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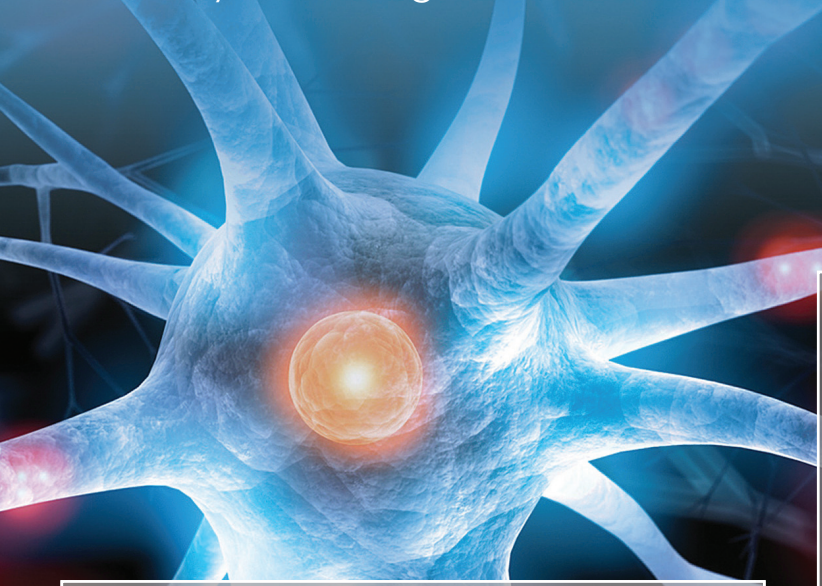
SMi present the inaugural conference...

Alzheimer's

Improving the utility of translatable models and early intervention strategies with informed data-driven approaches

Holiday Inn Kensington Forum, London, UK

10 - 11 MAY 2016



Business benefits for 2016:

- Establish new cohorts in **pre-clinical strategies** for early intervention
- Understand **psychiatric** and behavioural symptoms for actioning better treatments
- Gain new insights on the EU-wide **EPAD** and **IMI** projects to facilitate clinical trial designs and access to medical data
- Discuss the utility of data from **imaging biomarkers** and the clinical significance of **endpoint outcomes**
- Increase the likelihood of therapeutic success through strategic guidance on simultaneously targeting multiple pathogenic mechanisms
- Discover novel therapeutic strategies including **Alzinova's** lead **AβCC technology** and oligomer-specific vaccine development
- Enabling disease progression studies by revisiting endpoint outcomes in pre-dementia clinical trials

Chair for 2016:

Giulio Maria Pasinetti,
Saunders Family Chair and Professor of Neurology,
Icahn School of Medicine at Mount Sinai

Featured Speakers:

- **Luc Ver Donck,** Scientific Director, **Janssen Research & Development**
- **Steve Hood,** Director, Biotransformation & Drug Disposition, **GSK**
- **Matthew Kennedy,** Director, Early Discovery Neuroscience, **Merck**
- **Serge Van der Geyten,** Director, Neuroscience External Affairs, **Janssen Research & Development**
- **Michael J O'Neill,** Head of Molecular Pathology Group, **Eli Lilly**
- **Claude M Wischik,** Executive Chairman, **TauRx Therapeutics**
- **Anders Sandberg,** Chief Scientific Officer, **Alzinova AB**
- **Simon Ridley,** Director of Research, **Alzheimer's Research UK**

PLUS TWO INTERACTIVE HALF-DAY POST-CONFERENCE WORKSHOPS

Thursday 12th May 2016, Holiday Inn Kensington Forum, London, UK

Workshop A

Understanding tau pathology and new frontiers for disease modifying treatments

Workshop Leader: **Claude M Wischik,** Executive Chairman, **TauRx Therapeutics**
8.30am - 12.30pm

Workshop B

Using iPSCs to model Alzheimer's disease mechanism and discover therapeutic targets

