Lilly announces opening of patient enrollment for New IDEAS: Imaging Dementia - Evidence for Amyloid Scanning study

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- New IDEAS study will focus on African American and Latino participants

- Study to further assess the utility of amyloid brain PET scans for Alzheimer's Disease and other causes of cognitive decline

INDIANAPOLIS, Dec. 14, 2020 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced that qualified physicians may now enroll patients in the study New IDEAS: Imaging Dementia—Evidence for Amyloid Scanning at New IDEAS-Study.org. New IDEAS builds off the historic IDEAS Study, the largest Alzheimer's disease study ever conducted with over 18,000 participants.[1] The new study will enroll 7,000 participants and investigate the impact of amyloid positron emission tomography (PET) scans on patient management and associated health outcomes in a more diverse population, with a goal of over 50% of study participants identifying as Black/African American or Hispanic/Latino.[2] Lilly is pleased to provide a financial contribution to New IDEAS as part of an ongoing partnership with the Alzheimer's Association, Centers for Medicare & Medicaid Services (CMS) and the American College of Radiology (ACR).

"The timely and accurate use of diagnostic tools can facilitate appropriate patient management, treatment decisions and resource planning, which may enable tailored approaches that ultimately improve health," said Daniel M. Skovronsky, M.D., Ph.D., chief scientific officer, Eli Lilly and Company. "The study's particular focus on enrollment of diverse study participants matches Lilly's goal to increase racial and ethnic diversity in clinical trials to better ensure our study populations reflect the real world."

New IDEAS seeks to ensure patients living in under-served communities are included in Alzheimer's disease research. Studies show that in the U.S., Black/African American individuals are about 2 times and Hispanic/Latino individuals are approximately 1.5 times as likely to have Alzheimer's disease and other dementias as those who are white[3]. New IDEAS will also address additional gaps in knowledge that are highly relevant to improved precision in future coverage decisions and implementation of amyloid PET imaging in clinical practice.

"The IDEAS study has provided strong evidence that amyloid PET imaging can be a helpful tool to improve the accuracy of Alzheimer's diagnoses and lead to better patient management, especially in difficult-to-diagnose cases," said Maria C. Carrillo, Ph.D., Alzheimer's Association chief scientific officer and study co-chair. "We are excited that patient enrollment is now open for the New IDEAS Study. New IDEAS study champions will actively conduct outreach and build relationships in Black/African American and Hispanic/Latino communities nationally."

About the New IDEAS Study

The New IDEAS: Imaging Dementia—Evidence for Amyloid Scanning Study is a coverage with evidence development (CED) Study that will build upon the results from the original IDEAS Study.[1] The Study will assess the impact of amyloid PET brain scans on patient management and health outcomes, and will address additional gaps in knowledge that are highly relevant to improve precision in future coverage decisions and implementation of amyloid PET in clinical practice.[2]

A major limitation of the original IDEAS cohort is lack of racial and ethnic diversity, with 88% of participants identified as non-Hispanic White/Caucasian.[1] In addition, patients with typical clinical presentations of Alzheimer's disease were not included in the original IDEAS study, and ApoE genotyping was not performed.[1]

A total of 7,000 Medicare beneficiaries meeting specific inclusion criteria will be enrolled over 30 months at sites throughout the United States as part of this CMS CED program.[2] Dementia specialists will team with trained radiologists and nuclear medicine physicians at PET facilities to order, conduct and interpret amyloid PET scans; imaging results will be provided to the ordering physician for support in further decision making.[2] As in the original study, the New IDEAS Study will include the use of three FDA-approved amyloid PET imaging radiopharmaceuticals, including Amyvid® (Florbetapir F 18 Injection).[2]

Amyvid is indicated for the estimation of beta-amyloid neuritic plaque density in the brain.[4] It is important to note that a positive Amyvid scan does not establish a diagnosis of AD or other cognitive disorder.[4] Information about Amyvid reader training can be accessed at https://amyvid.myregistrationp.com/amyvid/index.do. Amyvid for intravenous use is supplied in multidose vials containing 500-1900 MBq/mL Florbetapir F-18.[4]

The study protocol for New IDEAS was approved by CMS in April 2020 and is currently one of the only ways eligible patients may obtain a Medicare-reimbursed amyloid PET scan.[5]

The New IDEAS Study is directed by the Alzheimer's Association, managed by ACR and advised by CMS. Board-certified neurologists, psychiatrists and geriatric medicine physicians interested in enrolling eligible patients in the New IDEAS Study, along with radiologists, nuclear medicine physicians, and PET facilities that would like to join the study as imaging sites, may apply for participation at https://www.ideas-study.org/Getting-Started. Primary care and other doctors not taking part in the New IDEAS Study are encouraged to refer eligible patients to participating physicians. Eligible patients are Medicare beneficiaries who meet clinical criteria for Mild Cognitive Impairment (MCI) or Dementia as defined by the 2018 National Institute on Aging – Alzheimer's Association Research Framework along with other eligibility requirements.[6] CMS has provided coverage for amyloid PET scans under CED.

