



Neurocrine Reports Results of FDA End-of-Review Meeting on Indiplon Capsules NDA

September 5, 2006

SAN DIEGO, Sept. 5 /PRNewswire-FirstCall/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today reported the results of its end-of-review meeting with the Food and Drug Administration (FDA) meeting for the indiplon capsules New Drug Application (NDA). The meeting with the FDA was specifically focused on determining the actions needed to bring indiplon immediate-release (IR) capsules from Approvable to Approval for the treatment of insomnia.

The Company summarized the results of the FDA meeting as follows: * The FDA requested that the Company supplement the pharmacokinetic/food effect profile of indiplon (IR) capsules to include several meal types. The Company will initiate such a study shortly after further consultation with the FDA. No other clinical trials were requested for the re-submission;

* The re-submission will also include further analyses and modifications of analyses previously submitted which address questions raised by the agency in the initial review.

"We are pleased to have clarified the outstanding issues with the FDA and expect to resolve the remaining issue in the coming weeks," said Gary A. Lyons, President and Chief Executive Officer of Neurocrine Biosciences. "Subject to those further consultations with the FDA we are expecting to provide a complete re-submission sometime before the end of the 2nd Qtr 2007. We are encouraged about the prospects for indiplon capsules to compete effectively in the marketplace upon approval and continue to evaluate alternatives for bringing it to market in a timely manner."

Separately, the Company has also confirmed that its request for an end-of- review meeting with the FDA to discuss and clarify action items for indiplon (MR) tablets has been scheduled towards late October 2006.

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 we will be unable to resubmit the indiplon capsule NDA in a timely manner or at all; risk that additional clinical and preclinical studies and data analyses required for resubmission may fail to support resubmission of the indiplon capsule NDA; risk that regulatory authorities may find our resubmission of the indiplon capsule NDA incomplete or insufficient or otherwise unapprovable or that approval may be delayed; risk that following approval of indiplon capsules, commercialization may be delayed for any of a number of reasons including market conditions and product supply; risk that we will not be able to independently commercialize indiplon capsules or find a marketing partner on reasonable terms or at all; risk that the indiplon capsule labeling granted by regulatory authorities may limit the commercial success of indiplon capsules; and risk relating to market acceptance of indiplon capsules following marketing approval; in addition to the other risks described in the Company's report on Form 10-K for the year ended December 31, 2005 and Form 10-Q for the quarter ended June 30, 2006. 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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