Workshop Leader: **Noel Buckley,** Professor of Neurobiology, **University of Oxford**
1.30pm - 5.30pm

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Alzheimer's

Day One | Tuesday 10th May 2016

8.30 **Registration & Coffee**

9.00 **Chair's Opening Remarks**
Giulio Maria Pasinetti, Saunders Family Chair and Professor of Neurology, **Icahn School of Medicine at Mount Sinai**

EARLY DIAGNOSIS AND BEHAVIOURAL CONCEPTS

9.10 **OPENING ADDRESS: Addressing the under-met areas of research and diagnosis**
- Revisiting classification of stages in subjects at high risk to develop Alzheimer's disease from preclinical to prodromal into mild cognitive impairment and dementia
- Revisiting endpoint outcomes in pre-dementia clinical trials that will enable disease progression studies
- Revisiting patient selection for clinical trials
- How can we monitor preclinical and model early indications of Alzheimer's disease onset and progression?

Giulio Maria Pasinetti, Saunders Family Chair and Professor of Neurology, **Icahn School of Medicine at Mount Sinai**

9.50 **The EPAD Project - Changing the way therapies are developed for the secondary prevention of Alzheimer's dementia**
- Building an AD readiness cohort
- Clinical trial design
- Assessing efficacy in a preclinical/MCI population

Serge Van der Geyten, Director, Neuroscience External Affairs, **Janssen Research & Development**

10.30 **Morning Coffee**

11.00 **Risk profiling Alzheimer's disease**
- Characterising trajectories of cognitive decline in the onset of AD
- Assessment of variables and time-dependant biomarkers
- Flexibility and issues of modelling Alzheimer's disease

Graciela Muniz Terrera, Senior Lecturer, Biostatistics, **University of Edinburgh**

11.40 **Beyond cognition – behavioural and psychiatric symptoms in Alzheimer's disease**
- Behavioural and psychiatric symptoms in Alzheimer's disease
- The case for action: Prevalence and impact
- Where we are and where we could be: Current and emerging treatments

Sophie Dix, Director of Research, **MQ Transforming Mental Health**

12.20 **Networking Lunch**

1.30 **Delivering macromolecules across the blood brain barrier – An alternative to small molecule drugs?**
- A review of the challenges of macromolecule distribution
- How can we measure CNS penetration?
- COMPACT – Introducing a European collaboration to address the challenges

Steve Hood, Director, Biotransformation & Drug Disposition, **GSK**

INHIBITING THE ONSET OF BETA-AMYLOID AND TAU AGGRESSION

2.10 **KEYNOTE ADDRESS: Tau aggregation inhibition as a target for Alzheimer's disease and related late life neurodegenerative disorders**
- Understanding the shift of late life neurodegenerative disorders with prion-like accumulation of toxic intracellular oligomers as driving molecular pathogenesis
- Assessing the effect of LMTX® - A Tau Aggregation Inhibitor (TAI) in transgenic cellular and mouse models to ameliorate the pathology and behavioural changes in transgenic mice, and evaluating the concentration required for cellular TAI activity close to the levels achieved in mouse brain
- Similar efficacies of LMTX® have been shown in Synuclein models of PD, Huntingtin models of HD and TDP-43 models. We are currently completing Phase 3 trials for LMTX® in AD and FTD which will report during the course of 2016, and will open the way to investigating efficacy in related disorders
- Improved biomarker diagnostics during the 20-year insidious prodrome of Tau aggregation in AD will substantially increase the clinical scope of use of TAIs. If the Phase 3 data with LMTX® confirm the 90% reduction in rate of disease progression seen in Phase 2, this will have important clinical and pharmaco-economic implications across a broad range of late-life neurodegenerative disorders

