



Joint analysis of two Phase II studies with Desmoteplase presented at the European Stroke Conference

Confirmatory study DIAS-2 started to confirm 3-9 hour treatment time window
with Desmoteplase in ischaemic stroke

Aachen, Bologna, 30 May 2005 – The joint analysis of DIAS and DEDAS, two Phase II studies sponsored by PAION that examined the investigational novel plasminogen activator Desmoteplase in the treatment of acute ischaemic stroke was presented at the European Stroke Conference in Bologna on 28 May, 2005. The analysis confirms the positive results of the individual studies.

DIAS and DEDAS were placebo controlled, double blind, multi-centre and multinational dose finding Phase II safety studies. Patients were diagnosed with magnetic resonance imaging. Altogether 142 acute ischaemic stroke patients were randomized in the US, Europe and AustralAsia within three to nine hours from the onset of stroke symptoms. The joint analysis includes all patients treated with either placebo, 90µg/kg or 125µg/kg (N=94). Main efficacy endpoints were the rate of reperfusion and positive clinical outcome after 90 days.

The combined rate of intracranial bleeding for the doses of 90µg/kg and 125µg/kg Desmoteplase was 1.7% (1 patient in the 90µg/kg group). Mortality was generally low: 5.7% on placebo, 6.9% on 90µg/kg and 3.3% on 125µg/kg. The reperfusion rates were 23.5% on placebo, 34.6% on 90µg/kg and 62.1% on 125µg/kg. Positive clinical outcomes at day 90 were 22.9% on placebo, 37.9% on 90 µg/kg and 60% on 125 µg/kg.

Prof. Dr. Werner Hacke, principal investigator of DIAS, presenting the joint analysis, said: "Successful treatment in the time window beyond 3 hours is urgently needed, as the number of patients arriving that early is still low. Desmoteplase may be a treatment option for patients that arrive later".

"These very positive results show that we are on the right track with Desmoteplase and now after two independent studies we are optimistic that these results will be confirmed in a larger study, DIAS-2, also using perfusion CT for diagnosis", comments Dr. Mariola Söhngen, CMO of PAION.

DIAS-2 (Desmoteplase in Acute Ischemic Stroke) aims to confirm the 3-9 hour treatment time window in ischaemic stroke with Desmoteplase in a larger number of patients. Conducted jointly by PAION and Forest Laboratories, Inc., it is a multi-centre, multinational, randomized, parallel-design dose-ranging study (90µg/kg, 125µg/kg, placebo) with about 60 participating hospitals in Europe, USA, Canada and AustralAsia. Perfusion computer tomography (pCT) and magnetic resonance imaging (MRI) will both be allowed as a diagnostic tool for the identification of patients who may benefit from reperfusion therapy (restoration of blood flow) with Desmoteplase.

About Desmoteplase and Stroke

*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.*

Stroke is the third leading cause of death in the industrialised world after heart disease and cancer. The treatment of acute stroke and related serious long-term disabilities currently represent a substantial unmet medical need. The only drug currently approved for the treatment of acute ischaemic stroke must be administered within three 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 PAION

PAION, a biopharmaceutical company based in Aachen, Germany, aims 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. PAION intends to build an integrated portfolio of drugs by exploiting its core expertise in identifying compounds with potential in the treatment of stroke and other thrombotic diseases, licensing or otherwise acquiring these compounds and advancing them through the clinical development and regulatory approval process. PAION's most advanced drug candidate, Desmoteplase, has received fast-track designation from the U.S. Food and Drug Administration for the indication acute ischemic stroke. PAION currently employs approximately 56 people. In February 2005 PAION conducted an IPO at the Frankfurt Stock Exchange (stock symbol PA8, ISIN: DE000A0B65S3). More information is available at www.paion.de.

About Forest Laboratories and Its Products

Forest Laboratories' growing line of products includes: Lexapro® (escitalopram oxalate), an SSRI antidepressant indicated for the initial and maintenance treatment of major depressive disorder and for generalized anxiety disorder in adults; Namenda® (memantine HCl), an N-methyl-D-aspartate (NMDA)-receptor antagonist indicated for the treatment of moderate to severe Alzheimer's disease; Benicar® (olmesartan medoxomil), an angiotensin receptor blocker indicated for the treatment of hypertension; Benicar* HCT® (olmesartan medoxomil hydrochlorothiazide), an angiotensin receptor blocker and diuretic combination product indicated for the second-line treatment of hypertension; Campral®* (acamprosate calcium), a glutamate receptor modulator, indicated for the maintenance of abstinence from alcohol in patients with alcohol dependence who are abstinent at treatment initiation in combination with psychosocial support; and Combunox™ (Oxycodone HCl and Ibuprofen), an opioid and NSAID combination indicated for the short-term management of acute, moderate to severe pain. More information is available at www.frx.com.*

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