

Life Molecular Imaging announces presentation of new scientific data at the Human Amyloid Imaging Meeting

Research Presented Provides Further Insights into Amyloid and Tau Imaging Agents

BERLIN, Germany, 15 January 2020 – Life Molecular Imaging (LMI) announces today that new research results on its approved and investigational positron emission tomography (PET) neuroimaging tracers will be presented at the 14th Human Amyloid Imaging (HAI) meeting in Miami (January 15-17, 2020). The contributions cover nine (9) presentations demonstrating the value of its approved compound Neuraceq™ (florbetaben F18 injection), and fifteen (15) presentations supporting the potential of its investigational Tau-PET tracer PI-2620.

A comprehensive clinical evaluation with imaging biomarkers, such as amyloid PET imaging, can improve the diagnostic accuracy. In addition, the combination of Neuraceq™ and the investigational PI-2620 tracer for the detection of tau pathology, provides a powerful PET imaging biomarker platform for the appropriate characterization of subjects enrolled in clinical trials supporting drug development in neurodegenerative diseases. The value of imaging biomarkers, particularly the combination of amyloid-beta and tau in the same subjects, is increasingly recognized. Highlights also include the presentation of the results from a multi-center evaluation of PI-2620 in subjects with progressive supranuclear palsy (PSP) as well as a poster describing the performance of PI-2620 in subjects with corticobasal syndrome (CBS).

"We are particularly impressed by the data that the research groups collected over the last year in PSP patients" said Dr. Andrew Stephens, MD, PhD, CMO of Life Molecular Imaging. "PI-2620's ability to also detect 4R tauopathies, such as PSP and CBS allows us to pursue the development of PI-2620 not only for AD, but also for additional neurodegenerative diseases, where previous tau tracers showed limitations."

Datasets involving LMI compounds presented at the HAI meeting include the following presentations:

Amyloid-PET Neuroimaging presentations involving Neuraceq (florbetaben F18 injection):

January 15, 2020

- Bullich et al. (Poster #5 Session 1A): Early detection of amyloid load using ¹⁸F-Florbetaben PET
- Klein et al. (Poster #21 Session 1A): Concordance of visual and quantitative assessments of baseline amyloid scans in the GRADUATE gantenerumab studies
- Landau et al. (Poster #24 Session 1A): Validation of highly sensitive and specific florbetaben positivity thresholds using ADNI participants and young controls
- Lao et al. (Poster #25 Session 1A): Additive contribution of white matter hyperintensity to amyloid and neurodegeneration on cognitive decline in a diverse, community-based cohort of older adults

January 16, 2020

- Gispert et al. (Poster #84 Session 2A): Preliminary quantitative results of the AMYPAD prognostic and natural history study
- Seo et al. (Poster #88 Session 2A): Head-to-head comparison of F-Florbetaben and F-Flutemetamol uptakes in the cortex, striatum and white matter

- Ewers et al. (Poster #69 Session 2A): Higher microglia biomarker levels are associated with slower rates of amyloid-beta accumulation in humans and in a transgenic mouse model of amyloid-beta
- Kim et al. (Poster #91 Session 2A): Prevalence of amyloid PET positivity in cognitively normal East Asian populations

January 17, 2020

- Iaccarino et al. (Poster #137 Session 3A): In vivo amyloid-PET and tau-PET evidence in early-onset Alzheimer's Disease: taking the LEADS

Tau-PET Neuroimaging presentations involving PI-2620:

January 15, 2020

- Bischof et al. (Poster #4 Session 1A): A pons cluster detected by a data-driven approach may serve as a favorable reference region for ¹⁸F-PI-2620 Tau PET analysis
- Stevenson et al. (Poster #48 Session 1A): Monitoring disease pathophysiology using multiparametric PET acquisitions: The McGill TRIAD Cohort

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- Agüero et al. (Session 3: Neuropathology I): Comparison of autoradiographic binding profiles of Flortaucipir, MK-6240 and PI-2620 in human postmortem tissue samples across the spectrum of neurodegenerative diseases
- Malarte et al. (Session 4: Neuropathology II): In vitro characterization of second-generation tau pet tracers in human autopsy brain tissue
- Brendel et al. (Session 5: Clinical I): ¹⁸F-PI-2620 tau-PET in Progressive Supranuclear Palsy – A multi-center evaluation
- Stephens et al. (Poster #90 Session 2A): PI-2620 Tau PET is associated with amyloid-beta levels in scans from subjects of the elenbecestat MissionAD program
- Villemagne et al. (Poster #76 Session 2A): Assessing A β , tau, and reactive astrocytosis in aging and AD

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- Brendel et al. (Poster #122 Session 3A): Perfusion-phase ¹⁸F-PI-2620 tau-PET imaging as a surrogate marker of neuronal injury
- Brendel et al. (Poster #123 Session 3A): Binding characteristics of ¹⁸F-PI-2620 differentiate the clinically predicted tau isoform in suspected 3/4-repeat and 4-repeat tauopathies
- Brendel et al. (Poster #124 Session 3A): ¹⁸F-PI-2620 tau-PET for assessment of heterogeneous neuropathology in corticobasal syndrome
- Bullich et al. (Poster #125 Session 3A): Optimal reference region for the quantification of tau load in the brain using ¹⁸F-PI-2620 PET
- Koran et al. (Poster #143 Session 3A): Validation of clinical protocols for clinicians analyzing ¹⁸F-PI-2620 tau PET/MRI images
- Dore et al. (Session 7: Tau I): Towards a CenTauR cortical mask

- Toueg et al. (Poster #169 Session 3A): Elevated medial temporal lobe Tau PET with ¹⁸F-PI2620 in normal controls with “borderline” neuropsychological testing profiles
- Trelle et al. (Poster #170 Session 3A): Hippocampal tau accumulation predicts individual differences in episodic memory in cognitively normal older adults

About Neuraceq (florbetaben F18 injection)

Indication

Neuraceq™ (florbetaben F18 injection) is a radioactive diagnostic agent indicated for Positron Emission Tomography (PET) imaging of the brain to estimate β-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 β-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 PI-2620

Tau deposits, in conjunction with beta-amyloid plaques, represent the other pathological hallmark of Alzheimer's disease, with tau deposits further playing an important role in other neurodegenerative diseases. PI-2620 is binding to 3R/4R and 4R tau deposits and is a next generation 18F-labeled investigational PET tracer with favourable properties and imaging characteristics. It was discovered in a research collaboration between Life Molecular Imaging and AC Immune, a Swiss-based clinical stage biopharmaceutical company. Life Molecular Imaging has the exclusive, world-wide license for research, development and commercialization of tau PET tracers generated within the discovery program.

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

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. Visit lifehealthcare.co.za

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