Claude M Wischik, Executive Chairman, **TauRx Therapeutics**

2.50 **Assessing cognitive and functional outcomes of BACE inhibitor, Verubecestat**
- Clinical trial performance from BACE inhibitor, Verubecestat
- Planning early intervention strategies through Bmx-based patient selection
- Potential for combinatory methods applying anti-amyloid with tau or inflammation therapies

Matthew Kennedy, Director, Early Discovery Neuroscience, **Merck**

3.30 **Afternoon Tea**

4.00 **Funding investment and research**
- Academic drug discovery in AD
- Funding models and partnerships

Simon Ridley, Director of Research, **Alzheimer's Research UK**

4.40 **Understanding AD pathogenesis in Down's syndrome**
- Discovering the link between beta-amyloid in Down's syndrome and AD for targeted therapies
- Identifying biomarkers to track and predict deposition of amyloid plaques and tau pathology: Towards defining the pre-clinical state
- Suitability for an amyloid pathway based primary prevention trial

Shahid Zaman, Affiliated Lecturer and Consultant Psychiatrist, **University of Cambridge**

5.20 **Chairman's Closing Remarks and Close of Day One**

Who should attend:

This conference is intended for VPs, Senior Managers, CSOs or Directors working in but not limited to:

- Neuroscience
- Drug discovery R&D
- Early intervention and diagnostics
- Pre-Clinical /Clinical R&D
- Senior advisory board
- Dementia lead projects
- Clinical Pharmacology
- Biomarker discovery
- Functional and molecular imaging
- Bioinformatics/ Neuroinformatics
- Medical Directors

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8.30 **Registration & Coffee**

9.00 **Chairman's Opening Remarks**
Giulio Maria Pasinetti, Saunders Family Chair and Professor of Neurology, **Icahn School of Medicine at Mount Sinai**

EFFICACY OF ENDPOINTS AND TRANSLATABLE CLINICAL BENEFITS

9.10 **OPENING ADDRESS: Targeting multiple disease mechanisms for the treatment of Alzheimer's disease**
- Since 1998, there have been over 100 drug trials targeting specific AD pathogenic mechanisms, all of which have failed
- AD is a complex disease involving multiple interrelating pathogenic mechanisms
- Strategies that simultaneously target multiple pathogenic mechanisms may increase the likelihood of therapeutic success

Giulio Maria Pasinetti, Saunders Family Chair and Professor of Neurology, **Icahn School of Medicine at Mount Sinai**

9.50 **KEYNOTE ADDRESS: Translatable research of cognitive decline from animals to humans**
- How can we best translate early indications of Alzheimer's from animal models?
- Re-evaluating the clinical significance of endpoint outcomes in pre-dementia clinical trials
- Understanding behavioural responses from animal models for human pathology

Luc Ver Donck, Scientific Director, **Janssen Research & Development**

10.30 **Morning Coffee**

11.00 **Specific targeting of synapse-damaging oligomers of amyloid-beta with AβCC technology**
- The merits of AβCC proprietary technology in for novel therapeutics and diagnostics
- Lead candidate vaccine development showing extreme specificity of oligomer toxins and prevention of cross-reactivity
- Pre-clinical trial preparations of ALZ-101 lead candidate

Anders Sandberg, Chief Scientific Officer, **Alzinova AB**

11.40 **Representing clinically-meaningful data from a disease-modifying drug trial**
- Efficacy vs effectiveness
- What is meant by clinically meaningful data
- What would represent a clinically relevant difference to a prescribing physician

Alan Lenox-Smith, Senior Clinical Research Physician, **Eli Lilly**

12.20 **Networking Lunch**

1.30 **Regulatory view on the efficacy of endpoints and safety assessment**
- Pharmacology and the CNS
- Biomarkers or clinical benefit?
- Problems with composite endpoints
- Balancing risk-benefit

John Warren, Director, **Medicines Assessment Ltd**

MODELLING DISEASE PROGRESSION AND BIOMARKER EVALUATION

2.10 **KEYNOTE ADDRESS: The use of transgenic models in drug discovery: Focus on tau pathology**
- Examples of tau transgenic models
- Modelling progressive tau pathology
- Modelling the propagation of pathology
- What are the best end-points to measure?
- Tau therapeutic targets

