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Neuraceq Automated Synthesizer Synthera® (Neuraceq自動合成装置 Synthera®) Received Shonin Approval in Japan

Matran, Switzerland, November 1, 2016 – Piramal Imaging S.A. today announced that it has received Shonin (medical device) approval from the Ministry of Health, Labor and Welfare (MHLW) of Japan for Neuraceq Automated Synthesizer Synthera® (Neuraceq自動合成装置 Synthera®). The approval, obtained through Piramal Imaging's service partner, SCETI K.K., Tokyo, enables Japanese hospitals and imaging centers access to the equipment needed for on-site manufacturing of the β-amyloid imaging agent florbetaben 18F, which is approved in the EU, U.S. and South Korea under the brand name Neuraceq™.

"The availability of Neuraceq Automated Synthesizer Synthera® (Neuraceq自動合成装置 Synthera®) will contribute to further advance public health in Japan by assisting in the diagnosis of Alzheimer's disease and other forms of dementia, a growing concern in the Japanese society," said **Dr. Ludger Dinkelborg, Director of the Board, Piramal Imaging**. "In addition to expanding the market reach for Neuraceq™, the Shonin approval for Neuraceq Automated Synthesizer Synthera® (Neuraceq自動合成装置 Synthera®) supports our ambition of making this important diagnostic tool available on a global scale to the expanding population facing dementia", **Dinkelborg** added further.

Neuraceq Automated Synthesizer Synthera® (Neuraceq自動合成装置 Synthera®) is a medical device manufactured by IBA, SA RadioPharma Solutions, Belgium. MHLW has approved the device, IBA Synthera® V2, as the manufacturing platform for the in-house production of florbetaben 18F solution for Japanese hospitals. Florbetaben 18F, made on Neuraceq Automated Synthesizer Synthera® platform (Neuraceq自動合成装置 Synthera®), is a radioactive diagnostic agent approved in Japan for visualization of brain beta-amyloid plaques in patients with cognitive impairment suspected to have Alzheimer's disease.

Florbetaben 18F binds to neuritic beta-amyloid plaques in the human brain, a hallmark characteristic of Alzheimer's disease, a condition that slowly destroys memory and cognitive abilities and currently affects over 46 million people worldwide[1]. Until today, an estimated 20-30% of patients with dementia[2] have been misdiagnosed and often experience extended diagnostic episodes before receiving a clinical diagnosis. A definitive diagnosis of Alzheimer's disease can only be made after death based on autopsy findings of beta-amyloid plaques and neurofibrillary tangles in the brain. Today, a comprehensive clinical evaluation in

[1] Alzheimer's Disease International. World Alzheimer Report 2015, The Global Impact of Dementia: An analysis of prevalence, incidence, cost and trends. http://www.alz.co.uk/research/WorldAlzheimerReport2015.pdf, (accessed Sept 15, 2016)
[2] Beach TG, Monsell SE, Phillips LE, Kukull W Accuracy of the clinical diagnosis of Alzheimer disease at National Institute on Aging Alzheimer Disease Centers, 2005-2010. J. Neuropathol. Exp. Neurol. 71(4),266- 73 (2012).

combination with in-vivo biomarkers, such as beta-amyloid PET imaging, improves the diagnostic accuracy, allowing for improved patient management.

Recently, Piramal Imaging submitted a Summary Technical Document (STED) medical device dossier to the Pharmaceutical and Medical Devices Agency (PMDA) seeking approval for Neuraceq Automated Synthesizer Synthera® (Neuraceq自動合成装置 Synthera®). Under the Shonin approval process, Neuraceq Automated Synthesizer Synthera® (Neuraceq自動合成装置 Synthera®) is approved as a radioactive-material medical-treatment instrument (category: Equipment 10), with the general designation of radiopharmaceutical synthetic equipment (70009000), Class III. The device is to be distributed to Japanese hospitals by SCETI K.K., Tokyo, who will also train hospital personnel on its use.

About Neuraceq™ (florbetaben F18 injection)

Indication Neuraceq™ is 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:
    - 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 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 positive) 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 978 Neuraceq™ administrations were injection/application site erythema (1.7%), injection site irritation (1.2%), and injection site pain (3.9%).

About Piramal Imaging
Piramal Imaging S.A., a division of Piramal Enterprises, Ltd., was formed in 2012 with the acquisition of the molecular imaging research and development portfolio of Bayer Pharma AG. By developing novel PET tracers for molecular imaging, Piramal Imaging is focusing on a key field of modern medicine. Piramal Imaging 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. For more information please go to www.piramal.com/imaging.

About SCETI K.K.
A pioneer among foreign companies in Japan, SCETI was established in Tokyo in 1925, before it joined Denis Group in 1952. In its early years, the company served as agent for major French Heavy Industry companies. Along the way, SCETI became gradually involved in nuclear medicine, strengthening its portfolio in quantum equipment, isotopes, reagents and diagnostics. Meanwhile, it diversified its activities into Life Sciences importing advanced functional ingredients for food, health-food, cosmetics and pharmaceuticals manufacturing. Lately, the company ventured into medical imaging distributing high-end systems, equipment & services used in medical diagnosis and treatment.

As of today, SCETI markets innovative Health Science solutions focusing on Life Sciences, Medical and Bio-Medical. It works as importer, distributor and licensor operating under QMS compliance. It serves the Industrial, Medical, Clinical, Pharmaceutical and Research networks in Japan and export markets.

About IBA RadioPharma Solutions
Based on longstanding expertise, IBA RadioPharma Solutions supports hospitals and radiopharmaceutical distribution centers with their in-house radioisotopes production by providing them with global solutions, from project design to the operation of their facility. In addition to high-quality production equipment, IBA has developed in-depth experience in setting up GMP-compliant radiopharmaceuticals production centers. IBA is listed on the pan-European stock exchange EURONEXT. (IBA: Reuters IBAB.BR and Bloomberg IBAB.BB) and more information can be found at: www.iba-worldwide.com

(GLO/FBB/1016/0075)


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