Neurocrine Reports Positive Phase III Efficacy and Safety Results With Indiplon Modified Release (MR) Tablets in Treating Adult Patients With Chronic Insomnia

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SAN DIEGO, Feb 16, 2005 /PRNewswire-FirstCall via COMTEX/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced indiplon MR 15-mg tablets demonstrated statistically significant improvement for all primary and secondary endpoints in the Company's Phase III clinical trial involving 248 adult patients with chronic insomnia. Efficacy results with indiplon MR tablets demonstrated a highly statistically significant and clinically relevant improvement on the primary endpoint of patient reported Total Sleep Time (sTST) as compared to placebo (p=0.0002) over the four-weeks of treatment. Patients receiving indiplon gained approximately one hour of sleep over baseline. Safety results were consistent with those previously reported in other Phase III indiplon studies.

Study Design

The study was a randomized, double-blind, placebo-controlled, parallel-group, multi-center, out-patient Phase III clinical trial conducted in 248 adult patients with sleep maintenance difficulties. The study was conducted at 50 sleep centers in the U.S. Patients received nightly administration of 15 mg of indiplon MR tablets or placebo over a four-week period. The endpoints in this trial were the same as those studied in our elderly trial utilizing the 15 mg dose.

"These results once again confirmed the robustness, consistency, clinical relevance and safety profile of the data for indiplon. All sixteen Phase III trials with indiplon have demonstrated positive results, making this one of the most solid clinical evaluations of any new drug candidate," said Dr. Henry Pan, Executive Vice President and Chief Medical Officer for Neurocrine Biosciences. "As we had seen with the same measurements in our previous elderly study, the 15-mg dose showed significant improvement in sleep maintenance at every primary and secondary endpoint, as well as in next day functioning and alertness in this adult patient population. More importantly, this study also demonstrated favorable patient and investigator reported outcomes as well as in quality of life improvement. Neurocrine expects to submit an NDA for indiplon MR in the 2nd Quarter of 2005 that will include the results of this trial. We believe the registration of indiplon MR and IR will provide a broad spectrum of treatment for all sleep difficulties including sleep initiation, and sleep maintenance, and long term chronic usage," added Pan.

About Indiplon

Indiplon is a unique non-benzodiazapine agent that acts on a specific site of the GABA-A receptor. Indiplon has been shown to bind selectively to the specific subtype of GABA-A receptors within the brain believed to be responsible for promoting sleep. Two formulations of indiplon, IR capsules and MR tablets, are being evaluated in clinical trials to address different types of sleep problems. Indiplon was licensed from DOV Pharmaceutical in 1998.

Insomnia is a prevalent condition in the United States, with approximately 40 percent of the adult population reporting trouble sleeping a few nights per week or more, according to the National Sleep Foundation's (NSF) Sleep in America Poll 2002. Approximately 35 percent of the adult population reports that they have experienced insomnia every night or almost every night within the past year. Insomnia remains a disorder with high unmet medical needs, including prolonged awakenings during the night with difficulty falling back to sleep.

Neurocrine Biosciences, Inc. is a product-based biopharmaceutical company focused on neurological and endocrine diseases and disorders. Our product candidates address some of the largest pharmaceutical markets in the world including insomnia, certain female and male disorders, anxiety, depression, diabetes, multiple sclerosis, irritable bowel syndrome, eating disorders, pain, and autoimmunity. Neurocrine Biosciences, Inc. news releases are available through the Company's website via the Internet at http://www.neurocrine.com

In addition to historical facts, this press release may contain forward-looking statements that involve a number of risks and uncertainties. Among the factors that could cause actual results to differ materially from those indicated in the forward looking statements are risks and uncertainties associated with Neurocrine's business and finances in general including, but not limited to, risk and uncertainties associated with the Company's indiplon program and planned regulatory activities. Specifically, the risks and uncertainties the Company faces with respect to its indiplon program include, but are not limited to; risk that the Company will not be able to reformat the indiplon IR and/or MR NDA within the Company's projected timelines; risk that the Company will be unable to reformat the indiplon IR and/or MR NDA in a manner acceptable to the FDA; the risk that regulatory authorities may reject our regulatory submissions or find them incomplete or insufficient; risk that additional clinical studies may be required to support submissions for regulatory approval; risk that the indiplon labeling granted by regulatory authorities may limit the commercial success of indiplon; risk relating to the Company's dependence on contract manufacturers for clinical drug supply and compliance with regulatory requirements for marketing approval; risks associated with the Company's dependence on corporate collaborators for commercial manufacturing and marketing and sales activities; uncertainties relating to patent protection and intellectual property rights of third parties; risks and uncertainties relating to competitive products and technological changes that may limit demand for the Company's products; risk that the Company will be unable to raise additional funding required to complete development of all of its product candidates; and the other risks described in the Company's report on Form 10-K for the year ended December 31, 2003 and most recent report on Form 10-Q filed for the quarter ended, September 30, 2004. Neurocrine undertakes no obligation to update the statements contained in this press release after the date hereof.

SOURCE Neurocrine Biosciences, Inc.

Investors,
Elizabeth Foster or Claudia Jones of Neurocrine Biosciences,
+1-858-617-7600;
or
Media, Liz Frank of Cohn & Wolfe,
+1-212-798-9734,

for Neurocrine Biosciences, Inc.