Neurocrine Biosciences Provides Development Pipeline Update

November 9, 2023

Phase 2 Proof-of-Concept Study of NBI-921352 in Patients with Focal Onset Seizures Failed to Demonstrate Meaningful Reduction in Seizure Frequency

Phase 2 Proof-of-Concept Study of NBI-1065846 in Patients with Anhedonia in Major Depressive Disorder Failed to Meet its Primary Endpoint

SAN DIEGO, Nov. 9, 2023 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX), a leading neuroscience-focused biopharmaceutical company, today announced Phase 2 study results from two signal-seeking pipeline programs in focal onset seizures and anhedonia.

"We are disappointed with the outcome of these studies, but remain fully committed to finding new treatment options for patients living with serious neurological and neuropsychiatric disorders, including epilepsy and major depressive disorder," said Eiry W. Roberts, M.D., Chief Medical Officer at Neurocrine Biosciences, Inc. "Additionally, we are grateful to the study participants and everyone involved in these studies."

Epilepsy Update: The investigational selective Na_V 1.6 inhibitor, NBI-921352, licensed from Xenon Pharmaceuticals, Inc. (Xenon), failed to demonstrate meaningful seizure frequency reduction in the Phase 2 dose finding study assessing the safety, efficacy, tolerability and pharmacokinetics as adjunctive therapy in adults with focal onset seizures. No further development with NBI-921352 in Focal Onset Seizure (FOS) is planned at this time. Neurocrine is reviewing the data from the FOS study to understand any potential implication for its ongoing study in SCN8A-developmental epileptic encephalopathy and will provide an update once this review is complete. The company continues to advance a pre-clinical dual Na_V1.2/1.6 inhibitor as part of the Xenon collaboration.

Psychiatry Update: The investigational NBI-1065846, as part of the collaboration with Takeda Pharmaceutical Company Limited (Takeda), did not meet its primary endpoint in the Phase 2 TERPSIS™ study evaluating its efficacy compared to placebo in patients with anhedonia in major depressive disorder. No further development with NBI-1065846 is planned at this time. Neurocrine and Takeda continue to collaborate on several programs in clinical development including NBI-1065845 for the treatment of inadequate response to treatment in major depressive disorder (Phase 2), luvadaxistat for the treatment of cognitive impairment associated with schizophrenia (Phase 2), and NBI-1070770 for the treatment of major depressive disorder (Phase 1).

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, X (formerly 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 regarding the potential benefits to be derived from certain of our products and our future development plans. Among the factors that could cause actual results to differ materially

from those indicated in the forward-looking statements include: our future financial and operating performance; risks and uncertainties associated with the commercialization of our products; the risk that our products and/or product candidates will not be found to be safe and/or effective or may not prove to be beneficial to patients; that development activities for our products and/or product candidates 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 and/or interim clinical trial results, or may not be predictive of real-world results or of results in subsequent clinical trials; risks that regulatory submissions for our products and/or product candidates may not occur or be submitted in a timely manner; risks that our products and/or product candidates may not obtain regulatory approvals; or that the U.S. Food and Drug Administration or regulatory authorities outside the U.S. may make adverse decisions regarding our products and/or product candidates; risks and uncertainties relating to competitive products and technological changes that may limit demand for our products; risks associated with our dependence on third parties for development and manufacturing activities related to our products and our product candidates, and our ability to manage these third parties; 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 September 30, 2023. Neurocrine Biosciences disclaims any obligation to update the statements contained in this press release after the date hereof.

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