

## **Piramal Imaging SA and SWAN Isotopen AG Announce Regulatory Approval of Neuraceq™ in Switzerland and Market Launch**

*Piramal Imaging SA and SWAN Isotopen AG Announce Approval of Neuraceq™ by Swissmedic and Launch on the Swiss Market*

**Bern/Berlin, May 11, 2018** – Piramal Imaging SA and SWAN Isotopen AG announce today that Swissmedic has granted the Marketing Authorisation to SWAN Isotopen AG for Neuraceq™ (florbetaben F18 injection), for the commercial production and market supply of Neuraceq™ in Switzerland.

Neuraceq™ is indicated for Positron Emission Tomography (PET) imaging of  $\beta$ -amyloid neuritic plaque density in the brain of adult patients with cognitive impairment who are being evaluated for Alzheimer's disease (AD) and other causes of cognitive impairment.

"Neuraceq™ will provide physicians throughout Switzerland with a non-invasive method to accurately assess cognitively impaired patients with regard to their cerebral amyloid status" said Prof. Axel Rominger, Director Clinic of Nuclear Medicine Inselspital, Bern. "In the absence of an approved disease-modifying treatment for Alzheimer's disease, advancing our ability to make an earlier and more accurate diagnosis is important to provide optimal non-pharmacological and symptomatic treatments to better manage quality of life in these patients."

"We are pleased to bring this very important diagnostic imaging tool to markets like Switzerland," said Dr. Ludger Dinkelborg, Director of the Board, Piramal Imaging. "Piramal Imaging is proud to have chosen SWAN as a partner allowing us to continue our strategic endeavors to provide this significant solution to Swiss patients."

### **About Neuraceq (florbetaben F18 injection)**

#### **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:
  - 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 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 phase 1-3 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 Piramal Imaging SA**

Piramal Imaging SA, 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.piramalimaging.com](http://www.piramalimaging.com)

**About SWAN Isotopen AG**

SWAN-Isotopen AG is a spin-off company of the University Hospital of Bern, Inselspital, producing full GMP radiopharmaceuticals. The SWAN production site hosts together with the industrial production a multidisciplinary research team of high energy physicists and radiochemists of the University of Bern.

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**For More Information:**

Investor Relations: Hitesh Dhadha / Devanshi Dhruva | Piramal Enterprises Ltd.  
Tel #: +91 22 3046 6444 / +91 22 3046 6376 | [investor.relations@piramal.com](mailto:investor.relations@piramal.com)

**For Media Queries:**

Dimple Kapur | Corporate Communications | Piramal Enterprises Ltd.  
Tel#: +91 22 3351 4269 | [Dimple.Kapur@piramal.com](mailto:Dimple.Kapur@piramal.com)

Dr. med. Konrade von Bremen | CEO | SWAN Isotopen AG  
Tel # +41 31 384 00 50 | [info@swantec.ch](mailto:info@swantec.ch)