



## PRESS RELEASE

### PAION'S PARTNER LUNDBECK INITIATES JAPANESE CLINICAL PHASE II TRIAL WITH DESMOTEPLASE IN ISCHAEMIC STROKE

Aachen (Germany), 16 March 2010 – The biopharmaceutical company PAION AG (ISIN DE000A0B65S3; Frankfurt Stock Exchange Prime Standard: PA8) reports that its licensing partner H. Lundbeck A/S has initiated the first Japanese clinical Phase II trial with Desmoteplase in the treatment of acute ischaemic stroke (DIAS-J). This study is required for the approval of the substance for the Japanese market. In 2009 Lundbeck successfully performed a Phase I study in approximately 30 healthy Japanese volunteers with no safety concern observed.

The primary objective of this randomised, double-blind, placebo-controlled, dose-escalation Phase II study is to evaluate the safety and tolerability of Desmoteplase in 48 Japanese patients with acute ischaemic stroke. Two doses of Desmoteplase (70 and 90 µg/kg) will be tested versus placebo. The efficacy of Desmoteplase will be assessed after 90 days. The DIAS-J study is expected to take approximately 1½ years to conduct. Once DIAS-J is completed, Lundbeck will determine the subsequent development strategy and the clinical data package necessary for a Japanese NDA.

*"We are impressed with the effort and commitment that our colleagues at Lundbeck are investing to drive this project", said PAION CEO Dr Wolfgang Söhngen. "The development in Japan will expand the potential patient population which may benefit from Desmoteplase upon market entry and thus underscores the value of this licence for PAION."*

It is estimated that there are approximately 250,000 annual cases of acute ischaemic stroke in Japan<sup>i</sup>. In Japan, stroke is the third-leading cause of death with mortality rate of 105 per 100,000 populations, and it remains the most common cause of permanent disability in adults.<sup>ii</sup>

You will find further information in the Lundbeck press release published today under [www.lundbeck.com](http://www.lundbeck.com).

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#### **About Desmoteplase**

Desmoteplase, the most fibrin-specific plasminogen activator known today, is a genetically engineered version of a clot-dissolving protein found in the saliva of the vampire bat *Desmodus rotundus*. It is currently being developed for the treatment of acute ischaemic stroke for which it has received fast-track designation from the U.S. Food and Drug Administration. The treatment is being carried out in a timeframe of 3 to 9 hours post onset of stroke symptoms – a time window for which there currently is no approved drug treatment.

So far Desmoteplase has been tested in two Phase II studies and one Phase III study for the treatment of ischaemic stroke. In January 2008 H. Lundbeck A/S obtained worldwide rights to Desmoteplase from PAION AG.

A clinical Phase III programme with Desmoteplase was initiated by Lundbeck in December 2008, recruiting patients in Europe, North and South America, Africa and Asia Pacific. In parallel Lundbeck also focuses on the development of the compound for the Japanese market.

### **About PAION**

PAION is a biopharmaceutical company headquartered in Aachen, Germany and has a second site in Cambridge, UK. The company is specialized in developing and commercializing innovative drugs for the hospital-based treatment in indications for which there is a substantial unmet medical need. PAION has a "Search & Develop" business model, which is based on its core expertise in drug development. Where appropriate, particularly during the late stages of the clinical development, PAION seeks to collaborate with experienced partners.

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<sup>i</sup> Decision Resources: "Acute Ischemic Stroke", December 2009

<sup>ii</sup> Y. Yoneda et al.: Hospital cost of ischemic stroke and intracerebral hemorrhage in Japanese stroke centers / Health Policy 73 (2005) 202–211