

# 10th edition of Clinical Trials

# on Alzheimer's Disease

# **Preliminary Program**

Boston, November 1-4, 2017







# **CTAD 2017**







# BOSTON, USA

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#### Scientific Commitee

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#### Dear Colleague,

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

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

At CTAD 2017 several teams will report the results of their preclinical, Phase II and Phase III trials. This sharing of experiences converges towards a same goal: overcoming the hurdles and speed the development of effective treatments in AD.

We look forward to welcoming you to Boston this November!

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

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

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

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



4:00 – 4:30 p.m.

# **Welcome from the Organizing Committee** and and Presentation of the CtaD Lifetime Achievement Award to Prof. Bruno Dubois

Jacques Touchon, Paul Aisen, Bruno Vellas, Mike Weiner

4:30 – 5:00 p.m.

# Keynote 1

### The Evolution of Preclinical Alzheimer's disease: **Implications for Prevention Trials**

Reisa Sperling, MD

Professor of Neurology, Harvard Medical School Director, Center for Alzheimer Research and Treatment Brigham and Women's Hospital and Massachusetts General Hospital Memory Disorders Unit Boston, USA

5:00 - 6:00 p.m.

# Symposium 1

#### Importance of Serotonin in Alzheimer's Disease Psychosis and the Potential Role of Pimavanserin

Moderator: Jeffrey Cummings,

MD, ScD, Cleveland Clinic Lou Ruvo Center for Brain Health, Las Vegas, NV, USA

#### 1. Role of 5-HT2a Receptors in the Pharmacology of Alzheimer's disease Psychosis

Stephen M. Stahl, MD, PhD1, Ethan S. Burstein, PhD2

(1) University of California, San Diego, CA, USA; (2) ACADIA Pharmaceuticals Inc., San Diego, CA, USA

#### 2. Clinical Trial of Pimavanserin in Alzheimer's disease Psychosis

Clive Ballard, MBChB, MRCPsych<sup>1</sup>, Carol Banister, MBChB, MRCPsych<sup>2</sup>, Jim Youakim, MD<sup>3</sup>, Bruce Coate, MPH<sup>3</sup>, Srdjan Stankovic, MD, MSPH<sup>3</sup>, on behalf of the ADP Investigators

(1) University of Exeter Medical School, Exeter, UK ; (2) King's College, London, UK ; (3) ACADIA Pharmaceuticals Inc., San Diego, CA, USA

#### 3. Review of Pimavanserin Clinical Results in the Context of Historical Alzheimer's disease Psychosis Trials

Pierre N. Tariot, MD1, Randall Owen, MD2, Doral Fredericks, PharmD, MBA2

(I) Banner Alzheimer's Institute and University of Arizona College of Medicine, Phoenix, AZ, USA ; (2) ACADIA Pharmaceuticals Inc., San Diego, CA, USA

8:30 - 10:00 a.m.

#### Oral Communications

#### OCI - A Phase 2a Exploratory Endpoint Trial in Mild-Moderate Alzheimer's Disease of LM11A-31-BHS p75 neurotrophin receptor ligand.

Frank M. Longo, MD, PhD<sup>1</sup>, Manfred Windisch, PhD<sup>2</sup>, Niels Andreasen, MD<sup>3</sup>, Agneta Nordberg, MD, PhD<sup>4</sup>

(1) Department of Neurology and Neurological Sciences, Stanford University, Palo Alto, CA, USA.; (2) NeuroScios, GmbH, Graz, Austria; (3) Department of Neurobiology, Karolinska Institute, Stockholm, Sweden; (4) Center for Alzheimer's Research, Karolinska Institute,

#### OC2 - Tau Accumulation Observed using Repeated Tau PET Measures Predicts Cognitive **Decline in Normal Elderly**

<u>Bernard Hanseeuw</u><sup>12</sup>, Beth Mormino<sup>3</sup>, Alex Becker<sup>1</sup>, Aaron Schultz<sup>3</sup>, Jorge Sepulcrel, Kathryn Papp<sup>3, 4</sup>, Heidi Jacobs<sup>1</sup>, Jasmeer Chhatwal<sup>3</sup>, Dorene Rentz<sup>3, 4</sup>, Reisa Sperling<sup>3, 4</sup>, and Keith Johnson<sup>1, 3, 4</sup>

(I) Department of Radiology, Massachusetts General Hospital, Boston, MA, USA; (2) Department of Neurology, Cliniques Universitaires Saint-Luc, Brussels, Belgium; (3) Department of Neurology, Massachusetts General Hospital, Boston, MA, USA; (4) Center for Alzheimer Research and Treatment, Department of Neurology, Brigham and Women's Hospital, Harvard Medical School, Boston, MA, USA

#### OC3 - Clinical evaluation of 18F-PI-2620, a next generation TAU PET agent in subject with alzheimer disease and progressive supranuclear PALSY

Andrew Stephens<sup>1</sup>, John Seibyl<sup>2</sup>, Andre Mueller<sup>1</sup>, Olivier Barret<sup>2</sup>, Mathias Berndt<sup>1</sup>, Jennifer Madonia<sup>2</sup>, David Alagille<sup>2</sup>, Hanno Schieferstein<sup>1</sup>, Heiko Kroth<sup>3</sup>, Santiago Bullich<sup>1</sup>, Andrea Pfeifer<sup>3</sup> Andreas Muhs<sup>3</sup>, Gilles Tamagnan<sup>2</sup>, Kenneth Marek<sup>2</sup>, Ludger Dinkelborg<sup>1</sup>

(1) Piramal Imaging, Berlin, Germany, (2) Molecular Neuroimaging, New Haven, USA, (3) AC Immune SA, Lausanne, Switzerland

#### OC4 - Optimizing the Preclinical Alzheimer's Cognitive Composite (PACC) with Semantic Processing: The PACC 5

Kathryn V. Papp PhD<sup>12</sup>, Dorene M. Rentz PsyD<sup>12</sup>, Irina Orlovsky MA<sup>1</sup>, Reisa A. Sperling MD<sup>12</sup>, Elizabeth C. Mormino

(I) Center for Alzheimer Research and Treatment, Department of Neurology, Brigham and Women's Hospital, Harvard Medical School, Boston, USA ; (2) Department of Neurology, Massachusetts General Hospital, Massachusetts General Hospital, Harvard Medical School, Boston, USA ; (3) Department of Neurology and Neurological Sciences, Stanford University School of Medicine, Palo Alto,USA

#### OC5 - Can IT Help with the Screening for Alzheimer's Disease Trials? From EHR to Web-Based Cognitive Tests and e-Consent.

