Lilly's P-tau217 Blood Test Shows High Accuracy in Diagnosis of Alzheimer's Disease in Data Published in JAMA

July 28, 2020

New Alzheimer's disease blood test could enable early diagnosis and advance understanding of how disease impacts those living with it

INDIANAPOLIS, July 28, 2020 /PRNewswire/ -- A new study on Lilly's blood test for Alzheimer's disease (AD), P-tau217 (phosphorylated tau at threonine-217), was published today in *JAMA*. The results showed that P-tau217 distinguished AD from other neurodegenerative diseases significantly better than other blood-based biomarkers or magnetic resonance imaging (MRI). These data will also be presented at the upcoming 2020 Alzheimer's Association International Conference® (AAIC) ®. Eli Lilly and Company (NYSE: LLY) and Avid Radiopharmaceuticals Inc., a wholly owned subsidiary of Lilly, are studying P-tau217 as a biomarker of AD pathology.

The cross-sectional three-cohort study included patients from an Arizona-based neuropathology cohort, the Swedish BioFINDER-2 cohort and a cohort of Colombian autosomal-dominant AD relatives. The study findings showed that P-tau217 accurately identified AD from other neurodegenerative diseases in both an Arizona-based neuropathology cohort and in the Swedish BioFINDER-2 study. In the third Colombian cohort, P-tau217 in mutation carriers' blood was elevated about 20 years before anticipated symptom onset and was associated with memory performance. The collaborative study was led by Oskar Hansson, M.D., Professor of Neurology at Lund University and Consultant Neurologist at Skåne University Hospital, with support from Eric Reiman, M.D., CEO of Banner Research and Executive Director of Banner Alzheimer's Institute, and was co-authored by Shorena Janelidze, Ph.D. and Sebastian Palmqvist, M.D., of Lund University.

"Blood tests like P-tau217 have the potential to revolutionize Alzheimer's research, treatment and prevention trials, and clinical care," said Eric Reiman, M.D., a co-senior author who supported the research on the Colombian cohort. "While there's more work to do, I anticipate that their impact in both the research and clinical setting will become readily apparent within the next two years."

The *JAMA* publication provides strong support that P-tau217, measured in plasma, could be used to improve the differential diagnosis of patients with cognitive impairment. The analysis also showed the test did not perform significantly different than cerebrospinal fluid (CSF)- or positron emission tomography (PET)-based tau biomarkers. A timely and accurate diagnosis of patients with cognitive impairment requires an approach which combines a variety of diagnostic tests.

"Differentiating AD pathology from other kinds of cognitive impairment is an important step in advancing our understanding of how the disease is impacting those living with it," said Jeffrey Dage, Ph.D., senior research advisor, Lilly, and co-author of the study. "As research progresses and we are able to identify AD earlier, we hope to tailor future treatment advances to the right patients at the right time. Lilly and Avid remain committed to conducting robust research in AD, from diagnostic tools through treatment opportunities."

"Today the majority of individuals with Alzheimer's disease around the world do not get a timely diagnosis, which results in suboptimal symptomatic treatment and care," said Oskar Hansson, M.D. "With rising prevalence of Alzheimer's disease, more patients will be evaluated in primary care and other clinics where CSF and PET biomarkers are not available. Blood-based biomarkers, like plasma P-tau217, together with digital tools for checking memory performance, such as smartphone-based apps, can considerably improve the diagnostic work-up of Alzheimer's disease patients in such clinics."

Lilly will continue to optimize the assay and determine its potential role in clinical care. The reliability and efficacy of P-tau217 has not been established and it is not approved by any regulatory authority worldwide. More data on P-tau217 will be presented at upcoming scientific meetings, including AAIC ® (July 27-31) and the Clinical Trials in Alzheimer's Disease Conference®, CTAD®, (November 4-7).

For more than 30 years, Lilly has been engaged in bringing innovative Alzheimer's disease therapies and diagnostics to patients and continues to lead the field in research, which also includes identifying biomarkers to support early detection of the disease.

About Alzheimer's Disease
Alzheimer's disease is a fatal illness that causes progressive decline in memory and other aspects of cognition. Dementia due to Alzheimer's is the most common form of dementia, accounting for 60 to 80 percent of all cases[1]. There are currently over 50 million people living with dementia around the world, with numbers expected to increase to nearly 152 million by 2050[2]. Almost 10 million new cases of dementia are diagnosed each year worldwide, implying one new case every 3 seconds, and a significant increase in the caregiving burden placed on society and families. In the US alone, there was an increase of 8 million new caregivers from 2015 to 2020[3]. The current annual societal and economic cost of dementia is estimated at $1 trillion, an amount that is expected to double by 2030 unless we find a way to slow the disease.

About Avid Radiopharmaceuticals
The mission of Avid Radiopharmaceuticals, a wholly owned subsidiary of Lilly, is to discover and develop radiopharmaceuticals and imaging methods that improve global health by accelerating the development of new medicines and enabling a tailored approach to healthcare.

About Eli Lilly and Company
Lilly is a global health care leader that unites caring with discovery to create medicines that make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please

visit us at lilly.com and lilly.com/newsroom. P-LLY

This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about P-tau217 as a potential diagnostic tool for adult patients with cognitive impairment who are being evaluated for Alzheimer's disease and reflects Lilly's current belief. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of development and commercialization. Among other things, there can be no guarantee that future study results will be consistent with the results to date or that P-tau217 will achieve its primary study endpoints or receive regulatory approvals. For further discussion of these and other risks and uncertainties, see Lilly's filings with the United States Securities and Exchange Commission. Lilly undertakes no duty to update forward-looking statements.

[1] https://www.alz.org/alzheimers-dementia/facts-figures
[2] https://www.alz.co.uk/research/WorldAlzheimerReport2019.pdf
[3] https://www.aarp.org/content/dam/aarp/ppi/2020/05/full-report-caregiving-in-the-united-states.doi.10.26419-2Fppi.00103.001.pdf

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