Neurocrine Announces Submission of New Drug Application for Indiplon Capsules

April 14, 2005

Promising New Treatment Option Shown to Improve Sleep Onset and Sleep Maintenance

SAN DIEGO, April 14 /PRNewswire-FirstCall/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) announced that they have submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for indiplon capsules for the treatment of insomnia in both adult and elderly patients. The filing was resubmitted to the FDA solely to address formatting difficulties with the electronic common technical document (e-CTDformat), originally submitted in late 2004, and did not pertain to the content of the filing.

"Insomnia takes a significant toll on the physical well-being, and emotional health of sufferers. This submission marks a major milestone in our commitment to provide people with a safe and effective treatment option," said Gary A. Lyons, President and CEO of Neurocrine Biosciences. "We believe that indiplon is an important advancement in the treatment of insomnia because it can provide the flexibility to address the individual sleep needs of people with insomnia for short or longer-term use."

The NDA for indiplon tablets will also be resubmitted to the FDA in the second quarter to address similar formatting difficulties encountered with the e-CTD format originally submitted in late 2004. Data from a recently completed clinical trial demonstrating the safety and efficacy of indiplon 15 mg tablets in adult patients will be added to the submission.

The indiplon NDA filings will contain data from 72 clinical trials and include a comprehensive safety and efficacy evaluation in more than 7,500 subjects. Clinical trial results have shown that indiplon capsules and tablets help patients consistently fall asleep faster, increase the amount of time they sleep during the night, decrease number of nighttime awakenings and improve overall sleep quality over the course of short or long-term treatment without evidence of next day effects.

About Indiplon

Indiplon is a unique non-benzodiazapine agent that acts on a specific site of the GABA-A receptor. Indiplon has been shown to bind selectively to the specific subtype of GABA-A receptors within the brain believed to be responsible for promoting sleep. Indiplon was developed to address different types of sleep problems. Indiplon was licensed from DOV Pharmaceutical in 1998. Upon approval, indiplon will be copromoted in the US with Pfizer.

Insomnia is a prevalent condition in the United States. According to the National Sleep Foundation's (NSF) Sleep in America Poll 2005 approximately half of America's adults report that they experienced at least one symptom of insomnia a few nights a week or more in the past year. Sleep loss has been found to impair the ability to perform tasks involving memory, learning, and logical reasoning, yet few people understand the importance of sufficient sleep.

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, diabetes, multiple sclerosis, irritable bowel syndrome, eating disorders, pain, and autoimmunity. 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 may contain 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 business and finances in general including, but not limited to, risk and uncertainties associated with the Company's indiplon program and planned regulatory activities. Specifically, the risks and uncertainties the Company faces with respect to its indiplon program include, but are not limited to; risk that the reformatted indiplon capsule NDA will not be acceptable to the FDA; risk that the Company will not be able to reformat the indiplon tablet NDA within the Company's projected timelines; risk that the Company will be unable to reformat the indiplon tablet NDA in a manner acceptable to the FDA; the risk that regulatory authorities may reject our regulatory submissions or find them incomplete or insufficient; risk that additional clinical studies may be required to support submissions for regulatory approval; risk that the indiplon labeling granted by regulatory authorities may limit the commercial success of indiplon; risk relating to the Company's dependence on contract manufacturers for clinical drug supply and compliance with regulatory requirements for marketing approval; risks associated with the Company's dependence on corporate collaborators for commercial manufacturing and marketing and sales activities; uncertainties relating to patent protection and intellectual property rights of third parties; risks and uncertainties relating to competitive products and technological changes that may limit demand for the Company's products; risk that the Company will be unable to raise additional funding required to complete development of all of its product candidates; and the other risks described in the Company's report on Form 10-K for the year ended December 31, 2004. Neurocrine undertakes no obligation to update the statements contained in this press release after the date hereof.

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04/14/2005
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