For additional information, please visit the study website at www.IDEAS-Study.org.

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.[3] There are currently over 50 million people living with dementia around the world, with numbers expected to increase to nearly 152 million by 2050.[7] 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 U.S. alone, there was an increase of 8 million new caregivers from 2015 to 2020.[8] 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.[7]

Indication and Important Safety Information for AMYVID
AMYVID is a radioactive diagnostic agent for positron emission tomography (PET) imaging of the brain to estimate beta-amyloid neuritic plaque density in adult patients with cognitive impairment who are being evaluated for Alzheimer's Disease and other causes of cognitive decline. A negative AMYVID scan indicates sparse to no neuritic plaques and is inconsistent with a neuropathological diagnosis of Alzheimer's Disease at the time of image acquisition; a negative scan result reduces the likelihood that a patient's cognitive impairment is due to Alzheimer's Disease. A positive AMYVID scan indicates moderate to frequent amyloid neuritic plaques; neuropathological examination has shown this amount of amyloid neuritic plaque is present in patients with Alzheimer's Disease, but may also be present in patients with other types of neurologic conditions as well as older people with normal cognition. AMYVID is an adjunct to other diagnostic evaluations.

Limitations of Use
A positive AMYVID scan does not establish a diagnosis of Alzheimer's Disease or other cognitive disorder. Additionally, the safety and effectiveness of AMYVID have not been established for predicting development of dementia or other neurologic condition, or monitoring responses to therapies.

AMYVID for intravenous use is supplied in multidose vials containing 500-1900 MBq/mL Florbetapir F 18.

Important Safety Information

Warnings and Precautions

Risk for Image Misinterpretation and other Errors
Errors may occur in the AMYVID estimation of brain neuritic plaque density during image interpretation.

Image interpretation should be performed independently of the patient's clinical information. The use of clinical information in the interpretation of AMYVID images has not been evaluated and may lead to errors. Other errors may be due to extensive brain atrophy that limits the ability to distinguish gray and white matter on the AMYVID scan as well as motion artifacts that distort the image.

AMYVID scan results are indicative of the brain neuritic amyloid plaque content only at the time of image acquisition and a negative scan result does not preclude the development of brain amyloid in the future.

Radiation Risk
AMYVID, similar to other radiopharmaceuticals, contributes to a patient's overall long-term cumulative radiation exposure. Long-term cumulative radiation exposure is associated with an increased risk of cancer. Ensure safe handling to protect patients and health care workers from unintentional radiation exposure.

Most Common Adverse Reactions
The most common adverse reactions reported in clinical trials were headache (1.8%), musculoskeletal pain (0.7%), blood pressure increased (0.7%), nausea (0.7%), fatigue (0.5%), and injection site reaction (0.5%).

For Full Prescribing Information, visit http://pi.lilly.com/us/amyvid-uspi.pdf.

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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 certain forward-looking statements about the IDEAS study and about Amyvid® (Florbetapir F 18 Injection), a radioactive diagnostic agent indicated for brain imaging of beta-amyloid plaques in patients with cognitive impairment who are being evaluated for Alzheimer's disease and other causes of cognitive decline. This release reflects Lilly's current beliefs; however, as with any clinical research and development of pharmaceutical products, there are substantial risks and uncertainties in the process of development and commercialization. There is no guarantee that the study will complete as expected or that future study results and patient experience will be consistent with study findings to date or that Amyvid will be commercially successful. 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.

References

1. New IDEAS. Original IDEAS Study. https://www.ideas-study.org/Original-Study. Accessed December 8, 2020.
2. New IDEAS. About Us. https://www.ideas-study.org/About-Us. Accessed December 8, 2020.
3. Alzheimer's Association. Facts and Figures. https://www.alz.org/alzheimers-dementia/facts-figures. Accessed December 8, 2020.
4. AMYVID (Florbetapir F18 Injection) for intravenous use. Full Prescribing Information. Eli Lilly and Company. Dec 2019.

Available at: https://pi.lilly.com/us/amyvid-uspi.pdf.
5. Rabinovici, G., et. al. (2019). Association of Amyloid Positron Emission Tomography With Subsequent Change in Clinical Management Among Medicare Beneficiaries With Mild Cognitive Impairment or Dementia. *JAMA*, 321(13), 1286–1294.
6. Jack, C., Bennett, D., Blennow, K., et al. (2018). NIA-AA Research Framework: Toward a biological definition of Alzheimer's disease. *Alzheimer's & Dementia*, 14(4), 535-562.
7. Alzheimer's Disease International. World Alzheimer Report 2019. https://www.alz.co.uk/research/WorldAlzheimerReport2019.pdf. Accessed December 8, 2020.
8. American Association of Retired Persons (AARP). 2020 Report: Caregiving in the U.S. https://www.aarp.org/content/dam/aarp/ppi/2020/05/full-report-caregiving-in-the-united-states.doi.10.26419-2Fppi.00103.001.pdf. Accessed December 8, 2020.

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