Neurocrine Biosciences Initiates Phase 2 Clinical Study Evaluating NBI-1117568 in Adults with Schizophrenia

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- **NBI-1117568 is an Investigational, First-in-Class, Muscarinic M4 Selective Agonist**

SAN DIEGO, Oct. 27, 2022 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX), a leading neuroscience-focused biopharmaceutical company, today announced the first patient has been randomized for its Phase 2 placebo-controlled, inpatient clinical study evaluating the efficacy, safety, tolerability, and pharmacokinetics of investigational compound NBI-1117568 in adults with schizophrenia. NBI-1117568 is an investigational, muscarinic M4 selective acetylcholine receptor agonist believed to be a key regulator of neurotransmitters impacted by schizophrenia.

"Initiation of this Phase 2 study for NBI-1117568 brings forward a first-in-class, orally active, highly selective investigational M4 agonist as a potential treatment for schizophrenia, a serious and complex psychiatric syndrome impacting 0.5-1.0% of the U.S. population and approximately 20 million people worldwide," said Eiry W. Roberts, M.D., Chief Medical Officer. "The differentiated profile of NBI-1117568 in terms of its selectivity as an M4 agonist may provide an opportunity for efficacy in treating the symptoms of psychosis with a potentially different side effect profile."

The NBI-1117568 Phase 2 multi-arm, multi-stage study will enroll approximately 200 adults and is being conducted at 15 centers throughout the United States. The placebo-controlled study will evaluate multiple active dose levels of NBI-1117568. The primary outcome measure will be the change in total Positive and Negative Syndrome Scale (PANSS) score from baseline to Week 6. For more information about this study (NBI-1117568-SCZ2028), visit ClinicalTrials.gov

About NBI-1117568
NBI-1117568 is an investigational, oral, muscarinic M4 selective agonist. Muscarinic receptors are central to brain function and validated as drug targets in psychosis and cognitive disorders. There are five muscarinic acetylcholine receptors involved in neurotransmission. As an M4 selective agonist, NBI-1117568 offers the potential for an improved safety profile without the need of combination therapy to minimize side effects, while also avoiding the need for cooperativity with acetylcholine. Neurocrine Biosciences acquired the rights to develop NBI-1117568 from Sosei Heptares.

Neurocrine Biosciences is currently conducting a Phase 2 clinical study of NBI-1117568 to evaluate the efficacy, safety, tolerability, and pharmacokinetics in adults with schizophrenia who warrant inpatient hospitalization. For more information about this study, visit ClinicalTrials.gov.

About Schizophrenia
Schizophrenia is a serious and complex syndrome with heterogeneous symptoms. As one of the leading causes of disability worldwide, it often results in significant emotional and functional burden for those who experience symptoms, as well as their family and friends. Schizophrenia impacts 0.5-1.0% of the U.S. population and more than 20 million people worldwide. Traditional treatment approaches for schizophrenia rely on the use of antipsychotic medications that have been associated with metabolic syndrome, as well as neurologic symptoms.

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, Parkinson's disease, endometriosis* and uterine fibroids*, as well as over a dozen mid- to late-stage clinical programs in multiple 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 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 safety, efficacy, and therapeutic potential of NBI-1117568; and the results, conduct, and timing of our NBI-1117568 Phase 2 clinical study. Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are: our future financial and operating performance; risks associated with the commercialization of INGREZZA and ONGENTYS; the impact of the evolving COVID-19 pandemic globally on our business and the business operations of our customers, collaborators, vendors, and clinical trial sites including the impact on the ability of patients to have in-person visits with their health care provider; risks related to the development of our product candidates; 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 clinical development activities may not be

initiated or completed on time or at all, or may be delayed for regulatory, manufacturing, COVID-19 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 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 our periodic reports filed with the SEC, including our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022. Neurocrine Biosciences disclaims any obligation to update the statements contained in this press release after the date hereof.

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Neurocrine Biosciences, Inc., Media: Linda Seaton, 1-858-617-7292, media@neurocrine.com; Investors: Todd Tushla, 1-858-617-7143, ir@neurocrine.com