Neurocrine Biosciences Presents Additional Phase 3 Data for KINECT-HD Study Evaluating Valbenazine for Chorea Associated with Huntington Disease at HSG 2022

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SAN DIEGO, Nov. 3, 2022 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ: NBIX), a leading neuroscience-focused biopharmaceutical company, today reported additional results from the Phase 3 KINECT-HD study investigating valbenazine for the treatment of chorea associated with Huntington Disease (HD). In December 2021, Neurocrine previously reported that once-daily administration of valbenazine was well tolerated with a statistically significant improvement in chorea associated with HD compared with placebo, along with substantial clinician- and patient-rated global improvement. The additional data includes an exploratory analysis of valbenazine effects over time, dosages at the end of the study, and detailed information about treatment-emergent adverse events (TEAEs) and safety parameters, such as electrocardiogram (ECG) and laboratory tests. These data (Poster #2: Valbenazine for the Treatment of Chorea Associated with Huntington Disease: Results from a Phase 3 Trial) will be shared at the 29th annual meeting of the Huntington Study Group in Tampa, Florida on November 3–5.

The KINECT-HD study met its primary endpoint of change in chorea severity using the Total Maximal Chorea (TMC) score of the UHDRS® from screening period baseline to maintenance period. Improvement in the TMC score was significantly greater with valbenazine versus placebo. The secondary endpoints of Clinical Global Impression of Change (CGI-C) Response Status and Patient Global Impression of Change (PGI-C) Response Status also significantly favored valbenazine treatment. Treatment emergent adverse events, including somnolence, fatigue, fall, and akathisia, were mild to moderate and consistent with the known safety profile of valbenazine. No suicidal behavior or worsening of suicidal ideation was observed in the valbenazine-treated subjects in this study.

"The additional findings of the Phase 3 KINECT-HD study presented in this poster demonstrate an improvement in chorea over time, with an increase in responder rates in the TMC primary endpoint, and CGI-C and PGI-C outcomes by study visit up to Week 12," said Eiry W. Roberts, M.D., Chief Medical Officer. "Data from the KINECT-HD and the ongoing KINECT-HD2 study formed the basis for our recent supplemental new drug application (sNDA) submission to the U.S. Food and Drug Administration."

The poster presents KINECT-HD data of valbenazine compared with placebo at Week 12, showing a placebo-adjusted lean-squares mean change (LSM) reduction of 3.2 units ($p<0.0001$) in the TMC primary endpoint, and a reduction in the secondary endpoints of 42.9% vs 13.2% ($p< 0.001$) reduction for CGI-C, 52.7% vs 26.4% ($p<0.01$) reduction for PGI-C. Secondary endpoints for Quality of Life in Neurological Disorders (NeuroQoL) for upper and lower extremity function did not reach statistical significance. Incidence of TEAEs was comparable between treatment groups (valbenazine vs placebo), including any TEAE (76.6% vs 63.5%); serious TEAEs (1.6% vs 3.2%); and discontinuation due to TEAEs (7.8% vs 6.3%). No clinically important changes in vital signs, ECG, or laboratory tests were found. In this study, no suicidal behavior or worsening of suicidal ideation was reported as a TEAE or per the C-SSRS in valbenazine-treated participants.

Enrollment continues in the KINECT-HD2 open-label study to evaluate the long-term safety and tolerability of valbenazine for the treatment of chorea in Huntington Disease.

About the KINECT-HD Study

KINECT-HD is a Phase 3, randomized, double-blind, placebo-controlled study designed to: evaluate the efficacy of valbenazine as a once-daily treatment to reduce chorea associated with Huntington disease (HD) and evaluate the safety and tolerability of valbenazine in patients with HD. The study enrolled 128 adults 18 to 75 years of age who have been diagnosed with motor manifest HD and who have sufficient chorea symptoms to meet study protocol criteria. For more information on this KINECT-HD study, please visit www.huntingtonstudygroup.org.

About KINECT-HD2

KINECT-HD2 is an open-label study to evaluate the long-term safety and tolerability of valbenazine in patients with chorea associated with Huntington disease (HD). The 158-week study is enrolling up to 150 adults 18 to 75 years of age who have been diagnosed with motor manifest HD and who have sufficient chorea symptoms to meet study protocol criteria. For more information on the KINECT-HD2 study, please visit www.huntingtonstudygroup.org or clinicaltrials.gov.

About Chorea Associated with Huntington Disease

Huntington disease (HD) is a hereditary progressive, ultimately fatal neurodegenerative disorder in which neurons within the brain break down, resulting in motor, cognitive and psychiatric symptoms. Symptoms generally appear between the ages of 30 to 50 and worsen over a 10- to 25-year period. Many people with HD experience chorea, a troublesome involuntary movement disorder, characterized by irregular and unpredictable movements. Chorea can affect various body parts and interfere with motor coordination, gait, posture, swallowing, and speech. HD is estimated to affect approximately 40,000 adults in the U.S., with more than 200,000 at risk of inheriting the disease.

About Huntington Study Group

Founded in 1993, the Huntington Study Group (HSG), a global not-for-profit organization, together with its wholly owned for-profit subsidiary, HSG Clinical Research, Inc., designs, implements, manages, and conducts clinical research trials. The HSG, a leader in conducting clinical trials for HD, has more than 800 HD experts at over 130 HSG Credentialed Research Sites worldwide. The mission of the HSG is seeking treatments that make a difference for those affected by HD. The HSG also offers educational services like CME4HD ™ for healthcare professionals and care providers on treating patients with HD. For more information, visit our website www.huntingtonstudygroup.org.

The KINECT-HD study was conducted in cooperation with the HSG and the Clinical Trials Coordination Center (CTCC) at the University of Rochester Medical Center's Center for Health + Technology (CHeT). For more information, visit the CTCC website https://www.urmc.rochester.edu/health-technology/our-expertise/clinical-trials-coordination.aspx.

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 regarding the potential benefits to be derived from the Company's products and product candidates. Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements include: risks and uncertainties associated with valbenazine development for chorea in Huntington disease (HD), that valbenazine development activities may not be completed on time or at all; risks that valbenazine development activities may not be completed or may be delayed for regulatory or other reasons, may not be successful or replicate previous clinical trial results, may fail to demonstrate that valbenazine is safe, tolerable or effective in the chorea in Huntington disease (HD) population, or may not be predictive of real-world results or of results in subsequent clinical trials; risks that regulatory submissions may not occur or be submitted in a timely manner; risks that valbenazine may not obtain regulatory approval for chorea in Huntington disease (HD), or that the U.S. Food and Drug Administration or regulatory authorities outside the U.S. may make adverse decisions regarding valbenazine; risks that valbenazine may have unintended side effects, adverse reactions or incidents of misuse; risks associated with the Company's dependence on third parties for development and manufacturing activities related to valbenazine; risks and uncertainties relating to competitive products and technological changes that may limit demand for valbenazine; the impact of the COVID-19 pandemic and efforts to mitigate its spread on the Company's business; risks and uncertainties associated with the scale and duration of the COVID-19 pandemic and resulting global, national, and local disruptions; 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, 2022. Neurocrine Biosciences disclaims any obligation to update the statements contained in this press release after the date hereof.

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