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**FOREST LABORATORIES, INC. AND CYPRESS BIOSCIENCE, INC ANNOUNCE  
RESULTS OF PHASE III STUDY FOR MILNACIPRAN AS A TREATMENT FOR  
FIBROMYALGIA**

*Preliminary Results Support Continuation of Development Program*

**New York, N.Y. September 28, 2005** – Forest Laboratories, Inc. (NYSE:FRX) and Cypress Bioscience, Inc. (NASDAQ:CYPB) today announced that preliminary top-line results from an 888 patient randomized, double-blind, placebo-controlled pivotal Phase III study support the continued development of milnacipran as a treatment for fibromyalgia (FMS). Although the results did not achieve statistical significance at the  $p < 0.05$  level, the planned development program for milnacipran, which includes an ongoing Phase III study and a soon to be initiated additional Phase III study by Forest Laboratories, will continue. At this time the Companies have only been able to review initial top-line results and further analyses must be completed in the coming months to confirm these development plans.

**Preliminary Study Results**

The primary endpoint of this trial was a composite response rate of an assessment of pain as measured by the Patient Experience Diary (PED)<sup>1</sup> and an assessment of overall impression of patient well-being as measured by the Patient Global Impression of Change (PGIC)<sup>2</sup>. Using the Last Observation Carry-forward (LOCF)<sup>3</sup> analysis, p-value for patients receiving 200 mg per day of milnacipran was 0.058. This result is supportive of continued development of milnacipran as a treatment for fibromyalgia.

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<sup>1</sup> Patient Experience Diary (PED) is patient self-reported pain data collected via an electronic diary system which asks patients to document random, daily and weekly pain levels.

<sup>2</sup> Patient Global Impression of Change (PGIC) is a patient reported periodic assessment of their perception of change in their condition.

<sup>3</sup> Last Observation Carry-forward (LOCF) is an analysis in which observations are carried forward to the last time point for patients who dropped out. The LOCF analysis treats the carried-forward data as observed data at the last time point.

In an analysis using the FDA-recommended Baseline Observation Carry-forward (BOCF)<sup>4</sup> analysis the p-value for patients receiving 200 mg per day of milnacipran was 0.048. Although the BOCF analysis yielded statistically significant results, the FDA may not accept this as a registration study.

The magnitude of the treatment effect observed in the three-month study results was maintained at the six-month analysis (p=0.053 and 0.067 for LOCF and BOCF analyses, respectively), indicating a durable response to milnacipran treatment.

An additional endpoint of fibromyalgia syndrome, which is a composite of the primary endpoint as well as a physical function assessment, was also evaluated. The results of this analysis were not statistically significant compared to placebo at either the three or six month timeframe.

Upon further analysis, the Companies will be in a position to better assess what impact these results will have on the timing of a New Drug Application (NDA).

### **Tolerability**

Milnacipran was generally well tolerated, with the majority of patient withdrawals occurring early in the trial. The adverse event profile was generally consistent with that seen in the previous worldwide experience with milnacipran, as well as in the Phase II trial. The most common adverse events leading to withdrawal among the milnacipran treated patients were nausea 6%, heart rate increase 2%, headache 2%, and depression 2%.

### **About Milnacipran**

Milnacipran is the first of a new class of agents known as norepinephrine serotonin reuptake inhibitors, or NSRIs, which exerts its effect by preferentially inhibiting the reuptake of norepinephrine over serotonin, two neurotransmitters known to play an essential role in regulating pain and mood. It has been approved for the treatment of non-pain indications in 32 countries and has been used safely by more than 3 million patients during more than six years of commercial availability outside the U.S. Milnacipran is being developed for fibromyalgia in the United States market jointly by Forest and its licensor, Cypress Biosciences, Inc.

### **About Fibromyalgia (FMS)**

FMS is a chronic and debilitating condition characterized by widespread pain and stiffness throughout the body, accompanied by severe fatigue, insomnia and mood symptoms. According to the American College of

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<sup>4</sup> Baseline Observation Carry-forward (BOCF) is an analysis that requires the patient remain active in the trial to be evaluated for response. If a patient withdraws from the trial for any reason they are classed as a non-responder regardless of their pain and global scores at the time of withdrawal.

Rheumatology, FMS is estimated to affect six to twelve million people in the United States. FMS is most often diagnosed in the primary care setting and in addition is the second most commonly diagnosed condition in rheumatology clinics in the United States after osteoarthritis. Despite the high prevalence and severity of this syndrome, there are no treatments specifically approved for FMS in the United States or elsewhere. For more information about fibromyalgia, visit [www.fmsresource.com](http://www.fmsresource.com).

### **About Cypress Biosciences, Inc.**

Cypress is committed to be the innovator and leader in providing products that improve the treatment of Functional Somatic Syndromes, including Fibromyalgia Syndrome (FMS), and other Central Nervous System conditions, such as Obstructive Sleep Apnea (OSA). Cypress' strategy involves acquiring/in-licensing central nervous system active compounds and developing them for new indications.

In August 2001, Cypress licensed from Pierre Fabre Medicament its first product for clinical development, milnacipran. In January 2004, Cypress entered into a collaboration agreement with Forest Laboratories for the development and marketing of milnacipran.

*This press release, as well as Cypress' SEC filings and web site at <http://www.cypressbio.com>, contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 including statements about the potential of milnacipran to treat FMS and our continued development of milnacipran,. Actual results could vary materially from those described as a result of a number of factors, including those set forth in Cypress Annual Report on Form 10-K, the most recent Quarterly Report on Form 10-Q and any subsequent SEC filings and including, but not limited to, the fact that because we did not achieve statistical significance on our primary endpoints, that the FDA may not accept this trial as one of the two pivotal trials required for NDA approval, that the FDA may not allow us to use the BOCF analysis and that upon further analysis of this trial, that we and Forest may elect not to continue development of milnacipran.*

### **About Forest Laboratories, Inc.**

Forest Laboratories' growing line of products includes: Lexapro(R) (escitalopram oxalate), an SSRI antidepressant indicated for the initial and maintenance treatment of major depressive disorder and for generalized anxiety disorder in adults; Namenda(R)(memantine HCl), an N-methyl-D-aspartate (NMDA)-receptor antagonist indicated for the treatment of moderate to severe Alzheimer's disease; Benicar(R)\*(olmesartan medoxomil), an angiotensin receptor blocker indicated for the treatment of hypertension; Benicar HCT(R)(olmesartan medoxomil hydrochlorothiazide), an angiotensin receptor blocker and diuretic combination product indicated for the second-line treatment of hypertension;

Campral(R)\*(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(TM)(Oxycodone HCl and Ibuprofen), an opioid and NSAID combination indicated for the short-term management of acute, moderate to severe pain. Further information is available at [www.frx.com](http://www.frx.com).

*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, 2005 and on form 10-Q for the period ended June 30, 2005. Actual results may differ materially from those projected.*

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

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