

Life Molecular Imaging is Proud to Support the New IDEAS Study to Further Demonstrate the Value of Amyloid PET for Diagnosing Alzheimer’s Disease in Diverse Communities

Alzheimer’s Association and American College of Radiology lead New IDEAS Study of Brain Amyloid Imaging in a diverse population including participants from Black/African American and Hispanic/Latino communities

Boston, Dec 11 2020 - Life Molecular Imaging is proud to announce it will provide funding and support, along with other industry partners, for a major clinical research study called New IDEAS: Imaging Dementia-Evidence for Amyloid Scanning ([New IDEAS](#)) Study.

The New IDEAS study expands on the aims of the original [IDEAS](#) Study by gathering more data to determine if an amyloid PET scan as an adjunct to clinical workup helps physicians provide a more accurate diagnosis and better treatment decisions for a diverse population, including more than 50% Black/African American and Hispanic/Latino study participants.¹ Neuraceq[®], the Life Molecular Imaging’s radiopharmaceutical for the detection of amyloid plaque, will be one of the three tracers used in the study.

“By enrolling a diverse population, the New IDEAS Study demonstrates the commitment to better understanding the role of brain amyloid imaging for all people,” said Andrew Stephens, M.D., Ph.D., Chief Medical Officer of Life Molecular Imaging. “We believe that the inclusivity of this study will further help to inform the Center for Medicare and Medicaid Services (CMS) and the medical community of the value of amyloid PET scans.”

By 2050, the number of people age 65 and older with Alzheimer’s dementia in the U.S. is projected to reach 13.8 million, with Black/African American and Hispanic/Latino communities disproportionately more likely than whites to have Alzheimer’s or other dementias.² The New IDEAS Study, which is led by the Alzheimer’s Association, managed by the American College of Radiology, and advised by CMS, will enroll 7,000 Medicare beneficiaries who meet clinical criteria for mild cognitive impairment (MCI) or dementia. At least 4,000 enrolled will be Black/African American and Hispanic/Latino.

“Life Molecular Imaging is confident that the New IDEAS study will add further evidence to demonstrate the value of amyloid PET scans for a more accurate diagnosis, better patient management and improved outcomes,” said Ludger Dinkelborg, Ph.D., Managing Director of Life Molecular Imaging. “We are honored to be part of such an inclusive trial and look forward to the results of the study.”

The study will enroll participants over the next 30-36 months at approximately 350 sites across the United States. Participating providers will be reimbursed for the Neuraceq[®] PET scan under the CMS Coverage with Evidence Development (CED) policy with participating patients responsible for their plan’s co-pay.

Qualifying dementia specialists — physicians trained and board certified in neurology, psychiatry or geriatric medicine — and radiologists or nuclear medicine physicians who offer amyloid positron emission tomography (PET) scans can now enroll patients in the New IDEAS Study. More information about becoming a participating site can be found [here](https://www.ideas-study.org/Getting-Started) (<https://www.ideas-study.org/Getting-Started>).

Doctors not directly enrolling study participants are urged to refer eligible patients to a New IDEAS [participating physician](https://www.ideas-study.org/Find-a-Site) for evaluation (<https://www.ideas-study.org/Find-a-Site>).

About Neuraceq® (florbetaben F18 injection)

Indication

Neuraceq® is a radioactive diagnostic agent indicated 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 (AD) and other causes of cognitive decline.

A negative Neuraceq® scan indicates sparse to no amyloid neuritic plaques and is inconsistent with a neuropathological diagnosis of AD at the time of image acquisition; a negative scan result reduces the likelihood that a patient's cognitive impairment is due to AD. A positive Neuraceq® scan indicates moderate to frequent amyloid neuritic plaques; neuropathological examination has shown this amount of amyloid neuritic plaque is present in patients with AD but may also be present in patients with other types of neurologic conditions as well as older people with normal cognition. Neuraceq® is an adjunct to other diagnostic evaluations.

Limitations of Use

- A positive Neuraceq® scan does not establish the diagnosis of AD or any other cognitive disorder.
- Safety and effectiveness of Neuraceq® have not been established for:
 - Predicting development of dementia or other neurologic conditions.
 - Monitoring responses to therapies.

Important Safety Information

Risk for Image Interpretation and Other Errors

Neuraceq® can be used to estimate the density of beta-amyloid neuritic plaque deposition in the brain. Neuraceq® is an adjunct to other diagnostic evaluations. Neuraceq® images should be interpreted independent of a patient's clinical information. Physicians should receive training prior to interpretation of Neuraceq® images. Following training, image reading errors (especially false positives) may still occur. Additional interpretation errors may occur due to, but not limited to, motion artifacts or extensive brain atrophy.

Radiation Risk

Administration of Neuraceq®, 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. It is important to ensure safe handling to protect patients and health care workers from unintentional radiation exposure.

Most Common Adverse Reactions

In clinical trials, the most frequently observed adverse drug reactions in 872 subjects with 1090 Neuraceq® administrations were injection/application site erythema (1.7%), injection site irritation (1.1%), and injection site pain (3.4%).

Neuraceq® is a registered trademark of Life Molecular Imaging SA in the US, EU and other countries.

About Life Molecular Imaging (LMI)

Life Molecular Imaging (LMI, formerly Piramal Imaging) was formed in 2012 with the acquisition of the molecular imaging research and development portfolio of Bayer Pharma AG. It is now part of the Alliance Medical Group (a member of the Life Healthcare Group) offering an integrated business including research and development laboratories, a network of cyclotrons, radiopharmacies and imaging facilities. By developing novel PET tracers for molecular imaging, LMI is focusing on a key field of modern medicine. The organization strives to be a leader in the Molecular Imaging field by developing innovative products that improve early detection and characterization of chronic and potentially life-threatening diseases, leading to better therapeutic outcomes and improved quality of life. Please visit <https://life-mi.com>.

About Life Healthcare Group

Life Healthcare Group is a market-leading, international, diversified healthcare organization. Life Healthcare has over 33 years' experience in the South African private healthcare sector, and currently operates 66 healthcare facilities in southern Africa. Services include acute hospital care, acute physical rehabilitation, acute mental healthcare, renal dialysis, and employee health and wellness services. The Group owns Alliance Medical Group, the leading independent provider of medical imaging services within Europe, operating across 10 international countries. Life Healthcare also owns Scanmed S.A. (Poland) which provides healthcare and medical services in 20 Polish cities, with over 65 medical specialisations and diagnostic services available in 32 facilities. For more information visit lifehealthcare.co.za

For media queries

Nicole Fletcher | Marketing Communications | Life Molecular Imaging
Tel#: 857-202-1122 | n.fletcher@life-mi.com

Additional New IDEAS Study news media contacts:
Alzheimer's Association Media Relations, 312-335-4078, media@alz.org
American College of Radiology, 703-648-8936, PR@acr.org

References

- 1 New IDEAS-study press release (Dec 2020) <https://www.ideas-study.org/News/New-Research-Study>
- 2 Alzheimer Association Facts and Figures. <https://www.alz.org/media/Documents/alzheimers-facts-and-figures.pdf>