



## Neurocrine Biosciences Announces Initiation of Phase I Trial With Urocortin 2 for Congestive Heart Failure

October 25, 2004

SAN DIEGO, Oct 25, 2004 /PRNewswire-FirstCall via COMTEX/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) announced today initiation of the Company's Phase I clinical trial with its proprietary compound, urocortin 2, to evaluate the safety, pharmacokinetics (PK), and pharmacodynamics (PD) of urocortin 2 in healthy volunteers and expects to initiate a Phase II clinical study in patients with mild to moderate congestive heart failure in early 2005.

"We are pleased to advance this compound into clinical development for the treatment of congestive heart failure. Urocortin 2 has a novel mechanism of action. Based on our preclinical efficacy and safety data, together with its known role in human physiology, we believe urocortin 2 has positive hemodynamic effects on cardiac output and blood pressure which may benefit patients with congestive heart failure," said Dr. Wendell Wierenga, Executive Vice President of Research and Development for Neurocrine Biosciences.

"In addition to urocortin 2, Neurocrine is or will be evaluating six compounds in clinical development including indiplon immediate release capsules and modified release tablets for insomnia, GnRH for endometriosis and benign prostatic hyperplasia, two APL compounds for multiple sclerosis and diabetes, and CRF for anxiety, depression and gastrointestinal disorders. We expect two additional compounds to enter clinical trials before year-end. Our strategic research & development goal is to advance at least one new compound into clinical development each year to continue to supplement our broadly diversified development pipeline," added Wierenga.

The study design for the Phase I clinical trial included a single-blind, placebo-controlled, dose escalation study to evaluate the safety, pharmacokinetic and pharmacodynamics of urocortin 2 in healthy volunteers. The study is being conducted in two parts: a pilot study which has been completed to refine dosing followed by a Phase I study in a group of healthy subjects. The Phase I study will transition into a Phase II dose escalating clinical trial, which will be conducted in patients with mild to moderate congestive heart disease in early 2005.

Urocortin 2 was discovered in the laboratory of Neurocrine's co-founder, Dr. Wylie W. Vale, Professor and Head, Clayton Foundation for Research for Peptide Biology from the Salk Institute. Neurocrine licensed urocortin 2 from the Clayton Foundation for Research to further expand the Company's franchise in corticotropin-releasing factor (CRF) research.

"Work on the urocortin family of peptides has focused on their role in the control of the hormonal, cardiovascular, gastrointestinal and behavioral responses to stress. It is gratifying to see this peptide, urocortin 2, advance from the basic science arena to clinical trials. Urocortin 2 has an array of effects on the cardiovascular system and metabolism, which may well prove beneficial for the treatment of cardiovascular and other diseases," said Dr. Wylie Vale.

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 urocortin 2 may prove unsuitable for continued clinical development; risk that our clinical trials will fail to demonstrate that urocortin 2 is safe and effective; risk relating to our reliance on contract manufacturers; risk that the Company could fail to meet its obligations under the urocortin 2 license which would cause it to forfeit product rights; uncertainties relating to patent protection for urocortin 2 and intellectual property rights of third parties in the urocortin 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 10-Q filed for the second quarter ended, June 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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