Michael W. Weiner, MD1, Peter Schueler, MD23 J. Wesson Ashford, MD, PhD456, Bruno Vellas, MD, PhD78

(1) UCSF, San Francisco, USA; (2) ICON, Langen, Germany; (3) University Duisburg-Essen, Germany; (4) Stanford/VA Alzheimer's Disease and Aging Clinical Research Centers, CA, USA; (5)VA Palo Alto Health Care System, CA, USA; (6) Stanford University, CA, USA (7) University Hospital's Department of Internal Medicine and Clinical Gerontology, Toulouse, France ; (8) Toulouse Gérontopôle, Toulouse,

#### OC6 - Amyloid Beta Oligomers in Alzheimer's Disease: a Missing Piece of the Alzheimer's **Puzzle**

Jeffrey Cummings MD<sup>1</sup>, Sandrine Andrieu MD, MPH<sup>2</sup>, Philip Scheltens MD, PHD<sup>3</sup>, Kaj Blennow MD, PHD<sup>4</sup>, Petr Kocis PHD<sup>5</sup>, John A. Hey PHD<sup>5</sup>, A. Power, MD<sup>5</sup>, Martin Tolar, MD, PHD<sup>5</sup>, Susan Abushakra, MD<sup>5</sup>

(I) Cleveland Clinic Lou Ruvo Center for Brain Health, Las Vegas, Nevada ; (2) University of Toulouse, Toulouse, France (3) VU University Medical Center, Amsterdam, Netherlands ; (4) The Sahlgrenska Academy at University of Gothenburg, Mölndal, Sweden (5) Alzheon, Inc., Boston, MA, USA

10:00 - 10:30 a.m.

# Coffee Break and Poster Session

10:30 - 11:30 a.m.

#### Oral Communications

OC7 - ABBV-8E12, a Humanized Anti-Tau Monoclonal Antibody for the Treatment of Early Alzheimer's Disease: A 96-Week, Multiple Dose, Randomized, Double-Blind, Placebo-Controlled Phase 2 Study

Kumar Budur<sup>1</sup>, Hana Florian<sup>1</sup>, Deli Wanq<sup>1</sup>, Weining Robieson<sup>1</sup>, Holly Soares<sup>1</sup>, Joel B. Braunstein<sup>2</sup>, David M. Holtzman<sup>3</sup>, Randall J. Bateman<sup>3</sup>, Beatrice Rendenbach-Mueller<sup>4</sup>, Nuno Mendonca

(I) AbbVie Inc, North Chicago, IL, USA ; (2) C2N Diagnostics LLC, Saint Louis, MO, USA ; (3) Washington University, St. Louis, MO, USA ; (4) AbbVie Deutschland GmbH & Co. KG, Ludwigshafen, Germany

#### OC8 - Stratification of Pre-Symptomatic and Cognitively Normal Individuals using Polygenic Scoring

Maryam Shoai, PhD1; Richard Pither, PhD2; Valentina Escott-Price, PhD3; Simon M Laws, PhD4; Harald Hampel, MD, PhD<sup>5</sup>; Simone Lista, PhD<sup>5</sup>; Rik Vandenberghe<sup>6</sup>; Isabelle Cleynen<sup>6</sup>; David Irwin, MD<sup>7</sup>; Vivian Van Deerlin, MD<sup>8</sup>; Greg Davidson, PhD<sup>9</sup>; Virginia M.-Y. Lee, PhD<sup>10</sup>; John Q. Trojanowski, MD, PhD<sup>10</sup>; John Hardy, PhD DSc.<sup>1</sup>

(1) UCL Institute of Neurology, London, United Kingdom; (2) Cytox Ltd, UK, Oxford, United Kingdom; (3) Cardiff University, Cardiff, United Kingdom; (4) Edith Cowan University, and Cooperative Research Centre (CRC) for Mental Health, Perth, Australia; (5) AXA Research Fund & UPMC Chair, Paris, France; (6) Katholieke Universiteit Leuven, Leuven, Belgium; (7) Hospital of the University of Pennsylvania, Department of Neurology, University of Pennsylvania, Philadelphia; (8) Hospital of the University of Pennsylvania, Department of Pennsylvania, Philadelphia; (9) Ledcourt Associates, UK; (10) Centre for Neurodegenerative Disease Research, University of Pennsylvania School of Medicine, Philadelphia



#### OC9 - Objective Cognitive Decline in Preceding Years Relates to Self-Report on the Cognitive Function Index in the Harvard Aging Brain Study

Rebecca E. Amariglio PhD<sup>123</sup>, Rachel F. Buckley PhD<sup>23,45</sup>, Elizabeth C. Mormino PhD<sup>23</sup>, Dylan R. Kirn MPH<sup>2</sup>, Gad A. Marshall MD<sup>123</sup>, Keith A. Johnson MD<sup>123</sup>, Dorene M. Rentz PsyD<sup>123</sup>, Reisa A. Sperling MD<sup>123</sup>

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

# OC10 - The Generation Program: Evaluating CNP520 Efficacy in Preclinical Alzheimer's

<u>Cristina Lopez Lopez, MD, PhD</u><sup>1</sup>, Pierre N. Tariot, MD<sup>2</sup>, Angelika Caputo, PhD<sup>1</sup>, Fonda Liu, Pharm.D<sup>1</sup>, Marie-Emmanuelle Riviere, PhD<sup>1</sup>, Marie-Laure Rouzade-Dominguez, PhD1, Ronald G. Thomas, PhD<sup>3</sup>, Jessica B. Langbaum, PhD<sup>2</sup>, Rob Lenz, MD, PhD<sup>4</sup>, Eric M. Reiman, MD, PhD<sup>2</sup>, Ana Graf, MD<sup>1</sup>.

