Neurocrine Biosciences Announces Initiation of Phase 1 Clinical Study Evaluating NBIP-01435, a Long-Acting Corticotropin-Releasing Factor Type 1 Receptor Antagonist

June 30, 2025

SAN DIEGO, June 30, 2025 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced the initiation of a Phase 1 first-in-human clinical study to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics and immunogenicity of investigational compound NBIP-01435 in healthy adult participants. NBIP-01435 is a long-acting corticotropin-releasing factor type 1 receptor antagonist administered as a subcutaneous injection for the potential treatment of congenital adrenal hyperplasia (CAH).

"As a leader in CAH, Neurocrine is dedicated to expanding treatment options for patients with congenital adrenal hyperplasia," said Sanjay Keswani, M.D., Chief Medical Officer, Neurocrine Biosciences. "This is the first investigational peptide from our biologics pipeline to proceed to the clinic, and we look forward to seeing the potential of these molecules and how they can complement our robust small molecule portfolio."

CAH is a rare genetic condition that results in an enzyme deficiency that alters the production of adrenal steroid hormones, such as cortisol, aldosterone and adrenal androgens. The deficiency of cortisol, an essential hormone for life, results in the production of excess adrenal androgens, which has typically been treated with supraphysiologic doses of glucocorticoids.

NBIP-01435 is an investigational long-acting corticotropin-releasing factor type 1 receptor (CRF_1) antagonist. CRF_1 antagonism has been shown to improve androgen control and allow for lower, more physiological glucocorticoid dosing regimens for patients with CAH. In December 2024, Neurocrine received FDA approval for crinecerfont, an oral CRF_1 antagonist, the first new treatment in 70 years for CAH.

In April 2021, Neurocrine entered into a research collaboration with Sentia Medical Sciences, Inc., for the discovery of novel peptide CRF receptor antagonists, including NBIP-01435, for which Neurocrine has exclusive rights to develop and commercialize.

About Neurocrine Biosciences, Inc.
Neurocrine Biosciences is a leading neuroscience-focused, biopharmaceutical company with a simple purpose: to relieve suffering for people with great needs. We are dedicated to discovering and developing life-changing treatments for patients with under-addressed neurological, neuroendocrine and neuropsychiatric disorders. The company's diverse portfolio includes FDA-approved treatments for tardive dyskinesia, chorea associated with Huntington's disease, classic congenital adrenal hyperplasia, endometriosis* and uterine fibroids,* as well as a robust pipeline including multiple compounds in mid- to late-phase clinical development across our core therapeutic areas. For three decades, we have applied our unique insight into neuroscience and the interconnections between brain and body systems to treat complex conditions. We relentlessly pursue medicines to ease the burden of debilitating diseases and disorders because you deserve brave science. For more information, visit neurocrine.com, and follow the company on LinkedIn, X and Facebook. (**in collaboration with AbbVie)*

Forward-Looking Statements
In addition to historical facts, this press release contains forward-looking statements that involve a number of risks and uncertainties. These statements include, but are not limited to, statements regarding the efficacy and therapeutic potential of NBIP-01435. Factors that could cause actual results to differ materially from those stated or implied in the forward-looking statements include, but are not limited to, the following: risks that clinical development activities may not be initiated or completed on time or at all, or may be delayed for regulatory, manufacturing or other reasons, may not be successful or replicate previous clinical trial results, may fail to demonstrate that our product candidates are safe and effective, or may not be predictive of real-world results or of results in subsequent clinical trials; risks that regulatory submissions for our product candidates may not

occur or be submitted in a timely manner; our future financial and operating performance; risks associated with our dependence on third parties for development, manufacturing and commercialization activities for our products and product candidates and our ability to manage these third parties; risks that the FDA or other regulatory authorities may make adverse decisions regarding our products or product candidates; risks that the potential benefits of the agreements with our collaboration partners may never be realized; risks that our products and/or our product candidates may be precluded from commercialization by the proprietary or regulatory rights of third parties, or have unintended side effects, adverse reactions or incidents of misuse; risks associated with U.S. federal or state legislative or regulatory and/or policy efforts which may result in, among other things, an adverse impact on our revenues or potential revenue; risks associated with potential generic entrants for our products; and other risks described in the Company's periodic reports filed with the Securities and Exchange Commission, including without limitation the Company's quarterly report on Form 10-Q for the quarter ended March 31, 2025. Neurocrine Biosciences disclaims any obligation to update the statements contained in this press release after the date hereof other than required by law.

View original content to download multimedia:https://www.prnewswire.com/news-releases/neurocrine-biosciences-announces-initiation-of-phase-1-clinical-study-evaluating-nbip-01435-a-long-acting-corticotropin-releasing-factor-type-1-receptor-antagonist-302494787.html

SOURCE Neurocrine Biosciences, Inc.

Neurocrine Biosciences, Inc., Media: Liz Reynolds, 1-818-749-8778, media@neurocrine.com; Investors: Todd Tushla, 1-858-617-7143, ir@neurocrine.com