

CTAD Alzheimer 2019

Clinical Trials on Alzheimer's Disease



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FINAL PROGRAM

SAN DIEGO, California

Hilton Bayfront San Diego

December 4-7, 2019

Montpellier '08 / Las Vegas '09 / Toulouse '10 / San Diego '11
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MONTPELLIER and TOULOUSE EADC Centers
European Alzheimer's Disease Consortium

Keck School of Medicine of USC
Alzheimer's Therapeutic Research Institute



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CTAD 2019
San Diego



CTAD Organizing Committee

Jacques Touchon MD, PhD
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Hospital of Toulouse
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● Wednesday, DECEMBER 4

- 4.00 p.m** **Opening Ceremony and CTAD Lifetime Achievement Award**
Paul Aisen, Jacques Touchon, Bruno Vellas, Mike Weiner
This year the Lifetime Achievement Award in Alzheimer's Disease Therapeutic Research is awarded to Zaven Khachaturian, Ph.D., in recognition for his work on the foundations of AD clinical trials
- 4.30 p.m** **KEYNOTE 1**
How to interpret recent failures for the Beta-Amyloid target?
Stephen Salloway, MD, MS - Chief of Neurology and Director of the Memory and Aging Program, Butler Hospital, Providence, RI, USA
- 5.00 p.m** **SYMPOSIUM 1**
New Results on the Relationship between Intensive Blood Pressure Control and Cognitive Function from SPRINT-MIND
Chair: Kristine Yaffe, University of California at San Francisco (UCSF), San Francisco, CA, USA
- PRESENTATION 1: Effect of intensive blood pressure control on subtypes of mild cognitive impairment**
Sarah Gaussoin, Wake Forest School of Medicine, Winston-Salem, NC, USA
- PRESENTATION 2: Lessons Learned from Cognitive Outcomes in SPRINT: Neuropsychological Test Scores, Domain-Specific Cognitive Function, and Adjudicated Outcomes**
Nicholas M. Pajewski, Wake Forest School of Medicine, Winston-Salem, NC, USA
- PRESENTATION 3: Effect of intensive blood pressure control on brain MRI biomarkers**
Ilya Nasrallah, University of Pennsylvania School of Medicine, Philadelphia, PA, USA
- 5.45 p.m** **LATE BREAKING COMMUNICATIONS**
- 5.45 p.m** **LB1 - HARMONY relapse-prevention study: pimavanserin significantly prolongs time to relapse of dementia-related psychosis**
Erin FOFF (1), Jeffrey CUMMINGS (2), Maria SOTO-MARTIN (3), Bradley MCEVOY (1), Srdjan STANKOVIC (1)
(1) ACADIA Pharmaceuticals Inc., United States, (2) Cleveland Clinic Lou Ruvo Center for Brain Health, United States, (3) Gerontopole Alzheimer Clinical Research Center/University Hospital of Toulouse, France
- 6.00 p.m** **LB2 - Masupirdine (SUVN-502), a 5-HT6 receptor antagonist in combination with donepezil and memantine in moderate Alzheimer's patients: Study outcomes from a phase-2 study**
Jeffrey CUMMINGS (1,2), Alireza ATRI (3), Ramakrishna NIROGI (4), John IENI (4), Vinod GOYAL (4), Pradeep JAYARAJAN (4), Jyothsna RAVULA (4), Satish JETTA (4), Venkat JASTI (4)
(1) Department of Brain Health, School of Integrated Health Sciences, University of Nevada; Cleveland Clinic, Lou Ruvo Center for Brain Health, United States, (2) Cleveland Clinic, Lou Ruvo Center for Brain Health, United States, (3) Banner Sun Health Research Institute, Banner Health, United States, (4) Suven Life Sciences, India
- 6.15 p.m** **LB3 - Results of the Reducing pathology in Alzheimer's Disease through Angiotensin TaRgeting (RADAR) Trial**
Patrick G KEHOE (1), Nicholas TURNER (1), Elizabeth HOWDEN (1), Lina JARUTYTE (1), Shona CLEGG (2), Ian MALONE (2), Josephine BARNES (2), Carole SUDRE (3), Peter S BLAIR (1), Elizabeth COULTHARD (1), Athene LANE (1), Anthony P PASSMORE (4), Jodi TAYLOR (1), Henk-Jan MUTSAERTS (5), David L THOMAS (2), Fox NICK (2), Ian WILKINSON (6), Yoav BEN-SHLOMO (1), Radar INVESTIGATORS (1)
(1) University of Bristol, United Kingdom, (2) University College London, United Kingdom, (3) Kings College, United Kingdom, (4) Queens University Belfast, United Kingdom, (5) Academic Medical Centre, United Kingdom, (6) Addenbrookes Hospital, United Kingdom

