Life Molecular Imaging announces presentation of new clinical data of the next generation Tau PET Tracer PI-2620 at the AD/PD™ 2019 Conference

Berlin, Germany, 27 March 2019 – Life Molecular Imaging (LMI, formerly Piramal Imaging) announced today the presentation of new clinical data of the next generation Tau PET tracer PI-2620 at the 14th International Conference on Alzheimer’s and Parkinson’s Diseases (AD/PD™), 26th – 31st in Lisbon, Portugal.

Tau depositions, in conjunction with beta-amyloid plaques, represent the critical pathologies in Alzheimer’s disease (AD) with Tau further playing an important role in other neurodegenerative diseases. Visualizing tau deposition and its spread in cognitively impaired subjects has the potential to provide a better understanding of the disease and to enable an earlier and more accurate diagnosis of AD and other neurodegenerative disorders.

“We are pleased by the promising data generated in collaboration with our academic and industry partners presented at this meeting”, said Andrew Stephens, M.D., Ph.D., Chief Medical Officer of Life Molecular Imaging. “LMI continues to develop the science and expand the availability of this innovative imaging agent. The combination of Neuraceq, our approved and globally available imaging agent for detection of beta-amyloid plaques, and PI-2620 for the detection of tau pathology, provides a powerful imaging biomarker platform for the appropriate characterization of subjects enrolled in clinical trials to support drug development in neurodegenerative diseases.”

The PI-2620 data presented at this year AD/PD conference highlight:

• Excellent signal-to-background ratio supporting the detection of Tau depositions in early stages of AD, particularly in mesialtemporal brain regions
• A broad dynamic range seen across subjects with mild cognitive impairment and AD
• A comprehensive kinetic analysis validating an early imaging window in AD
• Visualization of Tau accumulation in 4R-tauopathies such as progressive supranuclear palsy (PSP)

LMI, together with its academic and industrial manufacturing partners, has established a global supply network making PI-2620 available in the US, Canada, Europe, China, Thailand, South Korea, Japan and Australia.

Presentations on PI-2620 by Life Molecular Imaging, pharma and academic partners include:

1) Determination of the optimal scanning time for the assessment of Tau deposition in Alzheimer’s Disease using PI-2620 PET  
   March 29 | 10.30 - 10.45 | Auditorium III+IV | Oral presentation by A. Stephens

2) Evaluation of $^{18}$F-PI-2620, a novel selective Tau tracer for the assessment of Alzheimer’s and non-Alzheimer’s tauopathies  
   March 29 | 15:45 – 16:00 | Exhibition | Oral presentation by V. Villemagne

3) $^{18}$F-PI-2620 Tau-PET in progressive supranuclear palsy – a multi-center evaluation  
   March 31 | 14.00 - 14.15 | Auditorium VI+VII | Oral presentation by T. van Eimeren
4) Evaluation of Tau deposition in amyloid positive MCI or mild-AD dementia subjects from the elenbecestat MissionAD program using \(^{18}\)F-PI-2620 PET
   March 27-28 | 06.00 - 16.00 | Exhibition | Poster presentation by A. Stephens

5) Tau-PET Imaging of Alzheimer and non-Alzheimer dementia using \(^{18}\)F-PI 2620
   March 27-28 | 08.00 - 18.00 | Exhibition | Poster presentation by M. Mimura

About Life Molecular Imaging (LMI)

LMI (formerly Piramal Imaging) was formed in 2012 with the acquisition of the molecular imaging research and development portfolio of Bayer Pharma AG, and is now part of the Alliance Medical Group, 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. LMI 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 PI-2620

PI-2620 is an \(^{18}\)F-labeled investigational PET tracer that was discovered in a research collaboration between Life Molecular Imaging and AC Immune, a Swiss-based clinical stage biopharmaceutical company focused on neurodegenerative diseases. Life Molecular Imaging has the exclusive, world-wide license for research, development and commercialization of tau PET tracers generated within the discovery program.

About Neuraceq™ (florbetaben 18F)

Indication and Important Safety Information

Neuraceq is a radiopharmaceutical for diagnostic use indicated for Positron Emission Tomography (PET) imaging of beta-amyloid neuritic plaque density in the brains of adult patients with cognitive impairment who are being evaluated for Alzheimer’s disease (AD) and other causes of cognitive impairment. Neuraceq should be used in conjunction with a clinical evaluation. A negative scan indicates sparse or no plaques, which is not consistent with a diagnosis of AD. For the limitations in the interpretation of a positive scan, please refer to the approved product information.

The efficacy of florbetaben (18F) for predicting development of AD or monitoring response to therapy has not been established. Neuraceq images should only be interpreted by readers trained in the interpretation of PET images with florbetaben (18F). Following training, image reading errors (including false positive or false negative interpretation of Neuraceq images) may still occur. Administration of Neuraceq, as with other radiopharmaceuticals, results in a low amount of ionizing radiation exposure and appropriate safety precautions should be taken to avoid unintentional radiation exposure. The most common side effects observed in clinical trials were injection site pain and injection site erythema.

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