



## Neurocrine Biosciences Announces Additional Positive Phase II Results With NBI-34060 in 331 Subjects With Transient Insomnia

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NBI-34060 Demonstrates Statistical Significance in Sleep Initiation  
In Primary and Secondary Endpoints;  
Doses Selected for Pivotal Phase III Program to Begin Q4 2001

SAN DIEGO, Oct. 1 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced positive results with NBI-34060 in achieving both primary and secondary endpoints of sleep initiation in a Phase II clinical trial in subjects with transient insomnia. The study was a randomized, multi-center, multi-national, double blind, placebo-controlled, dose response study in 331 subjects with Transient Insomnia. The objective of this study was to assist in the selection of doses for pivotal Phase III clinical trials. The efficacy endpoints of this study were Latency to Persistent Sleep (LPS) as measured objectively by polysomnography and Time to Sleep Onset (TSO), the endpoints for approval of currently marketed sedative hypnotics. In this study NBI-34060 demonstrated a statistically significant effect on the primary endpoint of LPS relative to placebo ( $p < 0.004$ ) with up to a 40% improvement. The secondary efficacy endpoint of TSO also demonstrated improvements in the drug treated group as compared to the placebo group ( $p < 0.001$ ), indicating that the NBI-34060 subjects fell asleep more rapidly. There were no differences in residual sedation or in the incidence of adverse events as compared to placebo. This Phase II study demonstrated that NBI-34060 was safe, well tolerated and effective in these subjects with transient insomnia and achieved rapid sleep induction without next day residual effects associated with many currently marketed sedative hypnotics. These results are consistent with the safety and efficacy results seen in previous Phase II studies. Based upon the results of multiple successful Phase I and Phase II trials with NBI-34060 in Chronic (Primary) and Transient Insomnia administered in the beginning and middle of the night, Neurocrine has selected doses for the pivotal Phase III clinical program planned for initiation in the fourth quarter of 2001.

Commenting on the clinical results, James Walsh, Ph.D., a clinical investigator in the Phase II clinical trial and Executive Director, Sleep Medicine and Research Center St. Luke's Hospital, St. Louis, Missouri said, "These are encouraging results showing that NBI-34060 has demonstrated robust effects on sleep initiation and has demonstrated an excellent safety profile with no next day residual effects. This compound may offer important new benefits to those who suffer with insomnia."

"NBI-34060 has been administered to more than 900 adult and elderly male and female subjects. We have compiled a large database that confirms that this compound is well tolerated and is an active sedative hypnotic. We are proceeding with multiple Phase III safety and efficacy trials to support our registration. Based on recent discussions with the Food and Drug Administration (FDA) at our end of Phase II meeting, we will initiate our pivotal Phase III clinical programs this quarter," said Bruce Campbell, Ph.D., Senior Vice President of Development for Neurocrine Biosciences.

### Background on NBI-34060 for 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 therapeutic also produce their sleep-promoting effects.

Insomnia is a term used to describe conditions related to the perception of inadequate or non-restful sleep. It encompasses a heterogeneous set of complaints reflecting difficulties initiating and/or maintaining sleep. Insomnia is one of the most prevalent neurological disorders in the United States, with up to 58% of the adult population reporting one or more symptoms of insomnia each year, according to the National Sleep Foundation (NSF).

### Clinical Status Update on Neurocrine's Other Product Candidates:

Separately, Neurocrine reported on the status of its other clinical programs in development. One of the pivotal Phase IIb clinical trials for NBI-6024 is scheduled to begin early in the fourth quarter of 2001. This clinical trial is a randomized, double blind, placebo-controlled, multi-center, multinational study, in adolescent and adult patients. The study will involve at least 30 study centers and approximately 400 patients.

Neurocrine continues enrollment of its Phase I/II clinical trial with NBI-3001 for glioblastoma. The Company is on track to complete this study and initiate the pivotal program later this year. Neurocrine also expects to initiate Phase I studies with NBI-3001 for renal, breast and non-small lung cancer shortly.

In addition, an orally active GnRH antagonist development candidate has been selected for the treatment of endometriosis, uterine fibroids and prostate cancer. This program is expected to enter Phase I studies by the fourth quarter of 2001.

Neurocrine is also working with partner GlaxoSmithKline to complete a multi-dose Phase I clinical trial with NBI-34041 in development for anxiety and depression and irritable bowel syndrome (IBS).

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 development programs and business and finances including, but not limited to, risk that Neurocrine's development programs will not successfully proceed through all phases of clinical trials or that in later stage clinical trials will not show that Neurocrine's product candidates are

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.

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