● Wednesday,
DECEMBER 4



6.30 p.m

LB4 - A multicenter, Randomized, Double-blind, Placebo-Controlled, Parallel Design, Prospective, Phase II Clinical Trial to Evaluate the Safety and Efficacy of GV1001, a novel peptide mimicking human telomerase reverse transcriptase, for the Treatment of Moderate to Severe Alzheimer's Disease

Seong-Ho KOH (1), Seong Hye CHOI (2), Jee Hyang JEONG (3), Chan Nyoung LEE (4), Young Soon YANG (5), Ae Young LEE (6), Jae-Hong LEE (7), Kyung Won PARK (8), Hyun Jeong HAN (9), Byeong Cha KIM (10), Jin Se PARK (11), Jee-Young LEE (12), Sangjae KIM (13)

(1) Hanyang University Guri Hospital, Korea, Republic of, (2) Inha University Hospital, Korea, Republic of, (3) Ewha Womans University Mokdong Hospital, Korea, Republic of, (4) Korea University Anam Hospital, Korea, Republic of, (5) Veterans Health Service Medical Center, Korea, Republic of, (6) Chungnam National University Hospital, Korea, Republic of, (7) Asan Medical Center, Korea, Republic of, (8) Dong-A University Hospital, Korea, Republic of, (9) Myongji Hospital, Korea, Republic of, (10) Chonnam National University Hospital, Korea, Republic of, (11) Inje University Haeundae Paik Hospital, Korea, Republic of, (12) Seoul National University Boramae Medical Center, Korea, Republic of, (13) Teloid Inc., United States

6.45 p.m

Welcome networking cocktail

● Thursday, DECEMBER 5

8.00 a.m

LATE BREAKING ORAL COMMUNICATIONS

LB5 - Modulation of microRNA pathways by gemfibrozil in predementia Alzheimer disease: a randomized, placebo-controlled, double-blind clinical trial

Gregory JICHA, Richard KRYSZCIO, Brooke BEECH, Wangxia WANG, Bert LYNN, Frederick SCHMITT, Beth COY, Omar AL-JANABI, Erin ABNER, Peter NELSON

(1) University of Kentucky, United States

LB6 - One-month oral treatment with PTI-125, a new drug candidate, reduces CSF and plasma biomarkers of Alzheimer's disease

Lindsay BURNS (1), Hoau-Yan WANG (2), Zhe PEI (2), Kuo-Chieh LEE (2), Carrie CROWLEY (2), Michael MARSMAN (2), Nadav FRIEDMANN (2)

(1) Cassava Sciences, Inc., United States, (2) City of New York School of Medicine, United States

LB7 - Early changes in Alzheimer's disease biomarkers show interplay between tau metabolism, inflammation, synaptic damage and neurodegeneration: results from the ALFA study

José Luis MOLINUEVO (1), Gemma SALVADO (1), Marta MILA (1), Kaj BLENNOW (2), H ZETTERBERG (3, 4, 5), Grégory OPERTO (1), Carles FALCÓN (1), R BATRLA (6), G KOLLMORGEN (7), Gonzalo SÁNCHEZ-BENAVIDES (1), Juan Domingo GISPERT (1), Marc SUAREZ-CALVET (1)

(1) Barcelonabeta Brain Research Center, Fundació Pasqual Maragall, Pompeu Fabra University, Spain, (2) Department of Psychiatry and Neurochemistry, Institute of Neuroscience and Physiology, University of Gothenburg, Sweden, (3) Clinical Neurochemistry Laboratory, Sahlgrenska University Hospital, Sweden, (4) Department of Neurodegenerative Disease, UCL Institute of Neurology, Queen Square, United Kingdom, (5) UK Dementia Research Institute at UCL, United Kingdom, (6) Roche Diagnostics International Ltd, Switzerland, (7) Roche Diagnostics GmbH, Germany

LB8 - Blood plasma phospho-tau isoforms detect CNS change in Alzheimer's disease

Nicolas BARTHÉLEMY, Kanta HORIE, Chihiro SATO, Randall BATEMAN

(1) Washington University School of Medicine, United States

9.00 a.m

ORAL COMMUNICATIONS SESSION

9.00 a.m

OC1 - Comparative Effectiveness of behavioral interventions in Mild Cognitive Impairment: 12-month outcomes of a Randomized Clinical Trial

Glenn Smith, University of Florida, Gainesville, FL, USA

9.15 a.m

OC2 - AADvac1 tau vaccine completing the phase 2 study: a paradigm shift for the AD treatment hypothesis

Matej Ondrus, AXON Neuroscience CRM Services SE, Bratislava, Slovakia

9.30 a.m

OC3 - Treatment with Donanemab, a β -amyloid plaque-specific antibody, results in rapid and sustained reduction of amyloid measured by F-18 florbetapir imaging in Alzheimer's disease

