

# PAION AND LUNDBECK PARTNER ON PHASE III COMPOUND DESMOTEPLASE FOR ACUTE STROKE

**Aachen, 11 July 2005** – PAION Deutschland GmbH and H. Lundbeck A/S announced today that they have entered into an exclusive partnership agreement for the development and marketing of PAION's Phase III product Desmoteplase for stroke in Europe, Japan and the rest of the world except the United States (USA) and Canada. Forest Laboratories holds the marketing and development rights in the USA and Canada.

Desmoteplase, a novel plasminogen activator, or blood clot-dissolving agent, has the potential to treat patients with acute ischaemic stroke up to 9 hours after onset of symptoms. Ischaemic stroke is the most common type of stroke and occurs when an artery in the brain is obstructed by a blood clot. In the USA, Desmoteplase has received fast-track designation for ischaemic stroke from the U.S. Food and Drug Administration (FDA).

Under the terms of the agreement, Lundbeck will make an upfront payment of EUR 15 million and additional milestone payments of up to EUR 50 million for the indication of stroke. The total milestone amount depends on the number of co-promotion options in the major European markets that PAION chooses to exercise. The co-promotion option enables PAION to move towards its strategic goal to develop into an integrated biopharmaceutical company with commercial capabilities. Lundbeck and Forest will fund the majority of development activities. After deduction of its own royalty obligations towards the originator, PAION will receive double-digit royalties based on sales in the countries with exclusivity for Lundbeck. In countries with co-promotion, PAION will gain a 50/50 profit split in exchange for covering a proportional share of development, which could amount up to approximately 18% of the joint costs.

"The agreement will allow us to achieve our mid-term strategic goals and achieves a risk reduction matching our agreement with Forest. Forest and Lundbeck have shown that they co-operate successfully, which will be beneficial for the success of Desmoteplase in this, now three-party, joint development. The overall deal structure reflects the commitment of both partners to enter into a true partnership", comments PAION's CEO, Dr. Wolfgang Söhngen. "Lundbeck as a specialist has a strong track record to effectively launch and establish market leading brands in the CNS area. We look forward to introduce Desmoteplase as a breakthrough therapy in stroke together with Lundbeck in the major European markets", adds PAION's COO Alexander Vos.

Positive results from the two Phase II clinical studies DIAS (Desmoteplase In Acute ischaemic Stroke) and DEDAS (Dose Escalation study of Desmoteplase in Acute ischaemic Stroke) showed that the compound has the potential to treat patients up to 9 hours after the onset of stroke symptoms. The only currently available clot-dissolving agent must be administered within 3 hours of symptom onset; however, approximately eighty percent of stroke patients arrive at the hospital outside that treatment window. Desmoteplase, with a targeted 9-hour treatment window, could expand the number of patients who receive clot-dissolving therapy significantly.

"We are delighted to have reached an agreement with PAION. Desmoteplase is a product that has the potential for being available for the 80% of stroke patients that presently have no treatment opportunity for the potentially fatal and severe consequences of ischaemic stroke" says Claus Bræstrup, President and CEO of Lundbeck and continues, "with Desmoteplase Lundbeck strengthens the late stage pipeline."

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#### About Desmoteplase

Desmoteplase, first in a new class of plasminogen activators, is a genetically engineered version of a clot-dissolving protein found in the saliva of the vampire bat Desmodus rotundus. It possesses high fibrin selectivity, allowing it to dissolve a clot locally without affecting the blood coagulation system, which is thought to potentially reduce the risk of intracranial bleeding (a common risk when administering blood clot-dissolvers) as compared to less fibrin-specific plasminogen activators. Currently in Phase III, Desmoteplase was tested in two independent Phase II studies for the treatment of acute ischaemic stroke up to 9 hours after onset of symptoms and has received fast-track designation from the U.S. Food and Drug Administration for the indication of acute ischaemic stroke.

#### About Stroke

Stroke is the third leading cause of death in the industrialised world behind heart disease and cancer. The treatment of acute stroke and its serious long-term disabilities currently present an extensive unmet need. The only drug currently approved for the treatment of acute ischaemic stroke must be administered within 3 hours after the onset of stroke symptoms, which limits the potential patient population that can safely benefit from the rapid dissolution of the blood clot and the restoration of blood supply to the affected area of the brain.

#### About Lundbeck

H. Lundbeck A/S is an international pharmaceutical company engaged in the research and development, production, marketing and sale of drugs for the treatment of psychiatric and neurological disorders. In 2004, the company's revenue was DKK 9.7 billion (approx. EUR 1.3 billion). The number of employees is approx. 5,000. For further information, visit www.lundbeck.com

## **About PAION**

PAION Deutschland GmbH, a wholly-owned subsidiary of PAION AG, is a biopharmaceutical company based in Aachen, Germany, aiming to become a leader in developing and commercialising innovative drugs for the treatment of stroke and other thrombotic diseases for which there is a substantial unmet medical need. Currently, PAION's activities are focused on the development of the three drugs Desmoteplase, Enecadin, and Solulin. During the first quarter 2005, PAION employed on average 56 people. Since 11 February 2005, PAION AG is listed at the Frankfurt Stock Exchange (Prime Standard Official Market, Stock Symbol PA8, ISIN DE000A0B65S3). More information is available at www.paion.de

JSB Partners LP and KÖNIG SZYNKA VON RENESSE acted as advisors to PAION in this transaction.