Neurocrine Announces Acceptance of New Drug Application for Indiplon Tablets

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Indiplon NDA Filing Process Complete - Both Capsule and Tablet Filings Now Under Formal Review

SAN DIEGO, July 26 /PRNewswire-FirstCall/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) announced today that the U.S. Food and Drug Administration (FDA) has accepted the Company's New Drug Application (NDA) for indiplon tablets for review for the treatment of insomnia in both adult and elderly patients.

"This is an exciting milestone for Neurocrine and represents the company's first completed NDA filing," said Gary A. Lyons, President and CEO of Neurocrine Biosciences. "Data from these two submissions is supported by one of the most comprehensive clinical trial programs in insomnia and demonstrates the long-term safety and efficacy profile of indiplon in helping patients with sleep onset and sleep maintenance problems."

Indiplon is a unique non-narcotic, non-benzodiazepine 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. 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 including, but not limited to; risk that regulatory authorities find our regulatory submissions incomplete or insufficient or otherwise unapprovable; and the other risks described in the Company's report on Form 10-K for the year ended December 31, 2004 and report on Form 10-Q for the quarter ended March 31, 2005. Neurocrine undertakes no obligation to update the statements contained in this press release after the date hereof.

SOURCE Neurocrine Biosciences, Inc.
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