Phase II Studies Underway for Insomnia

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SAN DIEGO, July 30 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced the initiation of a Phase II clinical study of NBI-34060 for the treatment of insomnia. This study will evaluate NBI-34060 in a Phase II randomized-controlled, multi-center clinical trial in 228 subjects with transient insomnia. The Phase II study is a dose response study, which will assess safety and efficacy in a sleep laboratory setting and determine the dose range for future efficacy studies. In Phase I testing, NBI-34060 was found to be safe and well tolerated in healthy volunteers. The most commonly reported side effects with NBI-34060 were tiredness and drowsiness, strong indicators of the expected pharmacodynamic effects.

The primary endpoint of the first Phase II clinical trial is to assess latency to persistent sleep (LPS) as determined by polysomnography, the same primary endpoint used in the approval of currently marketed sleep hypnotic agents. The secondary endpoints will include additional laboratory measurements such as the Number of Awakenings after Sleep Onset (NAASO), Total Sleep Time (TST) and sleep architecture. The trial will enroll three treatment arms including two dose levels and placebo. This will be the first in a series of Phase II clinical trials to evaluate safety and efficacy of NBI-34060 in adult and elderly populations with chronic insomnia.

"Based on the encouraging pharmacodynamic effects seen in our Phase Ib trial, Neurocrine is commencing a comprehensive Phase II program in approximately 400-500 patients. We believe that NBI-34060 has the potential to become a successful new option for treating insomnia with enhanced potency and an improved side effect profile," said Stephen G. Marcus, M.D., Senior Vice President of Clinical and Regulatory Affairs and Chief Medical Officer of Neurocrine Biosciences.

Neurocrine's compound, NBI-34060, is a sleep-promoting drug that, like the benzodiazepines, produces its effects by enhancing the action of the inhibitory neurotransmitter GABA. To achieve this, NBI-34060 binds to specific sites on the GABAA receptor, the same site that is the target of benzodiazepines. Consequently, NBI-34060 works through a proven mechanism but since NBI-34060 is a non-benzodiazepine, it is expected to offer an improved side effect profile. Preclinical studies have generated data suggesting that NBI-34060 may produce a more rapid onset of sleep and fewer next-day hangover effects compared to currently marketed products. Preclinical studies have also suggested that NBI-34060 has minimal interaction with alcohol and may not produce rapid tolerance or amnesia at effective sleep promoting doses. In addition, NBI-34060 shows greater selectivity for GABAA receptor subtypes and is more potent than currently approved therapies like Ambien(R).

Insomnia is a frequent complaint in Western countries being reported by up to 45% of the adult population, with an even higher prevalence in the elderly. Insomnia is of the most concern because the effects of sleeplessness can influence quality of life and in some cases, compromise the safety of the patient and others, such as in car accidents. According to the National Sleep Foundation's "1999 Sleep in America" polls, 40% of adults say that they are so sleepy during the day that it interferes with their daily activities. Historically, benzodiazepines have been the major class of drugs used to treat insomnia. While the clinical efficacy of current benzodiazepines such as Halcion have been well established, they are associated with side effects including sedation and/or amnesic effects (memory impairment), development of rapid tolerance, potential for abuse and withdrawal symptoms as well as a next day hangover effects.

Neurocrine Biosciences is a leading neuroscience company focused on the discovery and development of novel therapeutics for neuropsychiatric, neuroinflammatory and neurodegenerative diseases and disorders. The Company's neuroscience, endocrine and immunology disciplines provide a unique biological understanding of the molecular interaction between central nervous, immune and endocrine systems for the development of therapeutic interventions for anxiety, depression, Alzheimer's disease, insomnia, stroke, malignant brain tumors, multiple sclerosis, obesity and diabetes.

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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 research and development programs and business and finances including, but not limited to, risks and uncertainties associated with, or arising out of, drug discovery, pre-clinical and clinical development of products including risk that research may not generate development candidates, development candidates will not successfully proceed through early clinical trials or that in later stage clinical trials will not show that they are effective in treating humans; determinations by regulatory and governmental authorities; changes in relationships with strategic partners and dependence upon strategic partners for performance of clinical and commercialization activities under collaborative agreements including potential for any collaboration agreement to be terminated without any product success; 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, 1998 and the current form 10Q 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.

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