

PRESS RELEASE

Life Molecular Imaging and Jubilant Radiopharma announce Neuraceq® availability in Mobile, AL

Improved supply capabilities of Neuraceq® to provide better patient access to beta-amyloid PET

Boston, July 9th, 2024 – Life Molecular Imaging (LMI) and Jubilant Radiopharma, a global company that offers radiopharmaceuticals and radiopharmacies for nuclear medicine, announce the expansion of their strategic partnership and licensing agreement to provide and distribute Neuraceq® from Jubilant’s single photon emission computed tomography (SPECT) and Positron Emission Tomography (PET) radiopharmaceutical manufacturing site located in Mobile, AL. The first doses have been made available on July 9th, 2024.



Neuraceq® is an FDA-approved imaging agent for the detection of beta-amyloid plaques in the brain of adult patients with cognitive impairment who are being evaluated for Alzheimer’s disease and other causes of cognitive decline. Neuraceq® is used in clinical routine and is also a powerful imaging biomarker for the appropriate characterization of subjects assessed for treatment eligibility with newly approved anti-amyloid drugs, or for enrollment in clinical trials to further support drug development in neurodegenerative diseases.

“Expanding Neuraceq® manufacturing in Mobile in collaboration with Jubilant, further reinforces Life Molecular Imaging’s commitment to meeting the increasing demand for amyloid detection to confirm eligibility for new therapies. We are excited to support the growing needs of the customers in the region, and to provide Neuraceq® access for the benefit of physicians, patients, and our pharma partners,” said Colleen Ruby, US Country Head and Chief Operating Officer, Americas and APAC.

“More than 6.2 million Americans are currently living with Alzheimer’s disease. A progressive brain disorder that impacts memory, thinking and language skills, and the ability to carry out the simplest tasks. The Jubilant Radiopharma Team is excited to bring Neuraceq® to physicians and patients in the Mobile, AL area,” said Renato Leite, President, Jubilant Radiopharmacies. “The availability of Neuraceq® offers new hope through the detection of beta-amyloid plaques in the brain of adult patients with cognitive impairment who are being evaluated for Alzheimer’s disease”

About Neuraceq (florbetaben 18F)

Indication

Neuraceq® 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 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

Errors may occur in the Neuraceq® estimation of brain neuritic β-amyloid plaque density during image interpretation. Image interpretation should be performed independently of the patient’s clinical information. The use of clinical information in the interpretation of Neuraceq® images has not been evaluated and may lead to errors. Errors may also occur in cases with severe brain atrophy that limits the ability to distinguish gray and white matter on the Neuraceq® scan. Errors may also occur due to motion artifacts that result in image distortion. Neuraceq® scan results are indicative of the presence of brain neuritic β-amyloid plaques only at the time of image acquisition and a negative scan result does not preclude the development of brain neuritic β-amyloid plaques in the future.

Radiation Risk

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. Ensure safe handling to protect patients and health care workers from unintentional radiation exposure.

Common Adverse Reactions

The overall safety profile of Neuraceq® is based on data from 1,090 administrations of Neuraceq® to 872 subjects. No serious adverse reactions related to Neuraceq® administration have been reported. The most frequently observed adverse drug reactions in subjects receiving Neuraceq® were injection site reactions consisting of erythema (1.7%), irritation (1.1%) and pain (3.4%).

For more information please visit: neuraceq.com

About Life Molecular Imaging (LMI)

Life Molecular Imaging (LMI) is an international pharma company dedicated to developing and offering novel cutting-edge PET radiopharmaceuticals for imaging of neurodegenerative and cardiovascular diseases. The organization strives to be a leader in the molecular imaging field. Our mission is to pioneer innovative PET products that improve early detection and characterization of chronic and life-threatening diseases, leading to better therapeutic outcomes and improved quality of life. By advancing novel PET radiopharmaceuticals for molecular imaging, LMI is focusing on a key field of modern medicine. LMI is an affiliate of Life Healthcare Group – an international people-centered, diversified healthcare organization with four decades of experience in the South African private healthcare sector. To learn more, please visit <https://life-mi.com>.

About Life Healthcare Group

Life Healthcare is a global people-centered, diversified healthcare organization listed on the Johannesburg Stock Exchange. Life Healthcare has over 40 years' experience in the South African private healthcare sector, and currently operates 64 healthcare facilities in southern Africa. Services include acute hospital care, acute physical rehabilitation, acute mental healthcare, renal dialysis, oncology, diagnostic and molecular imaging and health risk management services which include occupational health and wellness services. The Group also owns Life Molecular Imaging, a radiopharmaceutical business dedicated to developing and globally commercializing innovative molecular imaging agents for use in PET-CT diagnostics to detect specific diseases. Visit: <https://www.lifehealthcare.co.za/> | <https://life-mi.com/>

About Jubilant Radiopharma

Jubilant Radiopharma, a division of Jubilant Pharma Ltd., is an industry-leading radiopharmaceutical business that comprises development, manufacturing and commercialization of products through its Radiopharmaceuticals business and distribution through its national network of Radiopharmacies. The division's Radiopharmacies business is the second largest radiopharmacy network in the US with 46 pharmacies distributing nuclear medicine products to the largest national Group Purchasing Organisations (GPOs), regional health systems, stand-alone imaging centres, cardiologists and hospitals. This business has over 30 years of experience in serving the US nuclear medicine community and its current geographical reach enables it to serve over four million patients yearly. Jubilant Radiopharma is focused on "Improving Lives through Nuclear Medicine".

For media queries

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