



**FOREST LABORATORIES STARTS CONFIRMATORY STUDY OF DESMOTEPLEASE  
A NOVEL INVESTIGATIONAL TREATMENT FOR ACUTE, ISCHEMIC STROKE  
*To Confirm Expanded 9-Hour Treatment Window Seen in Two Phase II Studies***

**NEW YORK, NY – February 9, 2005** – Forest Laboratories, Inc. (NYSE: FRX) today announced the initiation of a phase IIb/III study of desmoteplase, an investigational novel plasminogen activator, or blood clot buster, for the treatment of acute ischemic stroke, a condition affecting over 600,000 patients annually in the U.S..

The DIAS2 (Desmoteplase in Acute Ischemic Stroke) study will be a multi-center, multinational, randomized, parallel-design dose-ranging study of more than 150 patients to confirm the results of earlier Phase II studies that demonstrated the potential of desmoteplase to treat acute ischemic stroke patients up to nine hours after the onset of stroke symptoms, three times longer than the currently available treatment allows. Because most stroke patients arrive at the hospital outside the accepted three hour treatment window, the majority of patients are not eligible for the currently available treatment. Lengthening that window may expand the number of patients who could benefit from treatment.

“Preserving brain function and restoring quality of life in patients after acute ischemic stroke is the goal of effective stroke treatment,” says Anthony Furlan, MD, Medical Director, Cleveland Clinic Foundation and primary investigator of the DIAS2 and DEDAS (Dose Escalation study of Desmoteplase in Acute Ischemic Stroke) studies. “The consistent results from two completed studies of desmoteplase in patients with acute stroke strongly support moving forward to further assess this potential breakthrough treatment in a large-scale worldwide trial.”

**Results of Desmoteplase Confirmed in Second Phase II Study**

Results from the recently completed DEDAS study, presented for the first time on February 4, 2005, as a late-breaker presentation at the 30<sup>th</sup> International Stroke Conference in New Orleans, Louisiana, showed trends indicating that desmoteplase administered intravenously in the time window up to nine hours after the onset of stroke symptoms:

- Improved blood flow in the damaged area of the brain in patients treated with 125µg/kg of desmoteplase.

- Improved clinical outcome after 90 days compared to placebo.

The DEDAS study was a multi-center, placebo-controlled, double-blind, randomized, dose-escalation Phase II trial conducted in 38 patients across 17 hospitals in the U.S. and three hospitals in Europe. This study showed similar results to the earlier DIAS (Desmoteplase in Acute Ischemic Stroke) trial, which was published in *Stroke* in January 2005 and presented at the 29<sup>th</sup> International Stroke Conference in February 2004. The former DIAS study used a similar protocol to DEDAS, with 104 patients across 25 hospitals in Europe, Australia and Asia. In both these studies, patients with the potential to benefit from reperfusion therapy were selected using MRI methods to determine whether they had salvageable tissue and were then administered intravenous (IV) desmoteplase or placebo in the time window up to nine hours after the onset of stroke symptoms. Both of these studies were pilot in nature and were not sized to show statistical differences.

### **About Desmoteplase**

Desmoteplase, first in a new class of plasminogen activators, is a genetically engineered version of a clot-busting agent found in the saliva of the vampire bat, *Desmodus rotundus*. It possesses high fibrin selectivity, potentially allowing it to dissolve a clot locally without adversely affecting the blood coagulation system, possibly reducing the risk of intracranial bleeding (a common risk when administering blood clot-dissolvers) as compared to other less fibrin-specific plasminogen activators.

Desmoteplase has received fast-track review designation from the U.S. Food and Drug Administration (FDA) for the treatment of acute ischemic stroke beyond the three-hour time window. Desmoteplase was licensed to Forest by PAION GmbH on June 30, 2004. Under the agreement, 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.

### **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 each year, 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, tPA (Activase®), 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. 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.

### **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; Celexa® (citalopram HBr), an antidepressant for adults; 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; Combunox™ (Oxycodone HCl and Ibuprofen) an opioid and NSAID combination indicated for the short-term management of acute, moderate to severe pain expected to be available in the U.S. in early 2005.

### **About PAION**

PAION, a biopharmaceutical company based in Aachen, Germany, aims to become a leading provider of innovative drugs for the treatment of stroke and other thrombotic diseases. In addition to Desmoteplase, the company is developing the neuroprotective drug Enecadin for stroke, and the anti-thrombotic Solulin. With a core competence in advancing purchased or in-licensed drug candidates through the clinical development and regulatory approval process, PAION believes it is well-equipped to achieve this goal. The company today employs approximately 60 people and has raised €51 million in four financing rounds since its founding in 2000. More information is available at [www.paion.de](http://www.paion.de).

*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, and on form 10-Q for the periods ended June 30, 2004, and September 30, 2004. Actual results may differ materially from those projected.*

\*Benicar® is a registered trademark of Sankyo Pharma, Inc., Campral® is a registered trademark under license from Merck Sante s.a.s., subsidiary of Merck KGaA, Darmstadt, Germany. Activase® is a registered trademark of Genentech, Inc.

Contact:            *CHARLES E. TRIANO*  
                         *Vice President, Investor Relations*  
                         *Forest Laboratories*  
                         *909 Third Avenue*  
                         *New York, NY 10022*  
                         *(212) 224 – 6714*  
                         *[charles.triano@frx.com](mailto:charles.triano@frx.com)*