

## Press Release

### For Immediate Release

#### **Life Molecular Imaging Applauds the Publication of the IDEAS Study Aim I Results**

Results show that Amyloid PET Imaging was associated with changes in clinical management for Medicare beneficiaries with MCI, dementia, cognitive impairment or Alzheimer's Disease

**BOSTON, MA - April 8, 2019** On April 2<sup>nd</sup>, 2019, the Journal of the American Medical Association (JAMA) published results from the multi-center Imaging Dementia-Evidence for Amyloid Scanning (IDEAS) study of more than 11,000 Medicare beneficiaries. Life Molecular Imaging's (LMI; formerly Piramal Imaging) Neuraceq<sup>TM</sup> (florbetaben F18 injection) amyloid PET Imaging tracer was one of the three tracers used in the study. The study was designed to determine if amyloid PET imaging is associated with subsequent changes in patient management of those with mild cognitive impairment (MCI) or dementia of uncertain etiology.<sup>1</sup>

Data reveals that physicians changed their clinical management of more than 60 percent of patients in the study, more than double the number the authors had predicted. Physicians' medical management changed in nearly two-thirds of cases including the use of medications and counselling. Further, knowledge of amyloid PET results altered the diagnosis of the cause of cognitive impairment in more than one in three study participants.<sup>2</sup>

"The accurate diagnosis of patients with cognitive impairment who are being evaluated for Alzheimer's disease and other causes of cognitive decline continues to be of utmost importance. The Aim I results of the IDEAS Study further support the need for a precise diagnostic tool in the clinical routine and add to the growing body of evidence to support a positive review by Centers for Medicare & Medicaid Services (CMS) for reimbursement of amyloid PET imaging," said Ludger Dinkelborg, Ph.D., Managing Director at LMI. "We congratulate the IDEAS Study team on these important results and look forward to continuing our collaboration on the next step towards solidifying the role of amyloid PET imaging for patients with cognitive impairment or dementia."

The IDEAS team is currently analyzing data on the study's second aim: how amyloid PET scans affect health outcomes. The researchers are using CMS claims data to document hospitalization rates and Emergency Department visits for IDEAS participants and comparing them to similar patients who did not undergo amyloid PET. The study team plans to publish their findings in 2020. In addition, the researchers are developing a second study (known as New IDEAS) to include more people with both typical and atypical clinical presentations of Alzheimer's and recruit a study group that better reflects the racial and socioeconomic diversity of the national population.<sup>2</sup>

The IDEAS study was managed by the American College of Radiology and led by scientists at the Alzheimer's Association, UC San Francisco, Brown University School of Public Health, Virginia Commonwealth University School of Public Health, Washington University School of Medicine in St. Louis, UC Davis School of Medicine, and the Kaiser Permanente Division of Research.

## 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:
  - o Predicting development of dementia or other neurologic conditions;
  - o 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%).

### 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 life-threatening diseases, leading to better therapeutic outcomes and improved quality of life. Please visit <https://life-mi.com>.

### **About Life Healthcare Group**

The Life Healthcare Group has more than 33 years' experience in the private healthcare and hospital industry. Headquartered in Johannesburg, South Africa, the Group is a listed company on the Johannesburg Stock Exchange. The company's primary business is private acute hospital care with 65 healthcare facilities in seven of South Africa's nine provinces and one hospital in Botswana, as well as providing services for acute physical rehabilitation, acute mental healthcare and renal dialysis. Life Employee Health Solutions services both occupational health and employee wellness to private and public employers. The Group includes an international presence through Alliance Medical Group (UK/Europe) and Scanmed S.A. (Poland). For more information visit [lifehealthcare.co.za](http://lifehealthcare.co.za)

### **References:**

1. JAMA. 2019;321(13):1286-1294. doi:10.1001/jama.2019.2000;
2. IDEAS-study press release (April 2019) "Alzheimer's Diagnosis, Management Improved by Brain Scans <https://www.ideas-study.org/2019/04/01/results-of-the-ideas-study-just-published-in-jama/>

### **For media queries**

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

###