Neurocrine Biosciences Announces Positive Phase II Efficacy and Safety Results With NBI-34060 Modified Release (MR)

January 18, 2002

SAN DIEGO, Jan. 18 /PRNewswire-FirstCall/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced positive efficacy results with NBI-34060 Modified Release (MR) tablets in a Phase II study in 47 adult patients with primary (chronic) insomnia with sleep maintenance complaints. This study was a randomized, multi-center, double-blind, placebo-controlled, five-way crossover, dose-response study, in which four doses (20 mg, 30 mg, 35 mg, and 40 mg) of MR tablets were tested. The primary endpoint was Sleep Efficiency (SE), defined as Total Sleep Time divided by 8 hours, as measured objectively by polysomnography (PSG). NBI-34060-MR demonstrated a statistically significant improvement in SE relative to placebo at 30 mg, 35 mg and 40 mg dose levels ($p<0.002$). Furthermore, 60%, 51%, and 66% of the patients in the above three dose groups slept more than 7 hours compared with only 36% in the placebo group. NBI-34060 also demonstrated a statistically significant decrease in Number of Awakenings After Sleep Onset (NAASO) at all doses when compared to placebo ($p<0.01$). In addition, Latency to Persistent Sleep (LPS) relative to placebo as measured by PSG was improved for all doses when compared to placebo ($p<0.01$). The adverse event profile in this study is consistent with that seen in previously reported studies with NBI-34060. Overall, NBI-34060-MR was well tolerated with no serious adverse events. Neurocrine expects to initiate Phase III clinical trials with NBI-34060-MR in the second quarter of this year; the Immediate Release (IR) formulation of NBI-34060 is currently in Phase III clinical testing.

Patient reported Total Sleep Time (TST), Latency to Sleep Onset (LSO), and Number of Awakenings After Sleep Onset (NAASO) also demonstrated statistically significant improvement over placebo for all doses ($p<0.02$ for TST, $p<0.009$ for LSO, and $p<0.0001$ for NAASO). These data indicate that the NBI-34060-MR treated patients not only fell asleep more rapidly but also stayed asleep longer and slept better. Patients on NBI-34060-MR had fewer awakenings during the night compared to placebo. There were no next day residual effects observed with NBI-34060-MR at 20 mg, 30 mg and 35 mg dose levels relative to placebo as measured by Digital Symbol Substitution Test (DSST), Symbol Copy Test (SCT) and Visual Analogue Scale (VAS) of sleepiness, the standardized sedation tests used in all previously reported studies.

Commenting on the clinical results, Dr. James Walsh, Executive Director, Sleep Medicine and Research Center St. Luke's Hospital, St. Louis, Missouri said, "These results demonstrate that unlike the most commonly prescribed hypnotics, the modified release form of NBI-34060 was found to improve both objective and subjective measures of sleep maintenance. In conjunction with other studies in the target population, these data demonstrated the efficacy of NBI-34060 in a reproducible and consistent manner. In addition these studies demonstrate that NBI-34060 is well tolerated with no next day impairment at doses likely to be used clinically."

"In this Phase II trial, patients with primary insomnia experienced rapid, high quality sleep with fewer awakenings on quantitative and patient reported measures, demonstrating a clear clinical benefit with NBI-34060-MR. We look forward to Phase III studies to learn more about this promising new approach to treat patients with sleep maintenance complaints," said Dr. Thomas Roth, Chief, Division Head, Sleep Disorders and Research Center, Henry Ford Hospital.

"Neurocrine's IR and MR formulations will provide the overall sleep solution to help those patients with different types of insomnia. Neurocrine previously reported positive efficacy data from numerous clinical trials using our Immediate Release (IR) formulation. Previously reported data showed NBI-34060-IR to be effective in sleep initiation. This latest study indicates for the first time that our MR formulation is equally effective in sleep initiation and in addition will be well suited for those patients with sleep maintenance problems. These results confirm what we expected from the detailed pharmacokinetic and pharmacodynamic modeling that went into the strategic development of the MR formulation," said Henry Pan, M.D., Ph.D., Executive Vice President of Clinical Development and Chief Medical Officer for Neurocrine Biosciences. "Our Phase III clinical program is currently underway and we expect to enroll over 2000 patients with transient and primary insomnia this year."

NBI-34060 is a non-benzodiazepine that acts on a specific site of the GABA-A receptor. It is through this mechanism that the currently marketed non-benzodiazepine therapeutics also produce their sleep-promoting effects.

Insomnia is a prevalent neurological disorder in the United States, with about one-half of the adult population reporting trouble sleeping a few nights per week or more, according to the National Sleep Foundation (NSF). Approximately 30% of the adult population reports that they experience insomnia every night or almost every night. Despite this widespread prevalence, insomnia remains a disorder with high unmet medical needs, including the ability to maintain sleep throughout the night without next-day residual effects.

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, anxiety, depression, malignant brain tumors and peripheral cancers, diabetes, multiple sclerosis, irritable bowel syndrome, eating disorders, pain, stroke, and certain female health disorders. 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 contains 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 NBI-34060 development program and business and finances including, but not limited to, risk that NBI-34060 will not successfully proceed through Phase III clinical trials or that in later stage clinical trials will not show that it is effective in treating humans; determinations by regulatory and governmental authorities; uncertainties relating to patent protection and intellectual property rights of third parties; impact of competitive products and technological changes; availability of capital and cost of capital; and other material risks. A more complete description of these risks can be found in the Company's Form 10K for the year ended December 31, 2000, as amended, the current form 10Q and its most recent registration statement, as filed with the Securities and Exchange Commission, each of which should be read before making any investment in Neurocrine common stock. Neurocrine undertakes no obligation to update the statements contained in this press release after the date hereof.

http://tbutton.prnewswire.com/prn/11690X79308741
SOURCE Neurocrine Biosciences, Inc.
Web site: http: //www.neurocrine.com
CONTACT: Elizabeth Foster or Paul Hawran, both of Neurocrine Biosciences, +1-858-658-7600