Life Molecular Imaging and Positron Pharma announce a strategic partnership for manufacturing and distribution of PI-2620 in Chile

*Investigational tau imaging agent PI-2620 added to the existing imaging biomarker platform for research studies in Chile. First patients have been examined.*

BERLIN and SANTIAGO, Chile (PRWEB) October 14, 2019 -- Life Molecular Imaging and Positron Pharma SA today announce that the companies have agreed to add the tau imaging agent PI-2620 to the existing imaging biomarker portfolio, providing Positron Pharma with rights to manufacture and distribute PI-2620 for clinical trials throughout Chile. This agreement builds on a long-lasting partnership. Neuraceq™, the LMI imaging agent for the detection of beta-amyloid plaques, has been available in Chile via Positron Pharma since 2018.

Alzheimer’s disease, a condition that slowly destroys memory and cognitive abilities, currently affects more than 188,000 people in Chile.1 An estimated 20-30% of patients with dementia have been misdiagnosed and often experienced extended diagnostic episodes before receiving a clinical diagnosis. Today, a comprehensive clinical evaluation in combination with in-vivo biomarkers, such as beta-amyloid and tau PET imaging, can improve the diagnostic accuracy, allowing for improved patient management. 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 and to also support drug development in neurodegenerative diseases.

“Alzheimer’s disease is a severe problem for the Chilean population and our government adopted a national plan on dementia in 2017 which includes improved access to care, support, treatment and research,” said Andres Amaral, General Manager of Positron Pharma. “In partnership with Life Molecular Imaging we have supported this common goal by providing Neuraceq™ in Chile. Brining PI-2620 to Chile for clinical trials adds to our commitment to provide the best diagnostic options for our patients. The first subjects have been recruited and imaged with both tracers to study patients with logopenic variant of primary progressive aphasia or early onset dementia in the context of two investigator sponsored studies.”

“Life Molecular Imaging continues to expand the availability of innovative molecular imaging agents and we are truly excited through this collaboration with Positron Pharma to better serve physicians and our pharma partners with both, Neuraceq™ and the investigational PI-2620 tau PET tracer for clinical trials,” said Ludger Dinkelborg, Ph.D., Managing Director at LMI.

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:
  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 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 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

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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

About Positron Pharma SA
Positron Pharma SA was founded in 2010 and is the leading provider of PET radiopharmaceuticals in Chile. By introducing cutting-edge technology and new radiopharmaceuticals Positron Pharma aims to support PET centers, physicians and their patients with best-in-class products allowing for early detection, characterization and treatment of life-threatening diseases. As part of this commitment Positron Pharma also supports different clinical trials and investigator sponsored studies in the field of oncology and neurodegenerative disorders.

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