(1) Novartis Pharma, Basel, Switzerland; (2) Banner Alzheimer's Institute, Phoenix, AZ; USA; (3) University of California-San Diego, San Diego, CA, USA; (4) Amgen, Thousand Oaks, CA, USA.

11:30 - 12:30 p.m.

# Symposium 2

#### CTAD 2017 Statistical Workshop: Estimands and Primary Analyses in AD Clinical Trials

Moderator: Hong Liu-Seifert Ph.D. Eli Lilly and Company, Indianapolis, IN USA

Fabian Model Ph D Roche, Basel Switzerland Paul Aisen M.D.

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

12:30 - 1:30 p.m.

# **Lunch and Poster Session**

1:30 – 2:30 p.m.

# Oral Communications

OC11 - A Phase 1b, Randomized, Double-Blind, Placebo-Controlled, Sequential Cohort, Dose-Ranging Study of the Safety, Tolerability, Pharmacokinetics, Pharmacodynamics, and Preliminary Efficacy of TPI 287 (abeotaxane) in Patients with Primary Four Repeat Tauopathies: Corticobasal Syndrome or Progressive Supranuclear Palsy; or the Secondary Tauopathy, Alzheimer's Disease.

Adam Boxer, MD, PhD¹; Zachary Miller, MD¹, Richard Tsai, MD, MBA¹, Mary Koestler, RN, PhD¹; Julio Rojas, MD, PhD¹; Peter Ljubenkov, MD¹; Howie Rosen, MD¹; Gil Rabinovici, MD¹; Anne Fagan-Niven, PhD²; Yann Cobigo, PhD¹, June Jung, PhD¹; Phi Luong, BS¹; Emmeline Chuu, BA¹; Ryan Powers, BA¹; Paige Mumford, BA¹; Bruce Miller, MD¹; Erik Roberson, MD, PhD3

(I) Memory and Aging Center, Department of Neurology, University of California, San Francisco, CA, USA; (2). Department of Neurology, Washington University School of Medicine, Saint Louis, MO, USA; (3) Department of Neurology, University of Alabama School of Medicine, Birmingham, AL, USA

#### OC12 - High dose B Vitamin therapy selectively improves cognitive function indicative of cerebrovascular status in the randomized FAVORIT Ancillary Cognitive Trial

Tammy M. Scott<sup>1,2</sup>, Aron M. Troen<sup>1,3</sup>, <u>Irwin H. Rosenberg</u><sup>1,2</sup>

(I) Jean Mayer USDA Human Nutrition Research Center on Aging at Tufts University, Boston MA; (2) Friedman School of Nutrition Science and Policy, Tufts University, Boston MA; (3) Institute of Biochemistry, Food Science and Nutrition, The Robert H. Smith Faculty of Agriculture, Food and Environment, The Hebrew University of Jerusalem, Rehovot, Israel

#### OC13 - Investigational New Alzheimer's Drug Tricaprilin: Results of a Phase 3 Study in Mild-to-Moderate Alzheimer's Disease Patients

Samuel Henderson, PhD<sup>1</sup>, Michael Gold, MD<sup>2</sup>, Judith Walker, MD<sup>1</sup>, Sabrina Greer<sup>1</sup>, Janet Vogel<sup>1</sup>, Aaron Shenkin<sup>1</sup> (1) Accera Inc, Boulder, CO, USA; (2) PPD Inc, Wilmington, NC, USA

#### OC14 - Characterization of the selective in vivo and in vitro binding properties of crenezumab : insights into crenezumab's unique mechanism of action

William J. Meilandt<sup>1</sup>, Janice A. Maloney<sup>1</sup>, Jose Imperio<sup>1</sup>, Travis W. Bainbridge<sup>2</sup>, Mike Reichelt<sup>3</sup>, Danielle Mandikian<sup>4</sup>, Yanmei Lu<sup>5</sup>, James A. Ernst², Reina N. Fuji<sup>6</sup>, Jasvinder K. Atwal<sup>1</sup>

(1) Department of Neuroscience, Genentech, South San Francisco, CA, USA; (2) Department of Protein Sciences, Genentech, South San Francisco, CA, USA; (3) Department of Research Pathology, Genentech, South San Francisco, CA, USA; (4) Department of Preclinical and Translational Pharmacology, Genentech, South San Francisco, CA, USA; (5) Department of Biochemical and Cellular Pharmacology, Genentech, South San Francisco, CA, USA ; (6) Department of Safety Assessment, Genentech, South San Francisco, CA, USA

2:30 – 3:00 p.m.

# Keynote 2 From Academy to Industry: Perspectives for Drug Trials in AD

Rachelle Doody, MD, PhD Global Head of Neurodegeneration PD Neuroscience, F. Hoffmann-La Roche, Basel, Switzerland

3:00 - 4:00 p.m.

# **Late Breaking Oral Communications**

4:00 - 4:30 p.m.

# Coffee Break and Poster Session

4:30 – 5:30 p.m.

