



**EMBARGOED UNTIL 8:00AM EST, JANUARY 11, 2005**

**First New Treatment For Alcoholism In Ten Years, Now Available Campral<sup>®</sup> (Acamprosate Calcium) Delayed-Release Tablets**

**NEW YORK – January 11, 2005** — Forest Laboratories, Inc. (NYSE: FRX) announced today that Campral<sup>®</sup> (acamprosate calcium) Delayed-Release Tablets are now available to physicians, patients and pharmacies nationwide. Campral was approved by the U.S. Food and Drug Administration (FDA) on July 29, 2004 for the maintenance of abstinence from alcohol in patients with alcohol dependence who are abstinent at treatment initiation. Treatment with Campral should be part of a comprehensive management program that includes psychosocial support. The approval of Campral was the first in nearly ten years of a treatment for alcohol dependence.

“We believe that Campral, in combination with psychosocial support, sets a new standard for treating the chronic disease of alcoholism,” said Howard Solomon, Chairman and Chief Executive Officer of Forest Laboratories. “Forest is committed to providing an effective and safe drug therapy to help the millions of Americans struggling with alcohol-dependence to maintain abstinence.”

**Campral and Complete Abstinence**

“A major treatment goal for alcohol dependence is to increase rates of abstinence,” said Barbara Mason, Ph.D., Professor of Neuropharmacology, Co-Director of The Pearson Center for Alcoholism and Addiction Research, The Scripps Research Institute. “Campral, when used in combination with psychosocial support, can help committed patients reach this goal because it is thought to help restore the brain’s chemical balance that has been disrupted by long-term excessive drinking.”

The mechanism of action of Campral in maintenance of alcohol abstinence is not completely understood. Chronic alcohol exposure is hypothesized to alter the normal balance between neuronal excitation and inhibition.<sup>1</sup> Campral interacts with neurotransmitter systems and is hypothesized to restore the normal balance.<sup>1</sup> This mechanism of action is different from that ascribed to currently available medications, which either block the “high” associated with alcohol<sup>2</sup> or induce vomiting if alcohol is ingested.<sup>3</sup>

FDA approval of Campral is based primarily on the Agency’s review of short and long-term efficacy and safety data from double-blind, placebo-controlled trials. In three of the trials, which lasted from 90 days to 360 days, Campral plus psychosocial therapy proved superior to placebo plus psychosocial therapy in maintaining abstinence, as indicated by a greater percentage of subjects being assessed as continuously abstinent throughout treatment.<sup>1</sup>

In a fourth study, the Campral-treated group failed to show a difference on the primary efficacy endpoint, cumulative abstinence duration. In this trial, patients were not required to be abstinent prior to randomization as required in the positive studies.<sup>1</sup>

In the clinical trial program, side effects for Campral were generally mild with the most frequently reported side effect being diarrhea.<sup>4</sup> Campral is contraindicated in patients with severe renal impairment (creatinine clearance  $\leq 30$  mL/min) and requires a dose reduction in patients with moderate renal impairment (creatinine clearance of 30-50 mL/min).<sup>1</sup>

The recommended dose of Campral is two 333 mg tablets taken three times daily.<sup>1</sup> Treatment with Campral should be initiated as soon as possible after the period of alcohol withdrawal, when the patient has achieved abstinence, and should be maintained if the patient relapses.<sup>1</sup>

Campral was developed by Merck Santé s.a.s., subsidiary of Merck KGaA of Darmstadt, Germany, and licensed to Forest Laboratories for the United States.

Interested parties can get more information on Campral and obtain the prescribing information by visiting [www.campral.com](http://www.campral.com) or by calling 800-678-1605.

## **About Alcoholism**

Nearly 8 million Americans are alcohol dependent<sup>5</sup>, but only 2.4 million have been diagnosed<sup>6</sup> with the disease and just 139,000 receive medication to treat it.<sup>7</sup> Left untreated, alcoholism increases the risk for heart disease, liver disease, infectious disease, and cancer.<sup>8</sup>

## **About Forest Laboratories and Its Products**

Forest Laboratories' growing line of products includes: Lexapro<sup>®</sup> (escitalopram oxalate), an SSRI antidepressant indicated for the initial and maintenance treatment of major depressive disorder and for generalized anxiety disorder in adults; Namenda<sup>®</sup> (memantine HCl), an N-methyl-D-aspartate (NMDA)-receptor antagonist indicated for the treatment of moderate to severe Alzheimer's disease; Celexa<sup>®</sup> (citalopram HBr), an antidepressant for adults; Benicar<sup>®</sup> \* (olmesartan medoxomil), an angiotensin receptor blocker indicated for the treatment of hypertension; Benicar HCT<sup>™</sup> (olmesartan medoxomil hydrochlorothiazide), an angiotensin receptor blocker and diuretic combination product indicated for the second-line treatment of hypertension; Campral<sup>®</sup> \* (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<sup>™</sup> (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. early 2005.

*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 period 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 Santé s.a.s., subsidiary of Merck KGaA, Darmstadt, Germany.

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

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<sup>1</sup> Campral® (acamprosate calcium) Delayed-Release Tablets Prescribing Information, Forest Laboratories, Inc., St.Louis, Mo, 2004. Pg. 1.

<sup>2</sup> Garbutt JC, West SL, Carey TS, Lohr KN, Crews FT. Pharmacological treatment of alcohol dependence: a review of the evidence. *JAMA*. 1999;281:1318-1325.

<sup>3</sup> Solhkhah R, M.D.; Wilens T, M.D. Pharmacotherapy of Adolescent Alcohol and Other Drug Use Disorders. *Alcohol Health and Research World*.1998; 22(2);122.

<sup>4</sup> Data on file, Forest Laboratories, Inc

<sup>5</sup> Grant, B.F.; Dawson, D.A.; Stinson, F.S.; Chou, S.P.; Dufour, M.C.; Pickering, R. The 12-month prevalence and trends in DSM-IV alcohol abuse and dependence: United States, 1991-1992 and 2001-2002. *Drug and Alcohol Dependence* 2004; (74); 229.

<sup>6</sup> Data on file, Forest Laboratories, Inc

<sup>7</sup> Verispan data on file, Forest Laboratories, Inc. slide

<sup>8</sup> Bagnardi V; Blangiardo M; Vecchia C, et al. Alcohol consumption and the risk of cancer. *Alcohol Research and Health*. 2001; 25(4); 263-270.