Michael J O'Neill, Head of Molecular Pathology Group, **Eli Lilly**

2.50 **IMI project on the development of a European Medical Information Framework for Alzheimer's disease**
- EU-wide framework to facilitate access to medical data
- Temporal evaluation of fluid biomarkers and cognitive markers
- New studies of risk factors in modelling AD

Pieter Jelle Visser, Senior Researcher, **VU University Medical Center**

3.30 **Afternoon Tea**

4.00 **Clearance of misfolded proteins and microglial activation**
- Detecting inflammatory response levels
- Microglial expression patterns
- Deposition of Aß aggregates and cytokine expression

Michael Heneka, Head Neurologist, **University Hospital Bonn**

4.40 **In vivo multi parametric MRI imaging of tau pathology in mice**
- Establishing imaging biomarkers of tau pathology in the rTg4510 mouse model of tau pathology
- Longitudinally assessment of biomarkers on conditional mouse model of tau pathology
- Glymphatic clearance of tau from the brain, and its involvement in Alzheimer's disease: Insights from imaging studies

Ian Harrison, Research Associate, **UCL**

5.20 **Chairman's Closing Remarks and Close of Day Two**

HALF-DAY POST-CONFERENCE WORKSHOP A
Thursday 12th May 2016
8.30am - 12.30pm
Holiday Inn Kensington Forum, London, UK

Understanding tau pathology and new frontiers for disease modifying treatments

Workshop Leader:
Claude M Wischik, Executive Chairman,
TauRx Therapeutics

Workshop overview:
Major advances in research have changed the understanding of late life neurodegenerative disorders. Alzheimer's disease is the most prevalent of these conditions, and understanding the tau pathways and its role in molecular pathogenesis of this disease creates new opportunities for early diagnosis, preventive intervention and monitoring. Emerging technologies in this field will have major pharmaco-economic implications in all aging populations.

Why you should attend:
- Understand the underlying pathobiology as an age-related continuum
- Review alternative strategies for therapeutic intervention
- Review emerging strategies for early diagnosis and monitoring of treatment response
- Gain insight into population prevalence and market implications for these disorders

Programme

8.30 **Registration and Coffee**

9.00 **Opening remarks and introductions**

9.10 **Basic biology of Tau protein and overview potential pharmaceutical approaches**
- Protein structure and mechanisms of tau aggregation
- Potential targets for drug development
- Epidemiology of tau aggregation and socioeconomic implications

09.50 **Brain imaging assessment of disease progression**
- Structural imaging to help define stages of disease progression
- Efficacy of biomarker endpoints

10.30 **Afternoon Tea**

11.00 **EEG and improved psychometric technologies for non-invasive early diagnosis and monitoring of treatment response**
- Value-added information relatable to drug effectiveness
- Utility for early diagnosis and correlations of abnormal EEG signals to AD progression

11.40 **Tau-based and other blood and CSF markers for diagnosis and monitoring**
- Identification of patients for early diagnosis and intervention
- Combinatory approaches with range of diagnostic and monitoring tools

12.20 **Closing remarks**

12.30 **Close of workshop**

About the workshop leader:

Professor Claude M Wischik holds the Chair in Old Age Psychiatry at the University of Aberdeen in Scotland, and is Executive Chairman of TauRx Pharmaceuticals. He studied medicine in Australia, completed his PhD at the Laboratory of Molecular Biology in Cambridge, and also higher psychiatric training in Cambridge. He was the first to identify Tau protein as the main constituent of the Alzheimer tangle and developed the first Tau Aggregation Inhibitors. He has lead the first clinical trials at Phase 2 and Phase 3 of a potential treatment for pathological aggregation of tau protein.