# Symposium 3 **EPOCH Trial of the BACE1 Inhibitor Verubecestat for**

Mild-to-Moderate Alzheimer's Disease

Michael Egan, MD<sup>1</sup>, James Kost, PhD<sup>1</sup>, Pierre N. Tariot, MD<sup>2</sup>, Paul S Aisen, MD<sup>3</sup>, Jeffrey L. Cummings, MD, ScD<sup>4</sup>, Bruno Vellas, MD, PhD<sup>5</sup>, Yuki Mukai, MD<sup>1</sup>, Tiffini Voss, MD<sup>1</sup>, Christine Furtek, MS<sup>1</sup>, Erin Mahoney, MS<sup>1</sup>, Rik Vandenberghe, MD, PhD<sup>6</sup>, Yi Mo, PhD<sup>1</sup>, David Michelson, MD<sup>1</sup>

(1) Merck & Co., Inc., Kenilworth, NJ, USA; (2) Banner Alzheimer's Institute, Phoenix, AZ, USA; (3) University of Southern California, San Diego, CA, USA; (4) Cleveland Clinic Lou Ruvo Center for Brain Health, Las Vegas, NV, USA; (5) Gerontopole, INSERM U 1027, Alzheimers' Disease Research and Clinical Center, Toulouse University Hospital, Toulouse, France; (6) University Hospital of Leuven, Leuven, Belgium



08:30 - 10:00 a.m.

#### Oral Communications

OC15 - Long-Term Cognitive Decline in Patients with Alzheimer's Disease in Association with Treatment with Cholinesterase inhibitors-data from SveDem, the Swedish Dementia Registry

Maria Eriksdotter MD, PhD 12, Sara Garcia-Ptacek MD, PhD 12, Ingemar Kåreholt PhD 34, Dorota Religa MD, PhD 1,5, Peter Nordström MD, PhD 6, Anders Wimo MD, PhD 1,5,7, Bengt Winblad MD, PhD 1,5,

(1) Department of Neurobiology, Care Sciences and Society, Center for Alzheimer Research, Division of Clinical Geriatrics, Karolinska Institutet, Huddinge, Sweden.; (2) Department of Geriatric Medicine, Karolinska University Hospital, Huddinge, Sweden.; (3) Aging Research Center, Center for Alzheimer Research, Department of Neurobiology, Care Sciences and Society, Karolinska Institutet and Stockholm University, Stockholm, Sweden; (4) Institute of Gerontology, School of Health and Welfare, Jönköping University, Jönköping, Sweden; (5) Department of Neurobiology, Care Sciences and Society, Center for Alzheimer Research, Division for Neurogeriatrics, Karolinska Institutet, Huddinge, Sweden; (6) Department of Community Medicine and Rehabilitation, Geriatric Medicine, Umeå University, Umeå, Sweden; (7) The primary Health care of Hudiksvall-Nordanstig, Sweden

#### OC16 - Selection of Amyloid Positive Pre-Symptomatic Subjects using Automatic Analysis of Neuropsychological and MRI Data for Cost-Effective inclusion Procedures in Clinical Trials

Manon Ansart, MSc12, Stéphane Epelbaum, MD, PhD123, Olivier Colliot, PhD1234, Didier Dormont, MD124, Bruno Dubois, Prof., MDI<sup>3</sup>, Harald Hampel, Prof., MD, PhDI<sup>3,5</sup>, Stanley Durrleman, PhD<sup>2,1</sup>, for the ADNI, and the INSIGHT study group (I) Sorbonne Universités, UPMC Univ Paris O6, Inserm, CNRS, Institut du cerveau et la moelle (ICM) - Hôpital de la Pitié-Salpêtrière, Boule-vard de l'hôpital, Paris, France ; (2) Inria Paris, Aramis project-team, Paris, France ; (3) AP-HP, Hôpital de la Pitié-Salpêtrière, Department of Neurology, Institut de la Mémoire et de la Maladie d'Alzheimer (IM2A), Paris, France ; (4) AP-HP, Hôpital de la Pitié-Salpêtrière, Department

#### OC17 - Physical Activity and Longitudinal Cognition: Results from the Harvard Aging Brain Study

<u>Hannah M. Klein<sup>1</sup>,</u> Dylan R. Kirn, MPH<sup>1</sup>, Aaron P. Schultz, PhD<sup>13</sup>, Jennifer S. Rabin, PhD<sup>34</sup>, Rachel Buckley, PhD<sup>135,6</sup>, Dorene M. Rentz, PsyD<sup>12</sup>, Kathyrn V. Papp, PhD<sup>12</sup>, Keith A. Johnson, MD<sup>123</sup> , Reisa A. Sperling, MD MMSc<sup>123</sup>, Jasmeer P. Chhatwal, MD, PhD MMSc1,2,3

(1) Department of Neurology, Massachusetts General Hospital, Boston, MA, USA; (2) Department of Neurology, Brigham and Women's Hospital, Boston, MA, USA; (3) Harvard Medical School, Boston, MA USA; (4) Department of Psychiatry, Massachusetts General Hospital, Boston, MA USA; (5) Florey Institutes of Neurosciences and Mental Health, Melbourne, Australia; (6) Melbourne School of Psychological Sciences, University of Melbourne, Melbourne, Australia

