



Neurocrine Biosciences Reports Positive Results From First Phase III Clinical Trial With indiplon-IR in 593 Subjects With Transient Insomnia Indiplon-IR Demonstrates Statistically Significant Improvement in Mul

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SAN DIEGO, Nov. 14 /PRNewswire-FirstCall/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced positive results from the Company's first Phase III clinical trial with indiplon-IR capsules, achieving both primary and secondary endpoints of sleep initiation. The study enrolled 593 subjects with Transient Insomnia. Results demonstrated that indiplon-IR was safe, well tolerated, and effective in these subjects with Transient Insomnia, achieving rapid sleep induction without next day residual effects. The study was a randomized, double-blind, placebo-controlled, parallel group Phase III clinical trial designed to assess the safety and efficacy of two dose levels of indiplon-IR (10 mg or 20 mg) in adult subjects with Transient Insomnia. The primary endpoint was Latency to Persistent Sleep (LPS) as measured objectively by polysomnography (PSG) and the secondary endpoint was patient reported Latency to Sleep Onset (LSO); the endpoints for approval of currently marketed sedative hypnotics. In this study indiplon-IR demonstrated a statistically significant improvement in the primary endpoint of LPS at both dose levels relative to placebo ($p < 0.0001$). Mean improvements over placebo were approximately 36% and 50% for the 10 and 20 mg dose group, respectively. The secondary efficacy endpoint of patient reported LSO also demonstrated statistically significant improvements in the drug treated groups as compared to the placebo group ($p < 0.0001$), indicating that the indiplon subjects felt that they fell asleep more rapidly, supporting the results demonstrated through polysomnography.

Indiplon-IR also demonstrated statistically significant efficacy results on additional secondary endpoints. Objective efficacy measures of Total Sleep Time (TST) and Sleep Efficiency (SE), patient reported assessments of Total Sleep Time (sTST) and sleep quality (SQ) also demonstrated statistically significant improvement over placebo for both doses. There were no statistical differences in next day residual sedation detected by any of the three validated measurement tools when compared with placebo. Both doses of indiplon were well tolerated. In addition there were no discontinuations or serious adverse events observed in the study.

With this trial, indiplon has been studied in approximately 2000 subjects and patients and the results have been consistently positive. Neurocrine has initiated and is completing all of its multiple Phase III safety and efficacy trials to support a New Drug Application (NDA) registration with the Food and Drug Administration (FDA). The NDA will include two formulations of indiplon: indiplon-IR capsules and indiplon-MR tablets for multiple indications associated with insomnia.

Commenting on the clinical results, Dr. Thomas Roth, Chief, Division Head, Sleep Disorders and Research Center, Henry Ford Hospital, said, "Transient Insomnia is a very common problem that remains under treated. This is the most consistent set of data in Transient Insomnia. The Phase III results demonstrate indiplon-IR has a significant impact on both the physiological measures and the patient's perception, without causing next day residual effects. The primary endpoint of LPS is a physiological measure of sleep induction using polysomnography and is one of the most important measures that we make when evaluating pharmaceutical compounds for this indication. The patient's perception of how quickly they fell asleep is also a very important measure in evaluating the efficacy when treating insomnia. Indiplon may offer significant benefits for patients suffering with Transient Insomnia."

"We are pleased with these positive results in the first Phase III study reported for indiplon. Neurocrine's indiplon program for the two formulations involves over 6000 adult, elderly, male, and female subjects and will include patients with up to one year of treatment. Our Phase III program alone will have data from over 4000 patients with different types of insomnia," said Henry Pan, M.D., Ph.D., Executive Vice President and Chief Medical Officer for Neurocrine Biosciences.

Neurocrine is conducting one of the most comprehensive clinical programs in insomnia to address the multiple needs of adult and elderly patients with insomnia such as sleep initiation, sleep maintenance, middle of the night awakenings and long-term use. In addition to this Phase III study just reported, Neurocrine is currently conducting four additional Phase III clinical trials with indiplon-IR and three Phase III clinical trials with indiplon-MR.

Indiplon 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. However, indiplon is more potent than the currently marketed non-benzodiazepines, including Ambien(R) and Sonata(R) at the specific subtype of receptors within the brain believed to be responsible for promoting sleep.

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 55% 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 indiplon development program and business and finances including, but not limited to, risk that indiplon will not successfully proceed through Phase III clinical trials or that Phase III clinical trials will not show that it is safe and effective in treating humans; determinations by regulatory and governmental authorities; our reliance on corporate collaborators for commercial manufacturing and marketing and sales activities; 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 December 31, 2001 and the quarterly report filed on Form 10-Q for the quarter ended September 30, 2002. Neurocrine undertakes no obligation to update the statements contained in this press release after the date hereof.

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