



Neurocrine Provides Update of Food and Drug Administration's Review of Indiplon

January 10, 2006

SAN DIEGO, Jan. 10 /PRNewswire-FirstCall/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) provided today an update of the Company's discussions with the Food and Drug Administration (FDA) regarding the review and approval of indiplon. The Company announced that the FDA has requested submission of results from the driving study completed in late 2005. The final report of this study was submitted to the agency as requested. Based on feedback from the FDA, the Company anticipates labeling that includes data from this study, which show no impairment in next-day driving performance. In addition, the FDA has stated its intent to issue a combined package insert in lieu of individual package inserts for each IR (capsule) and MR (tablet) NDA. Finally, the Company was advised that the Controlled Substances Staff of the FDA has completed its scheduling recommendation which will be submitted to the Drug Enforcement Agency (DEA). Based on discussions with the DEA, the Company believes this "hand-off" will allow the DEA to complete its scheduling process in parallel with the FDA review process. To complete review of the driving study and the combined package insert, the FDA has advised the Company that the PDUFA dates for the IR and MR NDAs have been adapted accordingly to May 15 and June 27, respectively. However, the FDA has committed to an action by May 15 for both NDAs. Based on the above, the Company is moving forward with full commercialization as planned.

"We have been pleased with the ongoing discussions with the FDA and the Agency's commitment to review both applications in an expeditious manner which will result in a single package insert. A combined package insert will benefit consumers and prescribing physicians by providing a single source of indiplon information," said Gary Lyons, President & CEO of Neurocrine Biosciences.

The safety and efficacy of indiplon has been evaluated in the most thorough clinical registration program ever conducted for an insomnia agent. In over 70 clinical trials involving nearly 8,000 patients, indiplon has consistently demonstrated decreased time to sleep onset, improved measures of sleep maintenance and duration and improved sleep quality with no next day impairment.

Neurocrine Biosciences, Inc. is a product-based biopharmaceutical company focused on neurological and endocrine diseases and disorders. The 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 as well as, risk and uncertainties associated with the Company's indiplon program and planned commercialization activities, including but not limited to; risk that regulatory authorities find our indiplon NDAs incomplete or insufficient or otherwise unapprovable or that approvals may be delayed; risk associated with our reliance on our strategic alliance partner for manufacturing and commercialization of indiplon; risk that following approval of indiplon commercialization may be delayed for any of a number of reasons including market conditions and product supply; risk that the indiplon labeling granted by regulatory authorities may limit the commercial success of indiplon; and risk relating to market acceptance of indiplon following marketing approval; in addition to the other risks described in the Company's report on Form 10-Q for the quarter ended September 30, 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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