Neurocrine Biosciences Provides Update on ERUDITE™ Phase 2 Data for Luvadaxistat in Adults with Cognitive Impairment Associated with Schizophrenia

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- **Second Phase 2 Study for Luvadaxistat Fails to Meet Primary Endpoint as Potential Treatment for Cognitive Impairment Associated with Schizophrenia**
- **Results Confounded by Variability in Cognition Measures Across Population Studied and Potential Imbalance in Baseline Characteristics of Enrolled Subjects**
- **Neurocrine Biosciences to Focus Resources on Phase 3 Clinical Development of NBI-1117568 for Schizophrenia and NBI-1065845 for Major Depressive Disorder**

SAN DIEGO, Sept. 12, 2024 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced that its ERUDITE™ Phase 2 clinical study of investigational compound luvadaxistat (NBI-1065844) failed to meet its primary endpoint as a potential treatment to improve cognitive impairment in patients with schizophrenia.

The ERUDITE study was the second Phase 2 trial for luvadaxistat. It failed to replicate the cognitive endpoints data seen in the earlier INTERACT™ study, due in part to the large variability seen in the cognitive measures across the population studied and a potential imbalance in the baseline characteristics of subjects enrolled across the treatment arms.

In the INTERACT study, 50 mg luvadaxistat resulted in a statistically significant improvement in measure of cognition on the Brief Assessment of Cognition in Schizophrenia (BACS) and cognitive performance on the Schizophrenia Cognition Rating Scale (SCoRS). The INTERACT study represented the first time statistical significance had been demonstrated for both cognitive measure and function within a single study.

"While it's disappointing that luvadaxistat did not meet the primary endpoint in this study, we understand the challenges and hurdles that exist in identifying potential medicines for the treatment of cognitive impairment in schizophrenia. We therefore plan to halt further development of luvadaxistat at this time and instead will focus our efforts and resources on the advancement into Phase 3 clinical development of NBI-1117568 for schizophrenia and NBI-1065845 for major depressive disorder," said Eiry W. Roberts, M.D., Chief Medical Officer. "We are excited by the opportunity that lies ahead of us to bring forward potential medicines for patients in these important areas of unmet need in neuropsychiatry."

About Luvadaxistat
Luvadaxistat (NBI-1065844) is an investigational, oral, selective inhibitor with a high binding affinity to d-amino acid oxidase (DAAO), which metabolizes D-Serine, a primary NMDA receptor co-agonist in the limbic region of the brain. In schizophrenia, N-methyl D-aspartate (NMDA) receptor hypofunction on PV^{+} gamma-aminobutyric acid (GABA) interneurons results in disinhibition of cortical or hippocampal glutamate neurons projecting to the pyramidal neurons, which are associated with cognitive impairment seen in schizophrenia.

The ERUDITE™ Phase 2 clinical study is a randomized, double-blind, placebo-controlled, parallel group study to evaluate the efficacy safety and tolerability of luvadaxistat in adults with cognitive impairment associated with schizophrenia (CIAS). For more information about this study, visit ClinicalTrials.gov.

Neurocrine Biosciences acquired the rights to develop and commercialize luvadaxistat from Takeda Pharmaceutical Company, Ltd.

About Schizophrenia
Schizophrenia is a serious and complex syndrome with heterogeneous symptoms. This chronic and disabling mental health condition is thought to result from a complex interplay of genetic and environmental risk factors. The World Health Organization estimates that the disorder impacts more than 20 million people worldwide. Annual associated costs for schizophrenia are estimated to be more than $150 billion in the United States. It is estimated that approximately 80 percent of people living with schizophrenia have cognitive impairment associated with schizophrenia (CIAS).

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, 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 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 related to the clinical results from, and our future development plans with respect to luvadaxistat. 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, 2024. Neurocrine Biosciences disclaims any obligation to update the statements contained in this press release after the date hereof other than required by law.

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