Stephen Lowe, Lilly Centre for Clinical Pharmacology, Singapore, Singapore

9.45 a.m

OC4 - Automatic speech recognition can deliver large-scale, remote assessments of cognition

Francesca Cormack PhD (1,2), Merina Su PhD (1), Jennifer H. Barnett PhD (1,2), Nick Taptiklis (1)

(1) Cambridge Cognition, Cambridge - UK, (2) University of Cambridge, Cambridge - UK

10.00 a.m



Coffee Break and poster sessions

● Thursday,
DECEMBER 5



10.30 a.m

SYMPOSIUM 2

New Predictive Platforms for Advancing Drug Combination Approaches for Alzheimer Pathology

Chairman: Lon Schneider, Keck School of Medicine of USC, Los Angeles, CA, USA

PRESENTATION 1: In Silico Screening of Medications for Slowing Alzheimer's Disease Progression in a Clinical Trials Meta-database

Richard E. Kennedy, University of Alabama, Birmingham, AL, USA

PRESENTATION 2: Drug Combination Identification through Correlation between a Clinical Dataset and a Computational Model

Thomas J. Anastasio, University of Illinois at Urbana-Champaign, Urbana, IL, USA

PRESENTATION 3: Evaluating Pharmacodynamic Interactions in Drug Combinations Using Quantitative Systems Pharmacology Analysis of Clinical Trials

Hugo Geerts, In Silico Biosciences, Berwyn, PA, USA

11.15 a.m

LATE BREAKING ORAL COMMUNICATIONS

LB9 - Persistence Of BAN2401-Mediated Amyloid Reductions Post-Treatment: A Preliminary Comparison Of Amyloid Status Between The Core Phase Of BAN2401-G000-201 And Baseline Of The Open-Label Extension Phase In Subjects With Early Alzheimer's Disease

Chad SWANSON (1), Yong ZHANG (1), Shobha DHADDA (1), Jinping WANG (1), June KAPLOW (1), Heather BRADLEY (1), Martin RABE (1), Keiichiro TOTSUKA (2), Robert LAI (3), Robert GORDON (3), Lynn KRAMER (1)
(1) Eisai Inc., United States, (2) Eisai Co., Ltd., Japan, (3) Eisai Ltd., United Kingdom

11.30 a.m

ORAL COMMUNICATIONS SESSION

11.30 a.m

OC5 - Development of cognitive go/no-go decision-making criteria in early clinical development of agents to treat Alzheimer's disease

Alette Wessels, PhD (1), Chris J. Edgar PhD (2), Gregory Light, PhD (3), Pradeep Nathan, PhD (4), Eric Siemers, MD (5), Paul Maruff, PhD (6), John Harrison, PhD (7)

(1) Eli Lilly and Company, Indianapolis, IN, USA, (2) Cogstate Ltd, London, UK, (3) Department of Psychiatry, University of California, San Diego, USA, (4) SoseiHeptares, Cambridge, UK; Department of Psychiatry, University of Cambridge UK; School of Psychological Sciences, Monash University, Australia, (5) Cogstate Ltd, New Haven, CT, USA, (6) Cogstate Ltd., Melbourne, Australia, (7) Metis Cognition Ltd, Kilmington Common, UK; Alzheimer Center AUmc, Amsterdam, The Netherlands; Institute of Psychiatry, Psychology & Neuroscience, King's College London, UK

11.45 a.m

OC6 - Efficacy and safety results of REVERSE-SD, phase-2b clinical study of the selective p38 α kinase inhibitor neflamapimod in early-stage Alzheimer's disease (AD)

Philip Scheltens, Alzheimer Center, Amsterdam UMC, Amsterdam, The Netherlands

12.00 p.m

OC7 - Phase III studies of crenezumab in early (prodromal-to-mild) Alzheimer's disease (CREAD/CREAD2): Biomarker results

Tobias Bittner, F. Hoffmann-La Roche Ltd, Basel, Switzerland

12.15 p.m

OC8 - DHA Brain Delivery Pilot Study: A randomized clinical trial

Hussein Yassine, USC, Los Angeles, CA, USA

12.30 p.m  Lunch (for pre-registered attendees) and Poster Sessions

● Thursday, DECEMBER 5

1.30 p.m

KEYNOTE 2

Overview of the NIA portfolio in AD clinical trials: Which new targets could be explored?

