



October 11, 2016

Leading Experts Warn Global Goal to Cure or Treat Alzheimer's Disease By 2025 is at Risk, Offer Solutions to Adjust Course

INDIANAPOLIS, Oct. 11, 2016 /PRNewswire/ -- Alzheimer's disease (AD) has an enormous impact on the lives of patients and caregivers, in addition to placing a significant burden on health care systems around the world. According to a paper published in *Alzheimer's Research & Therapy*, prominent experts in the field of AD state that under current conditions, only a limited number of disease-modifying therapies have a chance to be approved and available to patients by 2025. In "Drug Development in Alzheimer's Disease: The Path to 2025," the authors dissect the current realities and challenges of AD drug development and offer solutions to stimulate progress.

During the 2013 G8 Dementia Summit held in London, member nations established the goal to identify a disease-modifying therapy for dementia by 2025, setting the stage for coordinated global actions, including the initiation of the World Dementia Council. Many national policies or plans across the globe have also identified 2025 as the goal to effectively treat or prevent AD, including the U.S. National Plan to Address Alzheimer's Disease.^{[1],[2]}

AD is a fatal illness that causes progressive decline in memory and other aspects of cognition.^[3] By 2030, there will be an estimated 75 million people around the world with AD, while the cost of caring for people with dementia worldwide could rise to \$2 trillion USD if left unchecked.^[4]

"In order to have disease-modifying therapies available by 2025, significant changes need to be made in the areas of research and clinical development," said Jeffrey Cummings, M.D., director of the Cleveland Clinic Lou Ruvo Center for Brain Health, Las Vegas, Nevada, USA. "If we do not take immediate action to address the way we approach Alzheimer's disease, we will be doing a disservice not only to the many people around the world who are or will be impacted by this devastating disease, but also to our health care systems."

The working group proposes several solutions to accelerating research and development efforts, including:

- | **Improvement of clinical trial design:** combining research phases and choosing appropriate primary endpoints may lead to more efficient clinical trials
- | **Updating patient registries:** more advanced databases of healthy aged and symptomatic individuals could streamline clinical trial enrollment
- | **Encouraging earlier diagnosis:** current clinical assessment tools are neither sensitive nor specific enough to detect early signs of the disease; more sensitive cognitive-assessment tools may capture subtle clinical decline among individuals with minimal symptoms
- | **Shift in regulatory environment:** accelerated regulatory review processes, alignment of clinical trial endpoints with disease stage, and pivotal studies that test multiple patient populations could expedite drug approval

Implementing these solutions now and beyond 2025 requires further awareness and education, funding, and collaboration among academia, industry, government, health care systems and practitioners. Simultaneous progress in pipeline diversification and data sharing will allow the field to gain a deeper understanding of the disease's complex science.

"Our intent with this paper is simple - set the stage for continuing progress in the AD drug development field, and stimulate further discussion and action among industry, academia and regulatory bodies," said Philip Scheltens, M.D., Ph.D., VU University Medical Center, Amsterdam, Netherlands. "We're hopeful that with adjustments to existing processes and as these recommendations come to fruition, the goal of being able to treat or prevent Alzheimer's by 2025 will become a reality."

The full publication of "Drug Development in Alzheimer's Disease: The Path to 2025" can be accessed by visiting [Alzheimer's Research and Therapy](#).

About the Working Group

The working group consists of a number of highly regarded academic and industry experts, including Jeffrey Cummings, M.D., Cleveland Clinic Lou Ruvo Center for Brain Health (U.S.); Paul Aisen, M.D., Alzheimer's Therapeutic Research Institute, Keck School of Medicine of the University of Southern California (U.S.); Bruno DuBois, M.D., Ph.D., Neurological Institute of the University Salpêtrière Hospital (France); Lutz Frölich, M.D., Ph.D., Central Institute of Mental Health Mannheim (Germany); Clifford Jack Jr., M.D., Mayo Clinic (U.S.); Roy Jones, BSc, MB, FRCP, DipPharmMed, Research Institute for the Care of Older People (UK); John Morris, M.D., Washington University School of Medicine (U.S.); Philip Scheltens, M.D., Ph.D., VU University Medical Center (Netherlands); and Joel Raskin, M.D., FRCP, and Sherie Dowsett, Ph.D., from Eli Lilly and Company. The working group meets periodically to discuss how the AD environment needs to evolve and plans to publish additional papers in the future.

About the Alzheimer's Readiness Project

The mission of the Alzheimer's Readiness Project is to inspire action by fostering a deeper understanding of Alzheimer's, its evolving science, and the public health crisis it poses. Through outreach, events, and partnerships, the Project strives to be an important voice in the global Alzheimer's disease conversation, elevating awareness of the need for and value of advancements in the fight against Alzheimer's disease. For more information, please visit www.alzreadinessproject.com.

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[1] G8 Dementia Summit Declaration. December 2013.

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/265869/2901668_G8_DementiaSummitDeclaration_acc.pdf. Accessed October 2016.

[2] The National Plan to Address Alzheimer's Disease. <https://www.nia.nih.gov/alzheimers/publication/2012-2013-alzheimers-disease-progress-report/national-plan-address-alzheimers>. Accessed October 2016.

[3] 2016 Alzheimer's Disease Facts and Figures. Alzheimer's Association. *Alzheimer's & Dementia*. Available at http://www.alz.org/documents_custom/2016-facts-and-figures.pdf. Accessed October 2016.

[4] World Alzheimer Report 2015. Alzheimer's Disease International. August 2015. <https://www.alz.co.uk/research/WorldAlzheimerReport2015.pdf>. Accessed October 2016.

Refer to:

Tim Coulom; tim.coulom@lilly.com; 317-771-2241 (Lilly)
Janice Guhl Hammer; guhji@ccf.org; 216-312-0591 (Cleveland Clinic)

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