#### OC18 - Validation of Tau PET Imaging in Alzheimer's Disease and Other Tauopathies

Niklas Mattsson, MD, PhD<sup>12</sup>, Michael Schöll MD, PhD<sup>1</sup>, Tomas Ohlsson MD, PhD<sup>3</sup>, Andreas Hahn MD, PhD<sup>4</sup>, Olof Strandberg MD, PhD<sup>1</sup>, Jonas Jögi MD, PhD<sup>5</sup>, Ruben Smith MD, PhD<sup>16</sup>, Oskar Hansson MD, PhD<sup>12</sup>
(I) Clinical Memory Research Unit, Department of Clinical Sciences, Malmö, Lund University, Sweden; (2) Memory Clinic, Skåne University Hospital, Malmö, Sweden; (3) Department of Radiation Physics, Skåne University Hospital, Lund, Sweden; (4) Department of Psychiatry and Psychotherapy, Medical University of Vienna, Austria; (5) Department of Clinical Physiology and Nuclear Medicine, Skåne University Hospital, Lund, Sweden; (6) Department of Neurology, Skåne University Hospital, Lund, Sweden

#### OC19 - TOMMORROW: A Trial to Delay the Onset of MCI Due to AD and Qualify a Unique Genetic Algorithm Biomarker: Study Úpdate

Kathleen A. Welsh-Bohmer, PhD¹, Brenda L. Plassman, PhD¹, Carl Chiang, PhD², Meredith Culp, BS³, Patrick Harrigan, BChE³, Janet OʻNeil, MBA³, Ryan Walter, BS³, Stephen Haneline, MS², Julian Arbuckle, BSc (Hons)², Shyama Brewster, BSc (Hons)², Yuka Maruyama, D.V.M.², Tom Swanson, BSCE, MBA², Dominic Fitzsimmons, BSc (Hons)³, Alexandria S. Atkins, PhD⁴, Sarah Powell, MSW⁴, Richard Keefe, PhD⁴, Craig Metz, PhD², Deborah Yarbrough, MS, MBA³, Daniel K. Burns, PhD², Ann M. Saunders, PhD², Ferenc Martenyi, MD³ for the TOMMORROW study investigators

(1) Department of Psychiatry & Neurology, Duke University, Durham NC, USA; (2) Zinfandel Pharmaceuticals, Inc., Chapel Hill NC, USA; (3) Takeda Development Center Americas, Inc., Deerfield, IL, USA; (4) NeuroCog Trials, Durham, NC, USA

#### OC20 - Emerging Plasma-Based Therapies for AD

Montse Costa PhD1, D. Allan Butterfield PhD2, Norman Relkin MD, PhD3

of Neuroradiology, Paris, France ; (5) AXA Research Fund & UPMC Chair, Paris, France

(1) Grifols Institute S.A., Parets del Vallès, Spain; (2) Department of Chemistry, University of Kentucky, Lexington KY, USA; (3) Relkin Consulting LLC, New Jersey, USA

10:00 - 10:30 a.m.

# Coffee Break and Poster Session

10:30 – 11:00 a.m.

# Keynote 3 Genetic Aspects In Clinical Trials

John Hardy, Reta Lila Weston Institute of Neurological Studies, University College London, London UK

11:00 - 12:30 p.m.

# **Oral Communications**

#### OC21 - Cognitive Run-In Periods for Amyloid-Positive Enriched Secondary Prevention Trials.

Andrew J. Aschenbrenner<sup>1</sup>, PhD, Jason Hassenstab<sup>1,2</sup>, PhD, Eric McDade<sup>1</sup>, DO, Guoqiao Wang<sup>3</sup>, PhD, Tammie L.S. Benzinger<sup>4</sup>, MD, PhD, Randall J. Bateman, MD<sup>1</sup>, & John C. Morris<sup>1</sup>, MD.

(1) Department of Neurology, Washington University in St. Louis; (2) Department of Psychological and Brain Sciences, Washington University in St. Louis; (3) Department of Biostatistics, Washington University in St. Louis; (4) Department of Radiology, Washington University in St. Louis



#### OC22 - Eigen Combinations of Cognition and Biomarkers to Minimize the Sample Sizes in Prevention Trials on Alzheimer Disease

Chengiie Xiong 123.4,6, PhD, Anne M. Fagan 23.6, PhD, Tammie Benzinger 2.5,6, PhD, Jason Hassenstab 23.6, PhD, John C. Morris<sup>2,3,6</sup>, MD, Randall J. Bateman<sup>2,3,6</sup>, MD.

(1) Division of Biostatistics, Washington University School of Medicine, St. Louis, MO, USA; (2) Knight Alzheimer Disease Research Center, Washington University School of Medicine, St. Louis, MO, USA; (3) Department of Neurology, Washington University School of Medicine, St. Louis, MO, USA; (4) Department of Mathematics, Washington University, St. Louis, MO, USA; (5) Department of Radiology, Washington University School of Medicine, St. Louis, MO, USA ; (6) The Dominantly Inherited Alzheimer Network, Washington University School of Medicine, St. Louis, MO, USA

#### OC23 - The Alzheimer's Prevention Registry and GeneMatch: Accelerating Recruitment and **Enrollment into Alzheimer's Studies**

Jessica B. Langbaum, PhD<sup>1</sup>, Nellie High<sup>1</sup>, David Gordon<sup>1</sup>, Jodie Nichols<sup>1</sup>, Trisha Walsh<sup>1</sup>, Eric M. Reiman<sup>1</sup>, MD, Pierre N. Tariot<sup>1</sup>, MD

(1) Banner Alzheimer's Institute, Phoenix, AZ, USA

#### OC24 - An Examination of Rate of Decline as an Alternative to Change from Baseline

Howard Mackey, PhD1, Nan Hu, PhD1, Michael Ahmadi, MSc2, Yinghua Chen, MSc2, Pierre Tariot, MD2, Eric M Reiman, MD<sup>2</sup>, Francisco Lopera, MD<sup>3</sup>, Kewei Chen, PhD<sup>2</sup>, Ronald Thomas, PhD<sup>4</sup>

(I) Genentech, Inc., South San Francisco, CA, USA ; (2) Banner Alzheimer's Institute, Phoenix, AZ, USA ; (3) Universidad de Antioquia, Medellín, Colombia ; (4) UC San Diego Department of Neurosciences, CA, USA