Eliezer Masliah, MD - Director of the Division of Neuroscience, National Institute on Aging (NIA), Bethesda, USA

2.00 p.m

ROUNDTABLE

Pros and Cons of Weighted Composite Scores for Preclinical and Prodromal Alzheimer's Disease

Moderators: Sandrine Andrieu MD, PhD, Inserm, University of Toulouse, Toulouse, France, Pierre Tariot MD, Banner Alzheimer Institute, Phoenix, AZ, USA

PRESENTATION 1: Important Considerations for Statistically Deriving Weighted Composite Scores for Alzheimer's Disease

Suzanne Hendrix, Pentara Corp, Salt Lake City, UT, USA

PRESENTATION 2: The Weighting Game: What Impact Do Weights Have on Composite Scores - Are They Worth It?

Kun Jin, Statistical Team Leader, US Food and Drug Administrations, Washington, DC, USA

2.45 p.m

LATE BREAKING ORAL COMMUNICATIONS

2.45 p.m

LB10 - Improving measurement of agitation in dementia incorporating IPA Agitation Working Group definition

Zahinoor ISMAIL (1), Adelaide DE MAULEON (2), Jeannie LEOUTSAKOS (3), Cedric O'GORMAN (4), David MILLER (5), Paul ROSENBERG (3), Maria SOTO MARTIN (2), Constantine LYKETSOS (3)

(1) University of Calgary, Canada, (2) Centre Hospitalier Universitaire, France, (3) Johns Hopkins, United States, (4) Axsome, United States, (5) Signant Health, United States

3.00 p.m

LB11 - MAPT Trial: 5-year follow-up results

Bruno VELLAS (1), Sophie GUYONET (1), Jacques TOUCHON (2), Christele CANTET (1), Sandrine ANDRIEU (1) and the MAPT Group

(1) Toulouse University Hospital, France, (2) Montpellier University Hospital, France

3.15 p.m

LB12 - Item Response Theory Analysis of the Clinical Dementia Rating

Yan LI (1), Chengjie XIONG (1), Andrew ASCHENBRENNER (1), Chih-Hung CHANG (1), Virginia BUCKLES (1), Krista MOULDER (1), Michael WEINER (2), Dan MUNGAS (3), Rachel NOSHENY (2), Taylor HOWELL (2), John MORRIS (1)

(1) Washington University in St. Louis, United States, (2) University of California, San Francisco, United States, (3) University of California, Davis, United States

3.30 p.m



Coffee Break and poster sessions

4.00 p.m

SYMPOSIUM 3

Epigenetics and the BET-system in vascular dementia, Alzheimer's disease and mixed dementia – the problem and potential remedies

Chairman: Benkt Winblad, Karolinska Institutet, Karolinska University Hospital, Solna, Sweden

PRESENTER 1: Dementias, who and how to treat and by what specialty . Addressing problem and current and potential future therapeutic practices

Charles DeCarli, MD, FAAN, FAHA, UC Davis, CA, USA

PRESENTER 2: Fluid biomarkers that predict and project brain health

Henrik Zetterberg, Sahlgrenska Academy, University of Gothenburg, Gothenburg, Sweden

● Thursday,
DECEMBER 5



PRESENTER 3: The epigenetic inhibitor APABETALONE corrects pathophysiological brain endothelial and microglial cell activation that contributes to neurodegenerative disease

Ewelina Kulikowski, *SVP Research and Development, Resverlogix Corporation, Calgary, Canada*

PRESENTER 4: Epigenetics, the BET-system, Alzheimer's Disease and Vascular Cognitive Impairment; The BETonMACE study and effects of apabetalone 100 mg b.i.d. two years treatment on cognition in diabetes patients with established cardiovascular disease

Jeffrey Cummings, *Cleveland Clinic Lou Ruvo Center for Brain Health, Las Vegas, NV, USA*

4.45 p.m

ROUNDTABLE

BACE Inhibition: What do we know and what do we need to know?

Co-chairs: Maria Carrillo, *Alzheimer's Association, United States*, Reisa Sperling, *Brigham & Women's Hospital, United States*

PRESENTATION 1: Improve synaptic dysfunction in association with BACE1 inhibition

Yan RIQIANG, *University of Connecticut, United States*

PRESENTATION 2: The Generation Program: Preliminary data on baseline characteristics of participants randomized in Generation Study 1 and Generation Study 2

Pierre N TARIOT (1), Beth BOROWSKY (2), Fonda LIU (2), Marie-Emmanuelle RIVIERE (3), Marie-Laure ROUZADE-DOMINGUEZ (3), Laurie DUFF (2), Matt QUINN (2), Ingo SCHOLTEN (3), Jessica LANGBAUM (1), Angelika CAPUTO (3), Vissia VIGLIETTA (4), Eric REIMAN (1), Ana GRAF (3) - (1) *Banner Alzheimer's Institute, United States*, (2) *Novartis Pharmaceuticals, United States*, (3) *Novartis Pharma, Switzerland*, (4) *Amgen, Inc., United States*

PRESENTATION 3: API Perspective what we would learn from the discontinuation phase

Eric REIMAN, *Alzheimer's Prevention Initiative, United States*

PRESENTATION 4: A review of volumetric MRI changes in AD treatment trials and a framework for their interpretation

Adam Schwarz, *Takeda, Cambridge, MA, USA*

PRESENTATION 5: DIAN: Primary Prevention Discussion

Eric McDade, *University of Connecticut, United States*

PRESENTATION 6: Modeling of verubecestat Ph3 PK/PD data against to amyloid PET

Julie Stone, *Merck, USA*

DISCUSSION:

1) Is there a lowest dose that could be efficacious, using modeling or preclinical models, i.e. not just to avoid side effects but to identify a therapeutic window?

