

## PRESS RELEASE

### **Life Molecular Imaging and ITELPHARMA Announce a Strategic Partnership for Supply and Production of NeuraCeq™ in Puglia, Italy**

Improved supply capabilities of NeuraCeq™ in Puglia, Basilicata, Calabria and Campania to meet increased demand in Italy

**BERLIN-RUVO DI PUGLIA, 11 November, 2019.** Life Molecular Imaging (LMI) and ITELPHARMA (ITEL) announced today that both companies have entered into a strategic partnership and licensing agreement providing ITEL with rights to manufacture and distribute NeuraCeq™ throughout the Italian regions of Puglia, Basilicata, Calabria and Campania.

Until recently these Italian regions were served by Curium Pharma Italy S.r.l. (Curium) that will retain distribution rights to supply NeuraCeq™ in the framework of the current public tenders won by them up to the expiry of these contracts. LMI would like to thank Curium for their efforts in the past and going forward to serve these customers for the duration of their respective contracts.

ITEL will start manufacturing NeuraCeq™ tracers in their radiopharmacy in Ruvo di Puglia as soon as the necessary authorizations are garnered from the applicable Italian authorities.

NeuraCeq™ is an approved imaging agent for the detection of beta-amyloid plaques in clinical routine. It is also a powerful imaging biomarker for the appropriate characterisation of subjects enrolled in clinical trials to support drug development in neurodegenerative diseases.

*“Life Molecular Imaging continues to expand the availability of innovative molecular imaging agents and we are truly excited through this collaboration with ITEL to better serve physicians and our pharma partners with our approved NeuraCeq™ for clinical routine and research.”* said Ludger Dinkelborg, Ph.D., Managing Director at LMI.

*“We are very proud of this collaboration with Life Molecular Imaging”* - declares Michele Diaferia, ITEL CEO. *“This is an important goal in the process of increasing our company’s investments in the field of chemical-pharmaceutical activity in Italy. Our efforts in supporting competence, knowledge and research, materialize today in this strategic partnership. We are confident that, with our common activities in synergy with LMI, we will be able to give a strong scientific contribution to fight against diseases such as Alzheimer’s that still has a strong social impact”*.

#### **About NeuraCeq™ (florbetaben 18F)**

##### **Indication**

NeuraCeq™ is a radioactive diagnostic agent indicated for Positron Emission Tomography (PET) imaging of the brain to estimate beta 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 (i) predicting development of dementia or other neurologic conditions and (ii) monitoring responses to therapies.

#### **Important Safety Information**

##### **Risk for Image Interpretation and Other Errors**

NeuraCeq™ can be used to estimate the density of beta-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 artefacts 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 1077 subjects with 1295 NeuraCeq™ administrations were injection/application site erythema (1.7%), and injection site pain (3.4%).

#### **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](http://lifehealthcare.co.za)

### **About ITEL**

ITEL Telecomunicazioni Srl (also known as ITEL) is an Italian company established in 1982. It has three business sectors: 1) production of radiopharmaceuticals for PET diagnostics and supply of products and services for nuclear medicine, radioprotection and microbiology; 2) design and production of integrated technologies for diagnostics, nuclear medicine and advanced radiotherapy, including “turnkey” solutions; 3) an electromagnetic compatibility test laboratory, for CE marking of electrical and electronic products. In its Research & Development laboratory, ITEL is building an industrial prototype of a special linear proton accelerator, which, by means of a patented integrated system, ERHA, will be used to treat tumors with proton therapy. For more information please visit: [www.itelte.it](http://www.itelte.it)

### **For media queries**

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