical trial methodology.

Target Audience

The target audience for CtaD2013 includes neurologists, psychiatrists and other clinicians and scientists involved in geriatric care, research, imaging and drug development for patients with Alzheimer's disease and other neurodegenerative disorders. Other healthcare professionals who may benefit from this activity are clinical research coordinators, nurses, speech therapists and other AD and dementia occupational therapists, psychologists and neuropsychologists.

CTAD 2013: Learning objectives

During this event essential learning objectives will be covered so that at the end of the conference each participant should be able to:

- 1. Translate the significance to the drug development process of each individual phase of clinical trials from Phase I to Phase IV.
- 2. Articulate the involvement of neurotransmitters and cortical excitability in Alzheimer's disease pathology, and the implications for treatment.
- Interpret back outcomes of APOE4-related therapeutic strategies.
- 4. Identify and evaluate interdisciplinary approaches combining biochemistry, molecular and cell biology, and transgenic modeling to unveil AD molecular mechanisms.
- 5. Describe new drug combination therapies under study and their future applications in the field of AD.
- 6. Implement in research studies: cognitive, clinical and biomarker measures that characterize the progression through the asymptomatic, prodromal and dementia phases of AD.
- 7. Interpret back valuable information on new upcoming molecules in order to educate fellow physicians and propose alternatives to patients.
- 8. List the novel methodologies or biomarkers essential in identifying predementia patients most at risk of developing AD.
- List study findings, including safety, biomarker and clinical findings, presented at the conference underlying progress 9. in understanding the amyloid hypothesis.

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- 10. Describe new composite outcome scores that optimize the power for measuring clinical disease progression for trials in a MCI and pre-MCI populations.
- 11. Describe and interpret sensitive biochemical (e.g. CSF A-beta, tau andphospho tau levels) and neurophysiological (e.g. QEEG, ERP) biomarkers of early AD detection.
- 12. Interpret ERP data in AD clinical trials and drug development for cohort selection and monitoring disease progression.
- 13. Identify and evaluate new methods for optimally scoring each patient's test item responses and overall test performance, for determining the number of dimensions underlying the test's performance, and for adjusting for sample bias effects.
- 14. Interpret back AD impact in other populations like Down Syndrome.
- 15. Express appreciation for vertical integration and the impact it can have by improving knowledge transfer and drug development.

Needs Assessment

CTAD 2013 Scientific committee identified several practice gaps in designing and conducting AD Clinical Trials and developed the program to address these gaps, namely:

- The need to appreciate the full spectrum of AD from an asymptomatic stage through dementia
- The need for learning how dementia can affect specific population subgroups
- The need to elucidate risk factors for AD and other dementias
- · The need to identify and avoid methodological errors in the design of multicenter and international clinical trials
- · The need for improved measurement of cognitive deficits
- The need to keep up with scientific advances regarding biomarkers of AD pathologies.

Beyond these global practice gaps addressed throughout the conference other essential learning objectives will be covered so that at the end of the conference each participant will be able to understand:

- The importance of each individual phase of clinical trials from Phase I to Phase IV
- The relevance of neurotransmitters and cortical excitability in Alzheimer's disease pathology
- The cognitive, clinical and biomarker measures that characterize the progression through the asymptomatic, prodromal and dementia phases of AD.

Accreditation statement:

The University of California, San Diego School of Medicine is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

Credit designation statement:

The University of California, San Diego School of Medicine designates this live activity for a maximum of *18.0 AMA PRA Category 1 Credits*[™]. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Cultural and Linguistic Competency Statement:

California Assembly Bill 1195 requires continuing medical education activities with patient care components to include curriculum in the subjects of cultural and linguistic competency. It is the intent of the bill, which went into effect on July 1, 2006, to encourage physicians and surgeons, CME providers in the state of California, and the Accreditation Council for Continuing Medical Education to meet the cultural and linguistic concerns of a diverse patient population through appropriate professional development. The planners, speakers and authors of this CME activity have been encouraged to address issues relevant in their topic area. In addition, a variety of resources are available that address cultural and linguistic competency, some of which may be included in your syllabus or handout materials. Additional resources and information about AB1195 can be found on our website at http://cme.ucsd.edu.

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Raymond T. Bartus	Sangamo	Occasional consultant	х	х		
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