2) To what could still be done non-clinically to understand if anything would have predicted the adverse effects

Michael F. Egan, *M.D, Merck, USA*, Michael Irizarry, *Eisai, USA*, John Sims, *Eli Lilly & Co., USA*, Craig Sherring, *AstraZeneca, USA*

5.45 p.m

LATE BREAKING RESULTS

● Friday, DECEMBER 6

8.00 a.m LATE BREAKING ORAL COMMUNICATIONS

8.00 a.m LB13 - A Randomized Double-Blind Placebo-Controlled Phase 2A Clinical Trial of NA-831 in Patients with MCI and Mild and Moderate Alzheimer's Disease

Lloyd TRAN, Fern VU, Brian TRAN, Stephanie NEAVE
(1) NeuroActiva, Inc., United States

8.15 a.m LB14 - The CHARIOT-PRO Substudy: Baseline Characteristics of the Fully Enrolled Cohort

Gerald NOVAK (1), Susan BAKER (1), Chi UDEH-MOMO (2), Geraint PRICE (2), Tam WATERMEYER (3), Celeste LOOTS (2), Natalia REGLINSKA-MATVEYEV (3), Luc BRACOUD (4), Craig RITCHIE (3), Lefkos MIDDLETON (2)
(1) Janssen R&D, United States, (2) Imperial College London, United Kingdom, (3) University of Edinburgh, United Kingdom, (4) Bioclinica, France

8.30 a.m LB15 - Association between Neuraceq levels and [18F]PI-2620 Tau PET tracer accumulation in baseline scans of the elenbecestat MissionAD program

Andrew STEPHENS (1), Santi BULLICH (1), Andre MUELLER (1), Mathias BERNDT (1), Susan DE SANTI (1), David SCOTT (2), Katarzyna ADAMCZUK (2), Joyce SUHY (2), June KAPLOW (3), Monique GIROUX (3), Stephen KRAUSE (3), Julia CHANG (3), Bruce ALBALA (3)
(1) Life Molecular Imaging, Germany, (2) Bioclinica, United States, (3) Eisai Inc, United States

8.45 a.m LB16 - Exploring the patterns of cognitive symptoms tracked by caregivers and patients in online symptom profiles

Kenneth ROCKWOOD (1,2), Taylor DUNN (2), Jovita BALCAITIENE (3), Susan HOWLETT (1,2)
(1) Dalhousie University, Canada, (2) DGI Clinical, Canada, (3) Nutricia, Netherlands

9.00 a.m ORAL COMMUNICATIONS SESSION

9.00 a.m OC9 - Anchor- and Distribution-based methods to establish clinically meaningful score changes on the Clinical Dementia Rating Scale – Sum of Boxes in patients with prodromal Alzheimer's Disease

Claire Lansdall, Roche Products Limited, Welwyn Garden City, UK

9.15 a.m OC10 - Awareness of Genetic Risk in the Dominantly Inherited Alzheimer Network (DIAN)

Jason Hassenstab, Washington University in St. Louis, MO, USA

9.30 a.m OC11 - Umibecestat: a BACE1 inhibitor continuing to assess potential for AD prevention in the Generation Program

Ana Graf, Novartis Pharma, Basel, Switzerland

9.45 a.m OC12 - Recruitment Strategies for the Generation Program AD Prevention Clinical Trials: Lessons from the Butler Hospital Memory & Aging Program

Jessica Alber, University of Rhode Island, Kingston, RI, USA

10.00 a.m  Coffee Break and poster sessions

10.30 a.m KEYNOTE 3

Failure after failure, what's next in AD Drug Development?

