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Forest Laboratories, Inc. and PAION GmbH Announce Development and Marketing Agreement for Desmoteplase - Novel Investigational Treatment for Acute Stroke

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Forest Laboratories, Inc. (NYSE: FRX) and PAION GmbH announced today that the companies have entered into an agreement for the development and marketing of PAION's product, desmoteplase, in the United States (U.S.) and Canada. Desmoteplase, a novel plasminogen activator, or blood clot-dissolving agent, is currently under development in the U.S. and Europe for treatment of acute ischemic stroke, a condition affecting over 600,000 patients in the U.S. annually. Positive results from a Phase II study showed that the compound has the potential to treat patients up to nine hours after the onset of stroke symptoms. The only currently available clot-dissolving agent must be administered within three hours of symptom onset; however, the majority of stroke patients arrive at the hospital outside that treatment window. At present, only eleven percent of ischemic stroke patients are eligible for the treatment and fewer than four percent actually receive it. Desmoteplase, with a longer treatment window, could expand the number of patients who receive clot-dissolving therapy.

Forest and PAION entered into the agreement on June 30, 2004 and Forest made an undisclosed upfront payment to PAION on that date. Under the agreement, PAION will receive milestone payments and a royalty based on sales, and Forest will fund all continuing clinical development activities for the U.S. and Canadian markets. Forest will be responsible for regulatory and sales and marketing activities in the U.S. and Canada and will have development and marketing rights to other indications of the product in these territories. PAION retains commercial rights in Europe, Japan and the rest of the world. Desmoteplase has several issued composition of matter patents, including some that do not expire in the U.S. until 2015, with the potential for extensions.

PAION and Forest will be finalizing discussions with the U.S. Food and Drug Administration (FDA) regarding study protocols to serve as the basis for a new Biologics License Application (BLA) filing. It is anticipated that a Phase IIb study will be initiated in the third calendar quarter of this year. Desmoteplase was recently granted fast track status by the FDA, a designation granted for drugs that address an unmet medical need in life-threatening indications. Fast track designation allows the submission of portions of the application for approval in advance of the final section becoming available ("Rolling Biologics License Application"), and serves as the basis of an expedited review by the FDA, generally within six months of the filing date. If the trials are successful, it is possible that a BLA for desmoteplase would be submitted to the FDA as early as 2007.

Howard Solomon, Chairman and Chief Executive Officer of Forest Laboratories, Inc. said, "We are extremely pleased with our agreement with PAION GmbH. Desmoteplase is another late stage product to add to our pipeline of both late and early stage products. It is also our first biologic product, an important category of products that we have not participated in heretofore. Above all, desmoteplase is a product that, if successfully developed and approved, can make a very significant difference to stroke patients who presently have much more limited opportunity to ameliorate the potentially severe consequences of ischemic stroke which can be fatal or can severely limit the patient's mental and physical functioning. Desmoteplase is novel in two ways: early clinical results suggest that it can more precisely target the blood clots that cause stroke and that it can be used up to nine hours after patients first experience symptoms, expanding the population of patients who may be eligible for treatment to up to 300,000 patients each year who arrive at the hospital within the first nine hours of symptom onset -- a substantial increase over the estimated 66,000 patients who arrive within the first three hours. We have also been deeply impressed by the scientific creativity and intelligence of the management and personnel of PAION. We look forward to working with them in bringing this novel and crucially important product to the many patients who need it."

Wolfgang Soehngen, M.D., Chief Executive Officer of PAION commented, "The income from this agreement will secure the development for desmoteplase until approval. We have selected Forest for its proven development and regulatory expertise and its track record to successfully bring Central Nervous System products to market. We were especially impressed by the speed and pragmatism of decision making. The enthusiasm for this difficult indication from both the marketing and development colleagues, as well as the management at Forest, will be a key success factor for the collaboration. This is so important, since the successful development and launch of desmoteplase will require intensive educational efforts to increase stroke awareness and to overcome existing treatment barriers."

