Neurocrine Biosciences Provides Update on NBI-77860 Program for Congenital Adrenal Hyperplasia

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Based on Preclinical Observations, Two Clinical Studies of NBI-77860 Halted by the Company Prior to Patient Enrollment

SAN DIEGO, June 8, 2015 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ: NBIX) announced today that it has suspended two planned clinical studies of the Company's CRF antagonist NBI-77860.

"Out of an abundance of caution, we halted the implementation of these studies and notified the FDA of certain recent preclinical findings that we had not observed in previous animal studies," said Chris O'Brien, M.D., Chief Medical Officer at Neurocrine. "We intend to work closely with the FDA to elucidate these findings and determine the next steps for NBI-77860 in congenital adrenal hyperplasia."

The two clinical studies that were halted include a single dose study in adolescent females with classic congenital adrenal hyperplasia and a multiple dose study in adults with classic congenital adrenal hyperplasia. The Company had not enrolled any subjects in either study and accordingly, there have been no adverse events reported.

The Company has also been informed by the FDA that the NBI-77860 clinical development program would be placed on partial clinical hold.

About Classic Congenital Adrenal Hyperplasia (CAH)

Classic CAH is a genetic disorder that results in an enzyme deficiency altering the production of adrenal steroids. Because of this deficiency, the adrenal glands have little to no cortisol biosynthesis resulting in a potentially life-threatening condition. If left untreated, classic CAH can result in salt wasting, dehydration and eventually death. Even with cortisol replacement, persistent elevation of ACTH from the pituitary gland results in excessive androgen levels leading to virilization of females including precocious puberty, menstrual irregularity, short stature, hirsutism, acne and fertility problems.

Corticosteroids are the current standard of care for classic CAH which are used to both correct the endogenous cortisol deficiency and reduce the excessive ACTH levels and androgen excess. However, the dose and duration of steroid use required to suppress ACTH is well above the normal physiological level of cortisol; resulting in metabolic syndrome, bone loss, growth impairment, and Cushing's syndrome as common and serious side effects.

Additional information on CAH can be obtained from the National Institutes of Health http://www.nlm.nih.gov, and patient advocacy groups such as CARES http://www.caresfoundation.org.

About NBI-77860

NBI-77860 is a potent, selective non-peptide CRF receptor antagonist as demonstrated in a range of in vitro/in vivo assays and human clinical studies. Blockade of CRF receptors at the pituitary has been shown to decrease the release of ACTH, which in turn decreases the production of adrenal steroids including androgens, and potentially the symptoms associated with classic CAH. Lower ACTH levels would also reduce the amount of exogenous corticosteroid necessary for classic CAH patients to thrive avoiding the side-effects currently associated with excessive steroid therapy.

About Neurocrine Biosciences

Neurocrine Biosciences, Inc. discovers and develops innovative and life-changing pharmaceuticals, in diseases with high unmet medical needs, through its novel R&D platform, focused on neurological and endocrine based diseases and disorders. The Company's two lead late-stage clinical programs are elagolix, a gonadotropin-releasing hormone antagonist for women's health that is partnered with AbbVie Inc., and NBI-98854, a vesicular monoamine transporter 2 inhibitor for the treatment of movement disorders. Neurocrine intends to maintain certain commercial rights to its VMAT2 inhibitor for evolution into a fully-integrated pharmaceutical company. 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 product candidate NBI-77860 in general, including the risk that NBI-77860 will not be found to be safe and effective. Specifically, the risks and uncertainties the Company faces for NBI-77860

include risks that development activities may not be completed on time or at all; risks that clinical development activities may be delayed for regulatory or other reasons, may not be successful or replicate previous clinical trial results, or may not be predictive of real-world results or of results in subsequent clinical trials; risks that regulatory submissions may not occur or be submitted in a timely manner; risk that NBI-77860 candidates may not obtain regulatory approval; or that the U.S. Food and Drug Administration or regulatory authorities outside the U.S. may make adverse decisions regarding the Company's product candidates; and the other risks described in the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2015. Neurocrine disclaims any obligation to update the statements contained in this press release.

SOURCE Neurocrine Biosciences, Inc.

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