#### OC25 - The Safety and Efficacy of Edonerpic (T-817) in Patients with Mild to moderate Alzheimer's Disease

<u>Lon S. Schneider, MD</u>,¹ Ronald G. Thomas, PhD,² James Brewer, MD,² Suzanne Hendrix, PhD³, Robert Rissman, PhD,² David Salmon, PhD,² Hiroshi Kobayashi,⁴Howard Feldman, MD,² for the ADCS TCAD group

(1) Keck School of Medicine of the University of Southern California, Los Angeles, CA, USA; (2) University of California, San Diego, CA, USA; (3) Pentara Corporation, Salt Lake City, UT, USA; (4) Toyama Chemical, Ltd, Tokyo, Japan

#### OC26 - Safety of and Tolerability of Gantenerumab in the Open-Label Extension of SCarlet RoAD Trial, a Global Study in Patients with Prodromal Disease

Mirjana Andjelkovic, PhD1, Danielle Abi-Saab, Psy.D1, Nathalie Pross, PhD1, Paul Delmar, PhD1, Nicola Voyle, PhD2, Michaela Mertes<sup>1</sup>, Smiljana Ristic, MD<sup>1</sup>

(1)Hoffman LaRoche, Basel, Switzerland; (2) Roche Products Limited, Welwyn, UK

12:30 - 1:30 p.m.

# Lunch and Poster Session

1:30 - 3:30 p.m.

# **Late Breaking Oral Communications**

3:30 - 4:00 p.m.

## Oral Communications

OC27 - The European Prevention of Alzheimer's Dementia (EPAD) and Amyloid Imaging for Prevention of Alzheimer's Dementia (AMYPAD) Projects: Cohort Readiness for the Adaptive Clinical Trial Platform.

Andrew Satlin, MD<sup>1</sup>, Craig Ritchie MD PhD<sup>2</sup>, Miia Kivipelto MD PhD<sup>2</sup>, Alina Soloman MD PhD<sup>3</sup>, Brian Tom PhD<sup>4</sup>, Jose Luis Molinuevo MD PhD<sup>5</sup>. Scott Berry PhD<sup>6</sup> Frederik Barkhof MD PhD<sup>7</sup>, Gill Farrar PhD<sup>8</sup> (I)Eisai Pharmaceuticals, USA (2) Centre for Dementia Prevention, University of Edinburgh, UK (3) Ageing Research Centre, Karolinska Institute, Sweden (4) MRC Biostatistics Unit, University of Cambridge, UK (5) Barcelona Beta Brain Research Centre, Spain (6) Berry Consultants Ltd, Texas, USA (7) VU University Medical Centre, Amsterdam, The Netherlands (8) General Electric, Amersham, UK

#### OC28 - Towards a New Biomarker Battery for Drug Development in Alzheimer's Disease

Olivier Blin, MD, PhD1, Régis Bordet MD PhD2, Jill Richardson PhD3, Pierre Payoux MD PhD4, Claudio Babiloni MD PhD5, David Bartrés-Faz MD PhD6, Catherine Cassé-Perot PhD1 Giovanni Frisoni MD PhD7

(I) University of Aix-Marseille (2) University of Lille (3) GSK (4) University of Toulouse (5) University of Roma (6) University of Barcelona (7)

4:00 - 4:30 p.m.

# Coffee Break and Poster Session

4:30 - 5:00 p.m.

# Keynote 4

Rationale, Design and Progress of the 3 Active Alzheimer's **Prevention Initiative Trials** 

Pierre Tariot, MD, Banner Alzheimer's Institute, University of Arizona College of Medicine, Phoenix, AZ - USA

5:00 - 6:00 p.m.

# Symposium 4

Results from the Phase 3 MINDSET STUDY:

A Global, Double-Blind, Placebo-Controlled Study of Intepirdine in Mild-to-Moderate

Alzheimer's Disease

- Presentation 1: Analysis of primary efficacy and safety results
- Presentation 2: Analysis of secondary endpoints and measures of clinical meaningfulness
- Discussion and Q&A



08:30 - 10:00 a.m.

#### **Oral Communications**

#### OC29 - ORY-2001 Rationale in Mild to moderate Alzheimer's Disease

Roger Bullock MD<sup>1</sup>, Cesar Molinero MD,PhD<sup>1</sup>, Tamara Maes PhD<sup>1</sup> (1) Oryzon Genomics S.A. Barcelona Spain

#### OC30 - Plasma Amyloid Levels within the Alzheimer's Process and Correlations with Central **Biomarkers**

Olivier Hanon, MD, PhD¹, Jean-Sébastien Vidal MD, PhD¹, Sylvain Lehmann MD, PhD², Stéphanie Bombois MD, PhD³, Bernadette Allinquant MD⁴. Marie Godard Msc¹, Patrick Gelé MD⁵, Christine Delmaire MD³, Fredéric Blanc MD⁶, PhD, S Schraen MD<sup>5</sup>, <u>Audrey Gabelle MD</u>, <u>PhD</u><sup>7</sup> and the BALTAZAR study group.

(I) Department of Gerontology, Broca Hospital, Paris, France; (2) Laboratoire de Protéomique Clinique, Department of Biochemistry, Saint Eloi Hospital, IRMB, inserm U1183, France; (3) CMRR de Lille, Department of Neurology, Lille, France; (4) Centre de Psychiatrie et Neurosciences, Université Paris Descartes, Paris, France; (5) University of Lille Nord de France, Department of Biology and Pathology, Lille University Hospital, INSERM UNIVERSITY, 59037 Lille, France; (6) CMRR de Strasbourg, Department of Gerontology; Strasbourg, France; (7) CMRR de Montpellier, Department of Neurology; Inserm U1183, Montpellier, France.