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.

PAION presented positive results from a Phase II study (DIAS - Desmoteplase in Acute Ischemic Stroke) at the 29th International Stroke Conference in February 2004. The DIAS study was a multi-center, double-blind, placebo-controlled, randomized, dose-finding Phase II study conducted in 102 patients across 25 hospitals in Europe, Australia and Asia. Patients

were selected using magnetic resonance imaging and administered desmoteplase in the time window between three and nine hours after the onset of stroke symptoms. The study demonstrated that by administering desmoteplase, the blood flow in the damaged area of the brain was significantly improved and expansion of the damaged brain area was prevented, which led to improved clinical outcome after 90 days in up to 60 percent of patients who received the optimal dose. Additionally, only 3.3 percent of 30 patients who received the two effective doses selected for further clinical testing experienced a symptomatic intracranial bleed. Another U.S.-focused study with the same design, DEDAS (Dose Escalation study of Desmoteplase in Acute Ischemic Stroke), is ongoing in 18 centers in the U.S. and four centers in Europe.

About Stroke

Stroke is the third leading cause of death in the United States and Europe, behind heart disease and cancer. According to the American Heart Association, over 600,000 people in the U.S. fall victim to an ischemic stroke, which comprises approximately 88 percent of all strokes. The treatment of acute stroke and its serious long-term disabilities currently present an extensive unmet need.

Ischemic stroke occurs when a blood vessel, supplying the brain with oxygen and nutrients, is obstructed by a blood clot. The blockage or rupture of the vessel results in a lack of blood flow to part of the brain. Deprived of oxygen, nerve cells in the affected region die within minutes or hours after the event resulting in loss of function of the part of the body they control. Ischemic stroke requires emergency treatment to rapidly dissolve or remove the blood clots in the brain, but many people delay getting treatment.

The only drug currently approved for the treatment of acute ischemic stroke must be administered within three hours after onset of stroke symptoms, thus limiting the potential patient population who can safely benefit from the rapid dissolution of the blood clot and the reperfusion of blood supply to the affected area of the brain.

About Forest Laboratories and Its Products

Forest Laboratories' growing line of products includes: Lexapro(R), an SSRI antidepressant indicated for the initial and maintenance treatment of major depressive disorder and for generalized anxiety disorder; Celexa(R), an antidepressant; Namenda(R), an N-methyl-D-aspartate (NMDA)-receptor antagonist indicated for the treatment of moderate to severe Alzheimer's disease; Tiazac(R), a once-daily diltiazem, indicated for the treatment of angina and hypertension; Benicar(R),* an angiotensin receptor blocker indicated for the treatment of hypertension; Benicar HCT(TM), an angiotensin receptor blocker and diuretic combination product indicated for the second-line treatment of hypertension; and Aerobid(R), an inhaled steroid indicated for the treatment of asthma.

*Benicar(R) is a registered trademark of Sankyo Pharma, Inc.

About PAION GmbH

PAION GmbH, a biopharmaceutical company based in Aachen, Germany, is specialized in the development of innovative therapeutic products for the treatment of stroke. With core competencies in clinical development and international drug registration, PAION is ideally equipped to successfully launch and develop an emerging portfolio of stroke and cardiovascular products. The company today employs 50 people and has raised euro 51.2 million in four financing rounds since its foundation in the year 2000. An experienced international management team and the support of leading investors are the basis for rapid growth and the fulfillment of PAION's vision to become the "PAIONeer in Stroke".

Except for the historical information contained herein, this release contains "forward-looking statements" within the meaning of the Private Securities Reform Act of 1995. These statements are subject to risks and uncertainties that affect our business, including risk factors listed from time to time in the Company's SEC reports, including the Company's Annual Report on Form 10-K for the fiscal year ended March 31, 2004. Actual results may differ materially from those projected.

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