

Press Release

## **Piramal Imaging Taps M2i to Manufacture and Distribute NeuraCeq™ in Ireland**

***NeuraCeq to be first locally manufactured beta-amyloid tracer in Irish market***

**01 December 2014** – Piramal Imaging today announced it has entered into a definitive agreement with M2i for the exclusive manufacturing and distribution of NeuraCeq in Ireland. With this agreement M2i through their Dublin PET manufacturing site, aims to bring NeuraCeq to market as the first locally manufactured beta-amyloid tracer in the Republic of Ireland and Northern Ireland.

Alzheimer’s disease (AD) and related dementia rates in Ireland are predicted to grow rapidly from 38,000 people affected now to 50,000 in 2016 and 100,000 by 2036<sup>1</sup>. NeuraCeq, which received marketing authorization in the European Union and in the United States earlier this year, is indicated for imaging the density of beta-amyloid neuritic plaque in the brain as part of an evaluation for adult patients with cognitive impairment. A negative beta-amyloid scan may help rule out AD as a cause of a patient’s cognitive decline.

“Beta-amyloid imaging is a valuable new tool for assessing patients dealing with cognitive impairment symptoms,” said Ruairi O’Donnell, Managing Director, M2i. “The number of patients with dementia in Ireland mirrors that of many countries where populations are aging. Working with Piramal Imaging to bring NeuraCeq to experienced clinicians who diagnose and manage patients suspected of AD and dementia lets M2i play a key role in addressing this nationwide health concern and improving outcomes.”

“To help advance the accuracy of clinical diagnosis, Piramal Imaging is working quickly to build out its manufacturing and distribution network,” said Friedrich Gause, Chief Operating Officer, Piramal Imaging. “Our goal is to work with partners who share our ambition to accelerate and maximize access to beta-amyloid imaging and NeuraCeq for imagers, referring physicians and their patients. M2i offers the local knowledge, services and reach we need to get NeuraCeq to a new and ready market effectively.”

### **About NeuraCeq**

#### **Indication**

This medicinal product is for diagnostic use only.

NeuraCeq is a radiopharmaceutical indicated for Positron Emission Tomography (PET) imaging of beta-amyloid neuritic plaque density in the brains of adult patients with cognitive impairment who are being evaluated for Alzheimer’s disease (AD) and other causes of cognitive impairment. NeuraCeq should be used in conjunction with a clinical evaluation. A negative scan indicates sparse or no plaques, which is not consistent with a diagnosis of AD. For the limitations in the interpretation of a positive scan, please refer to the SmPC.

### **Important Safety Information**

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<sup>1</sup> <http://www.irishhealth.com/article.html?id=13433>

NeuraCeq is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

NeuraCeq can be used for the imaging of beta-amyloid neuritic plaque density in the brain. NeuraCeq cannot be used to diagnose Alzheimer's disease and it cannot predict a patient's predisposition for beta-amyloid plaque development in the future. NeuraCeq images should only be interpreted by readers trained in the interpretation of PET images with florbetaben (18F). Following training, image reading errors (including false positive or false negative interpretation of NeuraCeq images) may still occur. Additional interpretation errors may occur due to image noise, atrophy with a thinned cortical ribbon, or image blurs.

Administration of NeuraCeq, as with other radiopharmaceuticals, results in a low amount of ionizing radiation exposure. Safety precautions should be taken to ensure healthcare providers and patients do not receive unintentional radiation exposure from NeuraCeq.

#### **Most Common Adverse Events**

The most common side effects observed in clinical trials were injection site reaction and injection site pain.

#### **About M2i**

M2i, an independent privately owned Irish company, produces radiopharmaceuticals for use in Positron Emission Tomography (PET) imaging. Its manufacturing facility located in Dublin is fully licenced by the HPRA (Health Products Regulatory Authority) and has been supplying PET products to imaging centres across all geographical regions of Ireland since 2001. It is committed to the highest quality standards and strives to maintain an uptime performance that is second to none across Europe.

For more information please go to [www.m2i.ie](http://www.m2i.ie).

#### **About Piramal Imaging**

Piramal Imaging, 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](http://www.piramal.com/imaging).

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#### **For media inquiries, please contact:**

Emily Fisher - PR  
Piramal Enterprises – Imaging Division  
[emily.fisher@piramal.com](mailto:emily.fisher@piramal.com)

Akansha Pradhan  
Corporate Communications  
Piramal Group



Contact: +91 3351 4082  
akansha.pradhan@piramal.com