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Alzheimer's Disease [2017]

https://marketpublishers.com/r/AD615C91E4CEN.html
Date: September 2017
Pages: 0
Price: US$ 8,145.00 (Single User License)
ID: AD615C91E4CEN

Abstracts

Do KOLs see a future for beta-amyloid as a target in Alzheimer’s?

Despite the inexorable attrition rate, both big pharma and small biotechs continue to invest in Alzheimer’s disease R&D. Is the amyloid hypothesis dead or could the right drug candidate, studied in an optimally designed trial, gain approval for this much sought after indication? KOLs weigh in on how trials could be optimised and what part biomarkers can play. How can we learn from past failures? What are the chances of success for Biogen/Eisai’s aducanumab and the other beta-amyloid mAbs, as well as the BACE inhibitors, in light of the chequered history of these classes? Could tau finally prove itself as a valid target? Could drugs targeting inflammatory mechanisms or serotonin receptors play a part in this narrative? Four US and seven EU KOLs offer critical insights on four marketed and 15 pipeline drugs.

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Top takeaways

Clinical attrition in the AD pipeline remains remarkably high. What do KOLs attribute this to and how can these issues be overcome so that past mistakes can be learnt from and the field moved forward?

Several high profile failures of beta-amyloid mAbs have cast a shadow over this class.How do KOLs account for this chequered history and how do they rate the chance of success for Biogen/Eisai's aducanumab and other drugs in this class?

BACE inhibitors in the late-stage pipeline are extremely potent in terms of impacting beta-amyloid, but their clinical value remains uncertain. What is considered the optimal patient population for these drugs, and how do KOLs rate their safety and overall chance of success?

How do KOLs envisage that the pathophysiological heterogeneity of AD could be exploited for therapeutic gain? Could there be potential in targeting beta-amyloid, tau, inflammatory pathways or serotonergic neurotransmission, or a combination of these?

Biomarkers have played an increasingly important role in drug development for AD in recent years. How will their use evolve to shape trial design and the treatment of AD in the future?

Outcome measure selection will be of critical importance to the success of clinical trials going forward. How can their use be best appropriated in order to optimise outcomes in AD trials?

Quotes

"One of the reasons we haven't had success in approving a medication in the last 15 years is probably because we have not either used the appropriate dose or state of the disease to test that specific medication."EU Key Opinion Leader

"Clinical diagnosis will evolve in a way that helps solidify the groups that we're including

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in trials and who to best treat as the drugs come to market. Biomarkers have been a huge part of the development in the past few years and that will continue." US Key Opinion Leader

"This will be the revolution for neurodegenerative diseases. We'll go from complex, expensive, non-generalisable, inaccessible PET imaging that is also generally focused on amyloids, to multiple biomarkers. So combination therapy will be possible or people can be enrolled in a very homogeneous trial population, geared for a drug with a specific mechanism of action." US Key Opinion Leader

Sample of therapies covered

Marketed therapies

Aricept (donepezil; Eisai/Pfizer)

Exelon (rivastigmine; Novartis)

Razadyne (galantamine; Janssen/Shire)

Namenda/Ebixa (memantine; Merz/Allergan/Lundbeck)

Phase III therapies

Verubecestat (MK 8931; Merck & Co.)

Elenbecestat (E-2609; Eisai/Biogen)

Lanabecestat (AZD3293; AstraZeneca/Eli Lilly)

JNJ-54861911 (Janssen)

CNP520 (Novartis/Amgen)

Solanezumab (LY2062430; Eli Lilly)

Gantenerumab (R1450/RG-1450; Roche)

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Crenezumab (MABT5102A/R 5490245/RG 7412; Roche)

Aducanumab (BART/BIIB 037/NI-10; Biogen/Eisai)

CAD106 (amilomotide; Novartis)

Pioglitazone (Takeda)

Azeliragon (PF-04494700/TTP-488; vTv Therapeutics)

Intepirdine (RVT 101/742457; Axovant Sciences)

Idalopirdine (LU-AE58054/SGS-518; Lundbeck)

TRx0237 (LMTX; TauRx)

KOLs interviewed

KOLs from North America

Piero G. Antuono, Professor of Neurology, Pharmacology, and Toxicology; Director of the Dementia Research Center, Medical College of Wisconsin, Milwaukee, WI, USA

Joshua D. Grill, Associate Professor, Psychiatry & Human Behavior School of Medicine, University of California, Irvine, CA, USA

David Sultzer, Professor, Department of Psychiatry & Biobehavioral Sciences, UCLA School of Medicine, Los Angeles, CA, USA

Anonymous US KOL, Professor of Psychiatry, Neurology, and Gerontology at a major US university and director of an AD centre

KOLs from Europe

Harald Jürgen Hampel, Professor of Neuroscience, Sorbonne Universités, Université Pierre et Marie Curie Institut de la Mémoire et de la Maladie

d’Alzheimer; and Département de Neurologie Hôpital de la Pitié-Salpêtrière, Paris, France

Peter Johannsen, Consultant Neurologist, Copenhagen Memory Clinic, Rigshospitalet and University of Copenhagen, Denmark

José Luis Molinuevo, Scientific Director, Barcelonabeta Brain Research Center, Pasqual Maragall Foundation, Barcelona, Spain

Bruno Vellas, Professor of Medicine, Chairman, Toulouse Gerontopole, Department of Internal Medicine and Geriatrics, Toulouse University Hospital; Head of Alzheimer Disease Clinical Research Centre, University of Toulouse, France

Bengt Winblad, Professor and Director, Center for Alzheimer Research, Division of Neurogeriatrics, Karolinska Institutet, Huddinge, Sweden

Anonymous German KOL, Professor and Head, department of gerontopsychiatry at an institute for mental health

Anonymous German KOL, Head Neurologist, interdisciplinary clinical research center for neurodegenerative diseases at a major university hospital

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