Paul Aisen, MD - Director of the Alzheimer's Therapeutic Research Institute, Keck School of Medicine, USC, San Diego, CA, USA

● Friday,
DECEMBER 6



11.00 a.m

SYMPOSIUM 4

AMBAR (Alzheimer's Management By Albumin Replacement) Phase 2B/3 Trial: complete clinical, biomarker and neuroimaging results

Chairman: Jeffrey L. Cummings, MD, Sc.D, Cleveland Clinic Lou Ruvo Center for Brain Health, Las Vegas, USA

PRESENTER 1: AMBAR clinical, biomarker and neuroimaging results

Antonio Páez M.D., Grifols Bioscience Research Group (SPAIN)

Roundtable Discussion

Jeffrey L. Cummings MD, PhD Cleveland Clinic Lou Ruvo Center for Brain Health, Las Vegas, NV, USA

Mercè Boada MD, PhD, Fundació ACE, Universitat Internacional de Catalunya, Barcelona, Spain

Oscar L. Lopez MD, PhD, University of Pittsburgh School of Medicine, Pittsburgh, PA, USA

Zbigniew M. Szczepiorkowski, MD, PhD, Dartmouth Hitchcock Medical Center, Lebanon, NH, USA (To be confirmed)

Montserrat Costa, PhD, Grifols Bioscience Research Group, Barcelona, Spain

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

Antonio Páez M.D., Grifols Bioscience Research Group, Barcelona, Spain

12.00 p.m



Lunch (for pre-registered attendees) and poster sessions

1.00 p.m

ORAL COMMUNICATIONS SESSION

1.00 p.m

OC13 - Thirty-six-month amyloid PET results show continued reduction in amyloid burden with gantenerumab

Gregory Klein, Roche Pharma Research and Early Development, Basel, Switzerland

1.15 p.m

OC14 - A Phase 1 Study of ALOO2 in Healthy Volunteers and Patients With Mild-To-Moderate Alzheimer's Disease

Robert Paul, Alector, Inc., South San Francisco, CA, USA

1.30 p.m

OC15 - Predicting sporadic Alzheimer's progression via inherited Alzheimer's-informed machine learning

Nicolai Franzmeier, Ludwig Maximilians University, Institute for Stroke and Dementia Research, Munich, Germany

1.45 p.m

OC16 - Continuously Acquired, Home-Based Digital Biomarkers of Activity and Function Are Related to Alzheimer's Disease Neuropathology

Jeffrey Kaye, Oregon Health & Science University, Portland, OR, USA

2.00 p.m

OC17 - The Alzheimer's Clinical Trials Consortium Seeks Partners for Therapeutic Trials

Sarah Walter, Alzheimer's Therapeutic Research Institute (ATRI), University of Southern California, San Diego, USA

2.15 p.m

OC18 - The EXERT Trial: Testing a Model for Effective Community-Based Exercise Intervention Delivery for Adults with MCI

Jeffrey Katula, Wake Forest School of Medicine, Winston-Salem, NC, USA

2.30 p.m

OC19 - The effects of rasagiline upon cerebral glucose metabolism, cognition, and tau in patients with mild to moderate Alzheimer's disease: Results of a Phase II clinical trial

Dawn Matthews, ADM Diagnostics Inc, Northbrook, IL, USA

2.45 p.m

OC20 - Towards a florbetapir-based dual -biomarker screening strategy

Sergey Shcherbinin, Eli Lilly & Company, Indianapolis, IN, USA

● Friday, DECEMBER 6

3.00 p.m

KEYNOTE 4

Next generation of multidomain lifestyle clinical trials: Design and implementation for proof of scientific concept and pragmatic sustainability

Laura D. Baker, PhD - Associate Professor, Gerontology and Geriatric Medicine, Wake Forest School Medicine, Winston-Salem, NC, USA

3.30 p.m



Coffee Break and poster sessions

4.00 p.m

ORAL COMMUNICATIONS SESSION

4.00 p.m

OC21 - FCSRT inclusion criteria support recruitment of a population with early Alzheimer's disease likely to progress over 24 months: results from the CREAD trial

Kaycee Sink, Genentech, Inc., South San Francisco, CA, USA

4.15 p.m

OC22 - Assessing in Power in Phase II Proof-of-Concept Trials in Prodromal Alzheimer's Disease

Michelle Nuno, Department of Statistics, University of California, Irvine, CA, USA

4.30 p.m

OC23 - The Alzheimer's disease THERapy with NEuroaid (ATHENE) Study: Assessing the Safety and Efficacy of Neuroaid II (MLC901) in patients with mild to moderate Alzheimer's disease stable on Cholinesterase inhibitors or Memantine: A Randomized, double blind, placebo-controlled trial: BASELINE RESULTS

Christopher Chen, National University of Singapore, Singapore

4.45 p.m

OC24 - Phase 1 study of NDX-1017: safety, pharmacokinetics, and pharmacodynamics in healthy volunteers and dementia patients

Hans Moebius, Athira Pharma, Inc, Seattle, WA, USA

5.00 p.m

LATE BREAKING ORAL COMMUNICATIONS

5.00 p.m

LB17 - APTUS- $A\beta$ TM: Measurement of plasma $A\beta$ _{42/40} concentration ratios by mass spectrometry predicts brain amyloidosis in banked samples from multiple, diverse cohorts

