



Lilly Announces Positive Phase 3 Results in Study of Flortaucipir PET Imaging Agent

September 5, 2018

INDIANAPOLIS, Sept. 5, 2018 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) and Avid Radiopharmaceuticals, Inc., a wholly owned subsidiary of Lilly, today announced that a Phase 3 study of flortaucipir F 18, a Positron Emission Tomography (PET) imaging agent, met its two primary endpoints, defined as predicting brain tau pathology and predicting Alzheimer's disease diagnosis.

The study, referred to as A16, enrolled a total of 156 end-of-life patients with dementia, mild cognitive impairment, or normal cognition who underwent flortaucipir PET imaging. Subsequently, 67 of these patients were evaluated post-mortem. The study met pre-specified endpoints with flortaucipir demonstrating statistically significant sensitivity and specificity for detecting tau pathology of Braak Stage V/VI, a pathological staging scale for tau neurofibrillary tangles. Flortaucipir also demonstrated statistically significant sensitivity and specificity for detecting a high level of total Alzheimer's disease neuropathologic change (combining both tau and amyloid plaque densities), using the National Institute on Aging and Alzheimer's Association (NIA-AA) neuropathology criteria.

"These encouraging results are a major advance in our ability to image the pathology of Alzheimer's disease," said Mark Mintun, M.D., vice president of Lilly's pain and neurodegeneration research and development. "We hope this and other advances in the field can help speed development of treatments, as well as provide more diagnostic information for doctors taking care of patients suspected of having Alzheimer's."

The company plans to disclose more detailed study results in October at the Clinical Trials on Alzheimer's Disease meeting in Barcelona, and will discuss these findings and potential next steps with the U.S. Food and Drug Administration in the near future.

About Alzheimer's Disease

Alzheimer's disease is a fatal illness that causes progressive decline in memory and other aspects of cognition.¹ Dementia due to Alzheimer's disease is the most common form of dementia, accounting for 60 to 80 percent of all cases.² There are currently an estimated 50 million people living with dementia around the world, with numbers expected to increase to nearly 75 million by 2030 and 132 million by 2050. Almost 10 million new cases of dementia are diagnosed each year worldwide, implying one new case every 3.2 seconds. The current total annual societal and economic estimated cost of dementia is \$818 billion USD worldwide and this year may rise above a trillion USD.³

About Eli Lilly and Company

Lilly is a global healthcare leader that unites caring with discovery to 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 www.lilly.com and www.lilly.com/newsroom/social-channels. P-LLY

This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995). The words "estimate", "project", "intend", "expect", "believe", "target", "anticipate", "guidance" and similar expressions are intended to identify forward-looking statements. Such forward-looking statements reflect, among other things, the company's current expectations, plans and strategies, and anticipated financial results, all of which are subject to known and unknown risks, uncertainties and factors that may cause the company's actual results to differ materially from those expressed or implied by these forward-looking statements. Many of these risks are beyond the company's ability to control or predict. For additional information about the factors that could cause actual results to differ materially from forward-looking statements, please see the company's latest Form 10-K and Form 10-Q filed with the Securities and Exchange Commission. You should not place undue reliance on forward-looking statements, which speak only as of the date of this release. Except as required by law, the company expressly disclaims any obligation to publicly update or revise any forward-looking statements to reflect events after the date of this release.

¹Alzheimer's Association. What is Alzheimer's? http://www.alz.org/alzheimers_disease_what_is_alzheimers.asp. Accessed April 2018.

²Alzheimer's Association. What is Dementia? <http://www.alz.org/what-is-dementia.asp>. Accessed April 2018.

³ Alzheimer's Disease International. Dementia Statistics. <https://www.alz.co.uk/research/statistics>. Accessed April 2018.

Refer to: Nicole Hebert; nicole_hebert@lilly.com; 317.701.9984 (Media)
Kevin Hern; hern_kevin_r@lilly.com; 317.277.1838 (Investors)

Lilly

View original content with multimedia: <http://www.prnewswire.com/news-releases/lilly-announces-positive-phase-3-results-in-study-of-flortaucipir-pet-imaging-agent-300707314.html>

SOURCE Eli Lilly and Company