



Neurocrine Biosciences Announces Plans to Resubmit Indiplon Modified Release New Drug Application (NDA)

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SAN DIEGO, Jan 11, 2005 /PRNewswire-FirstCall via COMTEX/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) announced today that the Company will resubmit its New Drug Application (NDA) for indiplon modified release (MR) tablets to update its electronic formatting. The indiplon MR filing was submitted to the U.S. Food and Drug Administration (FDA) on November 22, 2004. Neurocrine previously reported that the NDA for indiplon immediate release (IR) capsules was not accepted by the FDA due to difficulties encountered in navigating the NDA in the electronic common technical document (CTD) format. The IR NDA included non-clinical, clinical and manufacturing information that was common to both the IR and MR applications. The reformatting of the indiplon MR NDA will ensure technical consistency with the indiplon IR NDA since the two applications share CTD modules. The formatting issues are based on technical difficulties with the electronic navigation and do not pertain to the content of either the IR or MR filings.

"We will be meeting with the FDA in late January to discuss our electronic reformatting changes and to finalize the filing strategies. Based on this meeting, we plan to submit both the IR and MR applications as soon as possible. We anticipate only a modest impact on the expected timelines for approval and launch of indiplon," said Gary A. Lyons, President and CEO of Neurocrine Biosciences.

The Division of Neuropharmacological Drug Products is now responsible for the indiplon review and approval process. The filing contains studies which comprise one of the most extensive programs conducted to date in insomnia, with data from 68 clinical trials and over 80 preclinical studies and includes a comprehensive safety and efficacy evaluation in over 7500 subjects. The NDAs were filed in eCTD electronic format, which contain approximately 1500 volumes or 524,000 pages of data.

Live Webcast Tomorrow at the 23rd Annual JP Morgan Healthcare Conference

As a reminder, Neurocrine will present at the 23rd Annual JP Morgan Healthcare Conference tomorrow, Wednesday, January 12, which will be webcast live at 1:30 PM Eastern Standard Time (10:30 AM Pacific Standard Time). Participants may access the live conference call by logging onto the Company's website at www.neurocrine.com and when prompted select the 23rd Annual JP Morgan Healthcare Conference. Upon registering, click on the menu for "Live Webcast," and then select the company name, Neurocrine, to view the live presentation. A replay of the webcast will be available approximately 24 hours later and will be archived until Wednesday, January 26, 2005. The live webcast can also be accessed during the presentation through JP Morgan at <http://equityconferences.jpmorgan.com> and following the above steps.

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, 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 Company will not be able to reformat the indiplon IR and/or MR NDA within the Company's projected timelines; risk that the Company will be unable to reformat the indiplon IR and/or MR NDA in a manner acceptable to the FDA; the risk that regulatory authorities may reject our regulatory filings or find them incomplete or insufficient; risk that additional clinical studies may be required to support filings for regulatory approval; 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 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; risk that the indiplon labeling granted by regulatory authorities may limit the commercial success of indiplon; and the other risks described in the Company's report on Form 10-K for the year ended December 31, 2003 and most recent report on Form 10-Q filed for the quarter ended September 30, 2004. 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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