Tim WEST, Kristopher KIRMESS, Matthew MEYER, Mary HOLUBASCH, Stephanie KNAPIK, Yan HU, Philip VERGHESE, Erin SMITH, Scott HARPSTRITE, Ilana FOGELMAN, Joel BRAUNSTEIN, Kevin YARASHESKI

(1) C2N Diagnostics, United States

5.15 p.m

LB18 - In vivo measurement of widespread synaptic loss in early Alzheimer's disease with SV2A PET

Christopher VAN DYCK, Adam MECCA, Ming-Kai CHEN, Ryan O'DELL, Mika NAGANAWA, Takuya TOYONAGA, Tyler GODEK, Joanna HARRIS, Hugh BARTLETT, Wenzhen ZHAO, Nabeel NABULSI, Brent VANDER WYK, Pradeep VARMA, Amy ARNSTEN, Yiyun HUANG, Richard CARSON

(1) Yale School of Medicine, United States

5.30 p.m

LB19 - Novel analytics framework for augmenting single-arm Phase 2a open label trials with Real-World external control data: Application to the Blarcamesine (ANAVEX®2-73) study in Alzheimer's disease matched with propensity corrected patients from Alzheimer's Disease Neuroimaging Initiative (ADNI) exploring treatment effect on cognition at Interim two-year (104-Week) timepoint

Mohammad AFSHAR (1), Coralie WILLIAMS (1), Nanthara SRITHARAN (1), Frederic PARMENTIER (1), Federico GOODSaid (2), Christopher MISSLING (3)

(1) Ariana Pharma, France, (2) Regulatory Pathfinders, United States, (3) Anavex, United States

5.45 p.m

LB20 - Should We Be Using Artificial Intelligence, Machine Learning, and Big Data Techniques to Improve Our Chances of Success in Alzheimer's Clinical Research?

Newman KNOWLTON, Sam DICKSON, Suzanne HENDRIX

(1) Pentara Corporation, United States

● Saturday, DECEMBER 7



8.00 a.m LATE BREAKING ORAL COMMUNICATIONS

8.00 a.m LB21- Cut points for cognitive decline using MMSE define baseline and longitudinal differences in both clinical and pathological Alzheimer's disease biomarkers

James DOECKE (1), Marcela CESPEDES (1), Cai GILLIS (2), Nancy MASEREJIAN (2), Pierrick BOURGEAT (3), Chris FOWLER (4), Victor VILLEMAGNE (5), Qiao-Xin LI (4), Steven COLLINS (4), Stephanie RAINEY-SMITH (6, 7), Paul MARUFF (4), Ralph MARTINS (6, 8, 9), David AMES (10), Colin MASTERS (4) (1) Australian e-Health Research Centre, CSIRO, Australia, (2) Biogen, United States, (3) Australian e-Health Research Centre, CSIRO, Brisbane, QLD, Australia, (4) The Florey Institute, The University of Melbourne, Australia, (5) Austin Health, Department of Molecular Imaging and Therapy, Center for PET, Australia, (6) Sir James McCusker Alzheimer's Disease Research Unit (Hollywood Private Hospital), Australia, (7) Centre of Excellence for Alzheimer's disease Research and Care, School of Medical and Health Sciences, Edith Cowan University, Australia, (8) Department of Biomedical Sciences, Macquarie University, Australia, (9) School of Psychiatry and Clinical Neurosciences, University of Western Australia, Australia, (10) National Ageing Research Institute, Australia

8.15 a.m LB22 - Using AI to Create Digital Twins to Accelerate Alzheimer's Disease Clinical Trials

Aaron SMITH, Jonathan WALSH, Charles FISHER (1) Unlearn.health, United States

8.30 a.m ROUNDTABLE

Sex/gender consideration in clinical trials and potential improvements to clinical trial design

Merce Boada (1,2,3), Rachele Doody (10), Kaveeta Vasisht (11), Antonella Santucci (4,7), Maria Teresa Ferretti MT (4,5,6), Cassandra Szoeki (8), Jennifer Ann Zimmer (9)

(1) Research Center and Memory Clinic. Fundació ACE, Institut Català de Neurociències Aplicades, (2) Universitat Internacional de Catalunya- Barcelona, Spain, (3) Networking Research Center on Neurodegenerative Disease (CIBERNED), Instituto de Salud Carlos III, Spain, (4) Women's Brain Project, Guntershausen, Switzerland, (5) Institute for Regenerative Medicine-IREM, University of Zurich, Zurich, Switzerland, (6) Neuroscience Center Zurich (ZNZ), University of Zurich, Zurich, Switzerland, (7) Global Medical and Scientific Affairs, Roche Diagnostics International Ltd., Rotkreuz, Switzerland, (8) Women's Healthy Ageing Project, Faculty of Medicine, Dentistry and Health Sciences, University of Melbourne, Australia, (9) Eli Lilly and Company, Indianapolis, IN, USA, (10) Roche Pharmaceutical Company, Basel, Switzerland, (11) Office of Medical Policy, Food and Drug Administration, USA

9.00 a.m KEYNOTE 5 (to be confirmed)

Digital Clinical Trials: It's Not (all) About the Tech!