About the organisation:

TauRx Pharmaceuticals
science, medicine, innovation

TauRx Pharmaceuticals Ltd. is based operationally in Aberdeen in Scotland. The company is focused on the discovery, development and commercialization of products for the diagnosis and treatment of neurodegenerative diseases caused through protein aggregation. Its lead product is LMTX®, the first Tau Aggregation Inhibitor (TAI) targeting the Tau pathology of Alzheimer's disease; it is in global Phase 3 clinical trials for the treatment of mild to moderate Alzheimer's disease (AD) and FrontoTemporal Dementia (FTD).

HALF-DAY POST-CONFERENCE WORKSHOP B
Thursday 12th May 2016
1.30pm - 5.30pm
Holiday Inn Kensington Forum, London, UK

Using iPSCs to model Alzheimer's disease mechanism and discover therapeutic targets

Workshop Leader:
Noel Buckley, Professor of Neurobiology,
University of Oxford

Workshop overview:
AD research has hitherto been limited by an absence of valid cellular models to interrogate disease mechanism and identify novel therapeutic targets. This workshop will discuss the emerging gestalt of iPSCs, genome editing and computational biology and their application to identify pathways, networks and targets directly attributable to specific human genetic variants conferring risk or protection to neurodegeneration.

Why you should attend:
This workshop will be beneficial to all those interested in use and limitations of iPSCs as models of neurodegeneration and in their application to model gene regulatory networks and identify novel therapeutic targets.

Programme

1.30 **Registration and Coffee**

2.00 **Opening remarks and introductions**

2.10 **iPSC as tools to investigate AD**
- Enabling the generation of patient-derived neuronal cells in a dish.
- A platform for drug screening and toxicology studies

02.50 **Analysing cellular complexity in iPSC models of AD**
- Unravelling pathway complexities of neuronal processes
- Protocols to derive the neurons from iPSC lines.

3.30 **Afternoon Tea**

4.00 **iPSCs, neurodegeneration and cellular phenotypes**
- Differentiating iPSC's into specific neuronal subtypes most relevant for disease phenotypes
- Understanding sources of phenotype variation

4.40 **Using iPSCs to infer networks and identify novel therapeutic targets**
- Correlating gene expression analysis and data
- Modelling actions of potential drug targets

5.20 **Closing remarks**

5.30 **Close of workshop**

About the workshop leader:

Noel Buckley has studied transcriptional and epigenetic mechanisms in neural stem cells with a particular focus on REST, a key transcriptional regulator, that plays a critical role in embryonic neurogenesis and in maintaining adult neuronal phenotype as well as mediating cell death in Huntington's Disease and in rescuing cell death in Alzheimer's disease.

He is currently working in collaboration with basic, clinical and translational neuroscientists, molecular biologists, stem cell biologists and computational biologists to understand how neuronal phenotype emerges from interactions among the underlying gene regulatory networks and translating this understanding into identification of novel therapeutic targets in AD.

About the organisation:

UNIVERSITY OF OXFORD

We work in close collaboration with clinical services particularly **Oxford Health NHS Foundation Trust** and the **Oxford University Hospitals NHS Trust,** with our leading clinical and translational academics providing a link with the world-class discovery science groups working in Oxford. We are committed to the translation of scientific discovery into benefits for patients. Our role is to champion our patients' interest by making basic research applicable to the causes, the diagnosis, and the treatment of disease. We use clinical and patient observation and experience to motivate and direct basic research, where it is likely to help real life problems. We have built expertise and extensive networks in a variety of research fields from molecular biology to brain imaging, from behavioural research to epidemiology, bringing together clinicians and scientists in all our research groups, and collaborating with leading experts in other departments and institutions.

ALZHEIMER'S

Conference: Tuesday 10th & Wednesday 11th May 2016, Holiday Inn Kensington Forum, London, UK **Workshops: Thursday 12th May 2016, London, UK**

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