Neurocrine Biosciences Announces Urocortin 2 Phase II Study Results in Patients With Acute Decompensated Heart Failure

May 17, 2012

Urocortin 2 Significantly Improved Cardiac Output

SAN DIEGO, May 17, 2012 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ: NBIX) today announced efficacy and safety results from a Phase II trial of urocortin 2 in 53 patients with acute decompensated heart failure. The UNICORN study was conducted over approximately a two year period by the Cardioendocrine Research Group from the University of Otago in Christchurch, New Zealand and included patients admitted to Christchurch Hospital with acute decompensated heart failure. After initial stabilization, subjects were randomized to receive a 4-hour infusion of either placebo or urocortin 2 in addition to standard-of-care treatments. Infusion of urocortin 2 was generally well tolerated and there were no treatment-related serious adverse events. There was one heart failure related death, not related to drug, in the urocortin 2 arm of the study that occurred 48-hours post infusion.

The hemodynamic profile of urocortin 2 infusion was consistent with what had been established in earlier Phase I and Phase II clinical studies including improved cardiac output, reduction in peripheral vascular resistance and absence of sympathetic overstimulation. Mean arterial pressures were significantly reduced ($p<0.001$) from 92 +/- 3 mmHg at baseline to 80+/-3 mmHg at end of the urocortin 2 infusion (n=27) in contrast to placebo (n=26) where the mean arterial pressure was 92 +/- 3 mmHg at baseline and 89 +/- 4 mmHg at the end of the placebo infusion. Heart rates were slightly higher during urocortin 2 infusion than placebo although these remained in normal range and comparable in both groups post infusion. In the subset of subjects undergoing right heart catheterization (n=20, 10 per arm), cardiac output increased markedly by over 50% in those randomized to urocortin 2 compared to unchanging values in the placebo group ($p=0.003$).

"The result of this Phase II study shows that urocortin 2 is very potent hemodynamically and improves cardiac output over the course of administration," said Christopher F. O'Brien, Chief Medical Officer, Neurocrine Biosciences. "We wish to thank University of Otago cardiologists Drs. Wandy Chan, Richard Troughton, and Mark Richards in Christchurch, New Zealand for their excellent work on this clinical trial and their ongoing elucidation of the role of urocortins in heart failure."

Clinical chemistry, hematology and urinalysis values were assessed and no statistically significant differences were reported between the subjects who received urocortin 2 or placebo, with the exception of an increase in plasma creatinine concentration during the 4-hour infusion period.

Adverse event reporting indicates that 55% of subjects randomized to urocortin 2 reported transient flushing (vs. 23% in the placebo group). Four subjects had lowering of systolic blood pressure below pre-set "stop" values which, although asymptomatic, per protocol required a decrease or cessation of urocortin 2 infusion.

"This study provides additional insights in the potential utility of urocortin 2 in the management of heart failure," said Dr. Mark Richards, Director of The Christchurch Heart Institute. "We look forward to presenting the detailed clinical and laboratory data at an upcoming scientific meeting later this year."

Kevin Gorman, Chief Executive Officer of Neurocrine Biosciences commented, "We are pleased with the results of this study and will continue to rely on outside parties to further investigate urocortin 2 in clinical settings, while we remain focused on our neurological and endocrine based pipeline."

About Urocortin 2

Urocortin 2 is present in the cardiovascular system, notably the heart and cerebral arterial system and plays a role in the control of the hormonal, cardiovascular, gastrointestinal, and behavioral responses to stress, along with an array of effects on the cardiovascular system and metabolism.

About Congestive Heart Failure

Congestive heart failure (CHF) is a condition where the heart cannot pump enough blood to supply all of the body's organs. It is a result of narrowing of the arteries combined with high blood pressure, which results in increased respiration as well as edema from water retention. According to 2011 data from the American Heart Association, over 6 million people experience CHF and about 670,000 new cases are diagnosed each year in the United States, coupled with over one million hospital discharges per year related to CHF.

About Neurocrine Biosciences

Neurocrine Biosciences, Inc. is a biopharmaceutical company focused on neurological and endocrine diseases and disorders. Our product candidates address some of the largest pharmaceutical markets in the world, including endometriosis, stress-related disorders, pain, tardive dyskinesia, uterine fibroids, diabetes, insomnia, and other neurological and endocrine-related diseases and disorders. 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 risks and uncertainties associated with the Company's urocortin 2 program and Company overall. Specifically, the risks and uncertainties the Company faces with respect to the Company's urocortin 2 program include, but are not limited to; risk that urocortin 2 will not proceed to later stage clinical trials and risk that clinical trials will fail to demonstrate that urocortin 2 is safe and effective. With respect to its pipeline overall, the Company faces risk that it will be unable to raise additional funding required to complete development of all of its product candidates; risk relating to the Company's dependence on contract manufacturers for clinical drug supply; risks associated with the Company's dependence on corporate partners for development, commercial manufacturing and marketing and sales activities for the Company's partnered programs; uncertainties relating to patent protection and intellectual property rights of third parties; risks and uncertainties relating to competitive products and technological changes that may limit demand for the Company's products; and the other risks described in the Company's report on Form 10-K for the year ended December 31, 2011 and the Company's report on Form 10-Q for the quarter ended March 31, 2012. Neurocrine undertakes no obligation to update the statements contained in this press release after the date hereof.

SOURCE Neurocrine Biosciences, Inc.

Neurocrine Biosciences, Investor Relations, +1-858-617-7600