

Life Molecular Imaging announces presentation of new research results at the European Association of Nuclear Medicine 2019 Annual Meeting

Research presented provides insights into LMI compounds comprising Neuraceq (florbetaben 18F), PI-2620, RM2, GP1 and FSPG

BERLIN, Germany, 13 October 2019 – Life Molecular Imaging (LMI) announces today the presentation of thirteen(13) oral presentations and fifteen(15) poster presentations demonstrating the value of its approved compound Neuraceq (florbetaben 18F) and the potential of its investigational tracers PI-2620, RM2, GP1 and FSPG, at the European Association of Nuclear Medicine Annual Meeting 2019, October 12th – 16th in Barcelona, Spain. These presentations cover neurodegenerative diseases like Alzheimers disease and Progressive Supranuclear Palsy, oncological, cardiovascular and inflammatory diseases.

Notable oral presentations comprise:

Florbetaben Amyloid-PET Neuroimaging:

- Schuerer et al. (OP-032, Sunday, October 13th): Impact of deep learning artificial intelligence approaches on amyloid PET diagnosis”

PI-2620 Tau-PET Neuroimaging:

- Barthel et al. (OP-226, Sunday, October 13th): “Multi-Centre Evaluation of the New-Generation Tau PET Tracer [18F]PI-2620 in Progressive Supranuclear Palsy”
- Mueller et al. (OP-379, Monday, October 14th): “Discovery and preclinical characterization of [18F]PI-2620, a next generation tau PET tracer for the assessment of tau pathology in Alzheimer’s disease and other tauopathies”
- Song et al. (OP-460, Sunday October 14th): “Cortical Binding Characteristics of 18F-PI-2620 Differentiate the Clinically Predicted Tau Isoform in Suspected 3/4-Repeat and 4-Repeat Tauopathies”
- Beyer et al. (OP-464, Monday, October 14th): “Early-Phase 18F-PI-2620 Tau-PET Imaging as a Surrogate Marker of Neurodegeneration”
- Mueller et al. (OP-602, Tuesday, October 15th): “Preclinical comparison of the first generation Tau PET tracer AV1451 and two next-generation Tau PET tracers, MK-6240 and PI-2620”

68Ga-RM2 Tumor Imaging & 177Lu-RM2 Tumor Therapy:

- Heuschkel et al. (OP-047, Sunday, October 13th): “Monocentric Intraindividual Comparison of 68Ga-RM2 and 68Ga-PSMA PET/CT in mCRPC”
- Fernandez et al. (OP-622, Tuesday, October 15th): „ Preliminary Evaluation of Tumor Uptake and Laboratory Parameters After a Single Dose of 177Lu-RM2 Radioligand Therapy in Metastatic Castrate-Resistant Prostate Cancer”
- Iagaru et al. (OP-726, Wednesday, October 16th): “68Ga-RM2 PET/CT in Patients with Newly Diagnosed Intermediate- or High-Risk Prostate Cancer”
- Schollhammer et al. (OP-729, Wednesday, October 16th): “Prospective comparison of 68Ga-RM2 PET/CT and 68GaPSMA-617 PET/CT for initial staging of prostate cancer”

- Kurth et al. (OP-755, Wednesday, October 16th): “First in human dosimetry of [177Lu]RM2: A gastrin-releasing peptide receptor antagonist for targeted radiotherapy of metastasized castration resistant prostate cancer”

18F-GP1 Thrombus Imaging:

- Hugenberg et al. (OP-234, Sunday, October 13th): “Detection of Thrombi inside LVADs using 18F-GP1-PET/CT – Preliminary Results”

18F-FSPG Inflammatory Bowel Disease:

- Lee et al. (OP-786, Wednesday, October 16th): “Diagnostic validity of (S)-4-(3-[18F]Fluoropropyl)-L-glutamic acid ([18F]FSPG) positron emission tomography/computed tomography (PET/CT) for the assessment of disease activity in patients with inflammatory bowel disease: a phase 2 pilot study

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 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 RM2

RM2 is a small peptide binding with high affinity to the GRP receptor, highly expressed in early and recurrent prostate cancer and other tumors. Its metal-chelate moiety allows for labeling with gallium-68 or with lutetium-177 for further exploration as theranostic agent.

About GP1

GP1 is a small molecule labeled with fluorine-18 designed for thrombus imaging. It binds with high affinity and selectivity to GPIIb/IIIa, the key receptor involved in thrombus formation. Clinical proof-of-concept study confirmed its potential for imaging acute deep vein thrombosis and pulmonary embolism.

About FSPG

FSPG is a small molecule labeled with fluorine-18. It is specifically targeting the system xc- transporter that is part of the cellular redox maintenance machinery balancing reactive oxidative stress conditions. High transporter activity is observed on tumors from several entities and other diseases associated with oxidative stress.

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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