



## Neurocrine Biosciences Ramps Up Phase III Clinical Trials for NBI-34060 In Primary (Chronic) and Transient Insomnia

March 19, 2002

The Company Is on Track Initiating the Most Comprehensive  
Clinical Program in Insomnia

SAN DIEGO, March 19 /PRNewswire-FirstCall/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) announced today that it is initiating three additional pivotal Phase III clinical trials of NBI-34060 Immediate Release (IR) in over 1200 patients. The Company's first Phase III study with NBI-34060-IR was previously initiated in 500 patients in late 2001. With this announcement the Company will currently be conducting four of eight planned Phase III clinical trials with NBI-34060. According to the clinical program accepted by the Food and Drug Administration (FDA) at the Company's end of Phase II meeting, Neurocrine plans to conduct a total of five Phase III clinical trials with NBI-34060-IR and three Phase III trials with NBI-34060 Modified Release (MR) in a total of approximately 3500 patients overall to support market registration of NBI-34060 for short term and long term treatment in adult and elderly patients with Primary (Chronic) or Transient Insomnia. The clinical program for NBI-34060 will be one of the largest and the most comprehensive evaluation of a therapeutic agent for insomnia, encompassing approximately 5000 patients, and addressing the multiple needs of patients who suffer with insomnia.

Neurocrine has recently initiated a new randomized, double-blind, placebo-controlled, outpatient, multi-center Phase III clinical trial to assess the long-term safety and efficacy of two dose levels of NBI-34060-IR in patients with Primary (Chronic) Insomnia. The primary endpoint for this study is Latency to Sleep Onset (LSO) as measured by patient self reported outcomes. Secondary endpoints will evaluate sleep quality and next day effects. Patients will be evaluated over a period of six months. This trial is being conducted at approximately 60 centers in the U.S., U.K. and Canada.

Neurocrine has also recently initiated a new randomized, double-blind, placebo-controlled, parallel group Phase III clinical trial to assess the safety and efficacy of NBI-34060-IR in adult subjects with Transient Insomnia. The primary endpoint will be Latency to Persistent Sleep (LPS) as measured objectively by polysomnography (PSG). Secondary endpoints will evaluate sleep quality and next day effects. This trial is being conducted at approximately 20 centers in the U.S. and Canada.

Neurocrine will initiate its fourth Phase III clinical trial in April 2002. This Phase III trial will be a randomized, double-blind, placebo-controlled, parallel-group, multi-center study to assess the safety and efficacy of two doses of NBI-34060-IR in adult patients with Primary (Chronic) Insomnia. This will be an in-patient/out-patient study with the primary endpoint of Latency to Persistent Sleep (LPS) as measured objectively by PSG. Secondary endpoints will measure sleep quality and next day effects. This trial will be conducted at approximately 20 centers in the U.S.

"Our Phase III clinical program will evaluate the safety and efficacy of NBI-34060 in patients with primary and transient insomnia to confirm the positive results we have demonstrated in Phase I and Phase II clinical trials. These latest Phase III trials are also significant in that patients will undergo extended dosing periods longer than previously studied in controlled trials involving the currently approved sleep aids. We remain on schedule with our first Phase III clinical trial initiated last year and have enrolled over 200 patients to date. In addition to the four Phase III studies currently being implemented, we plan to initiate an additional Phase III trials with NBI-34060-IR shortly and to initiate three Phase III trials with NBI-34060-MR this year," said Henry Pan, M.D. Ph.D, Executive Vice President of Clinical Development and Chief Medical Officer for Neurocrine Biosciences.

Commenting at the Phase III Clinical Investigators meeting held recently, Dr. James Walsh, Executive Director, Sleep Medicine and Research Center St. Luke's Hospital, St. Louis, Missouri said, "This is a great opportunity to participate as an investigator in the pivotal Phase III program for NBI-34060. In addition to evaluating efficacy for sleep initiation, this will be the first major program that addresses other areas of insomnia such as sleep maintenance, one of the largest unmet needs associated with the treatment of insomnia."

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 percent 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.

MAKE YOUR OPINION COUNT - [Click Here](#)

<http://tbutton.prnewswire.com/prn/11690X93278242>

SOURCE Neurocrine Biosciences, Inc.

Web site: <http://www.neurocrine.com>

CONTACT: Elizabeth Foster or Paul Hawran of Neurocrine Biosciences, Inc., +1-858-658-7600