Neurocrine Biosciences Announces Initiation of Phase 1 Clinical Study Evaluating Effects of NBI-1117570 in Healthy Adults

September 11, 2023

SAN DIEGO, Sept. 11, 2023 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX), today announced the initiation of its Phase 1 first-in-human clinical study to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of investigational compound NBI-1117570 in healthy adult participants. NBI-1117570 is an investigational, oral, muscarinic M1/M4 selective dual agonist that may have the potential to treat neurological and neuropsychiatric conditions.

"Initiation of this Phase 1 study represents an important step forward for NBI-1117570, a potentially first-in-class, orally active, selective investigational dual M1/M4 agonist," said Eiry W. Roberts, M.D., Chief Medical Officer at Neurocrine Biosciences. "The selectivity profile of NBI-1117570 in targeting M1 and M4 receptors may provide an opportunity to treat symptoms of both psychosis and cognition across a broad range of neurological and neuropsychiatric conditions."

About NBI-1117570
NBI-1117570 is an investigational, oral, muscarinic M1/M4 dual agonist. Muscarinic receptors are fundamental to activating signaling pathways in the brain. There are five muscarinic acetylcholine receptors involved in neurotransmission, two of which are selectively targeted by NBI-1117570 (M1 and M4), with M1 validated as a potential drug target in cognition and M4 in psychosis for clinical drug development. Neurocrine Biosciences acquired the rights to develop and commercialize NBI-1117570 from Sosei Heptares.

About Neurocrine Biosciences
Neurocrine Biosciences is a leading neuroscience-focused, biopharmaceutical company with a simple purpose: to relieve suffering for people with great needs, but few options. 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, Parkinson's disease, 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, Twitter, and Facebook.
(**in collaboration with AbbVie)*

Forward-Looking Statement
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 related to the potential benefits of NBI-1117570. Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are: 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; 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 June 30, 2023. Neurocrine Biosciences disclaims any obligation to update the statements contained in this press release after the date hereof.

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