#### OC31 - Online Clinical Research: Updates and Insights from the Brain Health Registry

 $\underline{Shannon\ Finley, MA^{I}}, Diana\ Truran^{I}, Derek\ Flenniken^{I,3}, Juliet\ Fockler^{I,3}, Rachel\ L\ Nosheny\ PhD^{I,3}, Monica\ Camacho^{I,3}, R\ Scott\ Mackin\ PhD^{I,2}, and\ Michael\ W\ Weiner\ MD^{I,3}$ 

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

#### OC32 - BPN14770 Phosphodiesterase-4D Negative Allosteric Modulator for Alzheimer's Dementia: Preclinical, PET Imaging and Human Phase 1 Results

 $\underline{\text{Mark Gurney. PhD}^1}$ , Chong Zhang PhD², Ying Xu PhD², James OʻDonnell PhD², Masahiro Fujita MD, PhD³, Robert Innis MD, PhD³, Victor Pike PhD³, Sanjay Telu PhD³ and Scott Reines, MD, PhD¹

(I) Tetra Discovery Partners, Inc. Grand Rapids, MI, USA; (2) School of Pharmacy and Pharmacological Sciences, University at Buffalo, Buffalo, NY, US; (3) National Institute of Mental Health, Bethesda, MD, USA

#### OC33 - Amyloid Beta Stable Isotope Labeling Kinetics and Concentrations of Human Plasma Detect CNS Amyloidosis

Vitaliy Ovod MS<sup>1</sup>, Kara Ramsey, BS<sup>1</sup>, James Bollinger PhD<sup>1</sup>, Kwasi Mawuenyega, PhD<sup>1</sup>, Terry Hicks, BA<sup>1</sup>, Theresa Schneider<sup>1</sup>, Thomas Kasten, PhD<sup>1</sup>, Wendy Sigurdson, RN<sup>1</sup>, Melissa Sullivan, MS<sup>1</sup>, Tamara Donahue<sup>1</sup>, RN, Katrina Paumier, PhDI, David Holtzman, MD<sup>1,24</sup>, John Morris, MD<sup>1,4</sup>, Tammie Benzinger MD, PhD<sup>2,3</sup>, Anne Fagan PhD<sup>1,24</sup>, Bruce Patterson, PhD<sup>5</sup>, and Randall Bateman, MD<sup>1,24</sup>

(1) Department of Neurology, Washington University School of Medicine, St Louis, MO; (2) Hope Center for Neurological Disorders, Washington University School of Medicine, St Louis, MO; (3) Department of Radiology, Washington University School of Medicine, St Louis, MO; (4) Knight Alzheimer's Disease Research Center, Washington University School of Medicine, St Louis, MO (5) Department of Medicine, Washington University School of Medicine, St Louis, MO

#### OC34 - Stereotypical Data-Driven Imaging Biomarker Trajectories across the Alzheimer's **Disease Spectrum**

Sergey Shcherbinin, PhD<sup>1</sup>, Mark A. Mintun, MD<sup>2</sup>, Adam J. Schwarz, PhD<sup>1</sup>, For the Alzheimer's Disease Neuroimaging

(1) Eli Lilly and Company, Indianapolis, IN, USA ; (2) Avid Radiopharmaceuticals, Inc., Philadelphia, PA, USA ; Alzheimer's Disease Neuroimaging Initiative (ADNI) database (adni.loni.usc.edu)

10:00 - 10:30 a.m.

# Coffee Break and Poster Session

10:30 – 11:30 a.m.

# **Late Breaking Oral Communications**

11:30 – 12:30 p.m.

# Symposium 5

## Synaptic and Network Dysfunction in Alzheimer's Disease (AD): Translational Insights and Therapeutic Opportunities

Moderator: Arjen Brussard, PhD, Amsterdam Neuroscience, VU Medical Center, Amsterdam, Netherlands

1. Targeting unfolded protein response and synaptic dysfunction to enhance memory function and prevent neurodegeneration

Giovanna Mallucci, MD PhD<sup>1,2,3</sup>

(I) Dept. of Clinical Neurosciences, University of Cambridge, Cambridge, UK; (2) UK Dementia Research Institute at University of Cambridge, Cambridge, UK (3) MRC Toxicology Unit, Leicester, UK

2. Modulation of synaptic and network activity and endocytosis with light flicker therapy reduces amyloid pathology in mouse model of AD

Li-Hueh Tsai, PhD1

(1) Picower Institute of Memory and Learning, Massachusetts Institute of Technology, Cambridge MA, USA

3. Preclinical rationale and early clinical results of p38 alpha kinase inhibition to reverse hippocampal synaptic dysfunction

John Alam, MD

(1) FIP Pharma, LLC, Cambridge MA, USA

12:30 - 1:30 p.m.

## Lunch and Poster Presentation

1:30 - 2:15 p.m.