Amy P. Abernethy, M.D., Ph.D - Principal Deputy Commissioner of Food and Drugs, USA

9.30 a.m ORAL COMMUNICATIONS SESSION

9.45 a.m OC25 - Regulation of glial cell activation and neurodegeneration by anti-semaphorin 4D antibody pepinemab (VX15/2503), a potential treatment for Alzheimer's and Huntington's Disease

Elizabeth Evans, Vaccinex, Rochester, NY, USA

10.00 a.m OC26 - Therapeutic ultrasound as a treatment strategy for Alzheimer's disease - preclinical data (including Aducanumab) and clinical trial design

Jürgen Götz, The University of Queensland, Queensland Brain Institute, Brisbane, Australia

10.15 a.m Coffee Break and poster sessions

10.45 a.m OC27 - Baseline Clinical and Biomarker Characteristics from a Phase 2 Trial of R07105705 in Prodromal-to-Mild Alzheimer's Disease (Tauriel)

Edmond Teng, Genentech, South San Francisco, CA, USA

11.00 a.m OC28 - COR388, A Novel Gingipain Inhibitor, Decreases Fragmentation of ApoE in Alzheimer's Disease Central Nervous System

Michael Detke, Cortexyme, South San Francisco, CA, USA

● Saturday, DECEMBER 7

11.15 a.m

SYMPOSIUM 5

Alzheimer's Disease in Down Syndrome: New Insights and Opportunities

Chairman : Michael Rafii, USC, San Diego, CA, USA

PRESENTATION 1: Cognitive markers of preclinical and prodromal Alzheimer's disease in Down syndrome

Andre Strydom, King's College London, London, UK

PRESENTATION 2: Neuroimaging biomarkers of AD in DS

Brad Christian, University of Wisconsin, Madison, WI, USA

PRESENTATION 3: Plasma and CSF biomarkers for the diagnosis of AD in DS

Juan Fortea, Hospital Saint Pau, Barcelona, Spain

12.00 p.m



Lunch (for pre-registered attendees) and Poster Sessions

ORAL COMMUNICATIONS SESSION

1.00 p.m

OC29 - Binding profiles of BAN2401 and aducanumab to different amyloid-beta species

Lars Lannfelt, Uppsala University, Uppsala, Sweden

1.15 p.m

OC30 - Non-GLP Toxicity and Toxicokinetics Studies of P8, a Peptide Drug Candidate for the treatment of Alzheimer's Disease

Nanzeen Dewji, Cenna Biosciences Inc., La Jolla, CA, USA

1.30 p.m

OC31 - An exploratory examination of NeuroToolKit biomarkers across AD stages

Carol Van Hulle, University of Wisconsin-Madison, Madison, WI, USA

1.45 p.m

OC32 - Improving Polygenic Risk Scores for Alzheimer's Disease

Samuel Dickson, Pentara Corp., Salt Lake City, UT, USA

2.00 p.m

OC33 - Evaluating mixed effects models for burst cognitive data in Alzheimer disease clinical trials

Guoqiao Wang, Washington University School of Medicine, St. Louis, MO, USA

2.15 p.m

OC34 - Safety, pharmacokinetics and pharmacodynamics of RDN-929: a potent and selective HDAC-CoREST complex inhibitor for the treatment of synaptopathies

J. Michael Ryan, Rodin Therapeutics, Cambridge, MA, USA

2.30 p.m

OC35 - A Phase 2 trial of GRF6019 in mild-to-moderate Alzheimer's disease

Jonas Hannestad, Alkahest, San Carlos, CA, USA

2.45 p.m

OC36 - HOPE4MCI Trial: Targeting Reduction of Hippocampal Overactivity to Treat Mild Cognitive Impairment due to Alzheimer's Disease with AGB101

Sharon Rosenzweig-Lipson, AgeneBio, Inc, Baltimore, MD, USA

3.00 p.m

End of conference

Registration



Early bird fees (until October 15)

Early bird registration (no lunches) - \$ 1,086 USD

Early bird registration (3 lunches) - \$ 1,227 USD

Regular registration (from October 16)

Full registration (no lunches) - \$ 1,405 USD

Full registration (3 lunches) - \$ 1,545 USD

Pack of 3 lunches - \$ 147 USD

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