Neurocrine Biosciences Announces Initiation of Phase I Trial With CRF1 Antagonist for Anxiety and Depression

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SAN DIEGO, Dec 14, 2004 /PRNewswire-FirstCall via COMTEX/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) announced today that its partner GlaxoSmithKline (GSK) has initiated a Phase I clinical trial with a lead Corticotropin Releasing Factor 1 (CRF1) receptor antagonist compound. The Phase I clinical trial is a double-blind, randomized, placebo controlled, single dose study to evaluate the safety and pharmacokinetics (PK) of a range of escalating doses of this compound in healthy volunteers. As part of their collaboration, Neurocrine and GSK are developing CRF antagonists for several indications including anxiety and depression.

"We are pleased to advance the GSK and Neurocrine collaboration's newest generation CRF1 antagonist into clinical development. This novel CRF1 antagonist lead compound was selected from several novel series of compounds discovered by GSK and Neurocrine, based on a rigorous preclinical safety and efficacy evaluation. Following completion of this initial Phase I clinical trial, we anticipate further evaluating this lead compound in extended Phase I and Phase II proof of concept trials," said Dr. Wendell Wierenga, Executive Vice President of Research and Development for Neurocrine Biosciences.

Dr. Wylie Vale, Neurocrine co-founder, first identified and cloned the CRF1 receptor along with his colleagues at the Salk Institute. Neurocrine further characterized the CRF receptor system and identified additional members of the CRF receptor family. CRF functions as a neurotransmitter in the brain and plays a critical role in coordinating the body's response to stress. The CRF1 receptor subtype largely mediates these effects. In preclinical models, selective CRF1 receptor antagonists block stress-related responses providing further evidence that this novel mechanism may result in improved anti-anxiety and anti-depressant properties. Neurocrine and GSK entered into a worldwide research, development and commercialization agreement in July 2001 for CRF receptor antagonists, to treat psychiatric, neurological and gastrointestinal diseases including anxiety, depression, and irritable bowel syndrome.

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 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 and specifically risk that the current lead CRF receptor antagonist may prove unsuitable for continued clinical development and that our research may fail to identify additional compounds suitable for clinical development; risk that our clinical trials will fail to demonstrate that CRF antagonists are safe and effective; risk relating to our reliance on contract manufacturers; uncertainties relating to patent protection for CRF receptor antagonists and intellectual property rights of third parties in the CRF field; impact of 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 and most recent report on Form 10-Q filed for the third 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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