# Clinical Trials Prescreening Focus Panel:

## Prescreening Initiatives to Identify Individuals with Preclinical or Early Alzheimer's Disease for Clinical Trials

Moderator: Jamie A Mullen, MD, AstraZeneca, Waltham MA, USA

- 1. The Funnel study: Prescreening for MCI and mild AD patients from the CHARIOT Register <u>Geraint J Price</u>, Maxwell J Benjamin, Lisa K Curry, Sabrina WL Smith and Lefkos T Middleton Neuroepidemiology and Ageing Research Unit, School of Public Health, Imperial College London, UK
- 2. A prescreening study using amyloid PET to improve recruitment for early Alzheimer's disease drug trials Christopher C Rowe, MD Austin Health, Melbourne, Australia
- 3. Models of Patient Engagement in Alzheimer's Disease (MOPEAD): a European project to move Alzheimer's disease environment towards an earlier diagnosis

Mercè Boada, MD, PhD'; Laura Campo²; Dhaval Desai³; Hans Peter Hundemer⁴; Octavio Rodriguez-Gomez, MDl; Bengt Winblad, Prof, MD, PhD⁵; Frank Jessen, MD, PhD⁶; Peter Jelle Visser, MD, PhD젹; Milica Kramberger, MD, PhDੳ; Rafael Simó, MD, PhD°; Rafael Navajo¹o; Annette Dumas¹¹; Jean Georges, BA¹²; David Krivec¹³; Peggy Maguire¹⁴;

(I) Fundació ACE. Barcelona Alzheimer Treatment & Research Center, Barcelona, Spain; (2) Eli Lilly and Company Ltd, Basingstoke, (I) Fundacio A.E. Barcelona Alzneimer Treatment & Research Center, Barcelona, Spain; (2) Ell Lilly and Company Ltd, Basingstore, United Kingdom; (3) AstraZeneca AB, Sodertalje, Sweden; (4) Lilly Deutschland GmbH, Bad Homburg, Germany; (5) Karolinska Institutet, Center for Alzheimer Research, Div. of Neurogeriatrics, Huddinge, Sweden; (6) German Center for Neurodegenerative Diseases (DZNE), Bonn-Cologne, Germany; (7) Stichting VUmc, Amsterdam, Netherlands; (8) University Medical Centre Ljubljana, Ljubljana, Slovenia; (9) Institut de Recerca Hospital Universitari Vall d'Hebron (VHIR), Barcelona, Spain; (10) GMV Soluciones Globales Internet S.AU., Barcelona, Spain; (11) ASDM Consulting, Auderghem, Belgium; (12) Alzheimer Europe, Luxembourg, Luxembourg; (13) Spomincica – Alzheimer Slovenia, Ljubljana, Slovenia; (14) European Institute of Women's Health, Dublin, Ireland; (15) KITE Innovation (Europe) Ltd, Huddersfield, Ligited (15) Kiter (16) Alzheimer Europe, Lixembourg, Lixembou United Kingdom

## **Oral Communications**

#### OC35 - Rapid, Remote, and Repeatable: Smartphone-Based "Burst" Cognitive Assessments for Global AD Prevention Trials.

nantly Inherited Alzheimer Network-Trials Unit.

(I) Department of Neurology, Washington University School of Medicine, St. Louis, MO USA; (2) Department of Psychological & Brian Sciences, Washington University in St. Louis, MO USA; (3) The Dominantly Inherited Alzheimer Network-Trials Unit (DIAN-TU), Washington University School of Medicine, St. Louis, MO USA; (4) Knight Alzheimer's Disease Research Center, Washington University School of Medicine, St. Louis, MO USA; (5) Department of Human Development and Family Studies, Pennsylvania State University, State College, PA USA ; (6) The Florey Institute, The University of Melbourne, Parkville, Victoria, Australia ; (7) Cogstate Ltd, Melbourne, Victoria,

#### OC36 - Associating Cognitive Functioning Profiles with Amyloid Status in ADNI2, with Implications for Adaptive Screening for Amyloid

Sarah J Carr PhD<sup>1</sup>, Judith Jaeger PhD<sup>2,3</sup>, Nancy Maserejian ScD<sup>4</sup>, Ahmed Enayatallah<sup>4</sup>, Alan Lerner<sup>1,5</sup>, Yanming Wang6, Sheng Yang<sup>7</sup>, Wenting Wang<sup>4</sup>, Shijia Biang4, <u>Curtis Tatsuoka</u> PhD<sup>1,5</sup> and for the Alzheimer's Disease Neuroimaging Initiative\*

(1) Department of Neurology, Case Western Reserve University, Cleveland, OH, USA; (2) CognitionMetrics, DE USA; (3) Department of Psychiatry and Behavioral Sciences, Albert Einstein College of Medicine, Bronx, NY USA; (4) Biogen, Cambridge, MA, USA; (5) Neurological Institute, University Hospitals Case Medical Center, Beachwood, OH USA; (6) Department of Radiology, Case Western Reserve University, Cleveland, OH USA ; (7) Department of Epidemiology and Biostatistics, Case Western Reserve University, Cleveland, OH USA

#### OC37 - Alzheimer's Disease Dementia and the Long-Term Impact on Caregiver Burden -36-Month results from GERAS

Catherine Reed, PhD1, Mark Belger, BSc1, J. Scott Andrews, PharmD2, Antje Tockhorn-Heidenreich, MSc1. (1) Eli Lilly and Company Limited, Windlesham, UK; (2) Eli Lilly and Company, Indianapolis, IN, USA

OC38 - Neuroprotective Effect of a New Photobiomodulation Technique against Amyloid Aß25-35 Peptide-Induced Toxicity in Mice.

Guillaume J. Blivet, MS<sup>1</sup>, Johann Meunier, PhD<sup>2</sup>, Francois J. Roman, PhD<sup>2</sup>, <u>Jacques Touchon, MD, PhD</u><sup>3,4</sup> (1) REGENLIFE SAS, Montpellier, France ; (2) Amylgen SAS, Montferrier-sur-Lez, France ; (3) INSERM U1061, Montpellier, France (4) University of Montpellier, France

# **Late Breaking Oral Communications**

4:15 – 4:30 p.m.

# **Closing Session**

# **CTAD 2017**

# REGISTRATION

#### Early bird fees (until September 1)

- Regular Registration (no lunches) 895€ Regular registration (with 3 lunches) 1024€
- 2. EADC Member registration (no lunches) 704€ Regular registration (with 3 lunches) 833€ (to benefit from this rate you must be an active member of the European Disease Consortium)

## Full registration fees (After September 2)

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