Neurocrine Biosciences Announces Study Showing Indiplon Immediate Release Safe for Middle of the Night Dosing Without Next Day Residual Effects

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Data Presented at the American Psychiatric Association (APA) Meeting

NEW YORK, May 4 /PRNewswire-FirstCall/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) announced results from a study in healthy volunteers presented today that shows that indiplon immediate release when taken in the middle of the night (MOTN) is safe and well tolerated without evidence of next day residual effects. These results were presented at the 157th annual meeting of the American Psychiatric Association (APA) in New York City.

"This is promising data for patients who have trouble staying asleep and wake up frequently in the middle of the night. They are often concerned that taking a sleep medication will leave them feeling groggy the next day," said Dr. Marty Scharf, Director, Tri-State Sleep Disorders Center and Clinical Professor of Psychiatry at the Wright State University Department of Psychiatry. "This study is exciting as it suggests this patient population can safely take indiplon immediate release without impacting their next day functioning."

No Evidence of Next Day Residual Effects with Indiplon Immediate Release

Results were presented from the Company's indiplon immediate release Phase I five-way crossover, randomized, double-blind, placebo and active drug controlled, single center clinical trial designed to assess safety and tolerability of indiplon, zolpidem 10 mg and zopiclone 7.5 mg administered in the middle of the night (MOTN) compared with placebo.

The data showed that indiplon immediate release 10 mg or 20 mg doses administered MOTN was well tolerated and subjects did not experience next morning residual effects as compared to placebo using the three validated measurements of Digital Symbol Substitution Test (DSST), Symbol Copy Test (SCT), and Visual Analog Scale (VAS) for sleepiness. Results demonstrated that there were no significant changes from pre-dosing baseline in the VAS sleepiness ratings for either indiplon immediate release 10 mg or 20 mg at four hours or at six hours post dosing as compared to placebo. In contrast, zopiclone 7.5 mg showed a significant increase in sleepiness on VAS compared to placebo at both four hours and six hours post dosing. Similarly, zolpidem 10 mg showed a significant increase in sleepiness compared to placebo at four hours post dosing. The MOTN dosing did not affect DSST or SCT at either time point for any drug administered. Safety results demonstrated that adverse events were comparable to placebo for both doses of indiplon immediate release and zolpidem. However, treatment-related adverse events were notably higher with zopiclone.

The study was conducted on an in-patient basis with 35 healthy subjects, aged 18 to 45 years. Subjects were awakened to an alert state 4 hours after they had fallen asleep at which time indiplon, zolpidem, zopiclone or placebo was administered. After falling back to sleep, subjects were awakened four hours later and residual effects were tested upon awakening and again two hours later using the three validated measurements of sleepiness.

"These results demonstrate that indiplon immediate release when administered to adult subjects after middle of the night is safe and well tolerated with no evidence of next morning residual effects. These findings are also consistent with a previously reported Phase I MOTN study conducted in the elderly population," said Dr. Henry Pan, Executive Vice President and Chief Medical Officer for Neurocrine Biosciences.

About Indiplon

Indiplon is a novel GABA-A receptor potentiator with high selectivity for the specific subtype of GABA-A receptors within the brain believed to be responsible for promoting sleep. Two formulations of indiplon, immediate release and modified release, are being developed to address different types of sleep problems. Indiplon was licensed from DOV Pharmaceutical in 1998.

Insomnia is a prevalent condition in the United States, with 58 percent of the adult population reporting trouble sleeping a few nights per week or more, according to the National Sleep Foundation's (NSF) Sleep in America Poll 2002. Approximately 35 percent of the adult population reports that they have experienced insomnia every night or almost every night within the past year. Insomnia remains a disorder with high unmet medical needs, including prolonged awakenings during the night with difficulty falling back to 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, certain female and male disorders, 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 and research programs in general including, but not limited to, risk and uncertainties associated with, or arising out of, drug discovery, pre-clinical and clinical development of products including risk that the Company's Urocortin and CRF research programs will not lead to clinical candidates, that the GnRH receptor antagonist, D2 receptor agonist and altered peptide ligand clinical candidates will not proceed to later stage clinical trials and risks and uncertainties associated with the Company's indiplon Phase III 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 indiplon may not successfully proceed through Phase III clinical trials including the risk that Phase III clinical trials may fail to demonstrate that indiplon is safe and effective in treating humans and the risk that additional clinical studies may be required to support filings for regulatory approval; risk that the Company may not complete indiplon Phase III clinical trials on the Company's projected timelines for various reasons, including the risk that the clinical investigators and contract research organizations upon which the Company relies to conduct its clinical programs may not be diligent, careful or timely, and may make mistakes, in the conduct of the programs; risk relating to the Company's dependence on contract manufacturers for clinical

drug supply and compliance with regulatory requirements for marketing approval; risk that the Company may not successfully co-ordinate the completion and submission of planned regulatory filings on the Company's projected timelines; risk that the Company may not receive regulatory approval for indiplon or approval may be delayed; 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, 2003. Neurocrine undertakes no obligation to update the statements contained in this press release after the date hereof.

SOURCE Neurocrine Biosciences, Inc.