Neurocrine Announces American Journal of Psychiatry Publication of Positive Results from Kinect 3 Phase III Study of INGREZZA TM (valbenazine) for the Treatment of Tardive Dyskinesia

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- Phase III study conducted in patients with tardive dyskinesia shows significant and meaningful reduction in symptoms with INGREZZA

- INGREZZA clinical development program is largest ever in tardive dyskinesia with over 1,000 persons having participated in 20 clinical trials

SAN DIEGO, March 21, 2017 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ: NBIX), a biotechnology company focused on neurologic, psychiatric and endocrine related disorders, announced today that positive results from the Kinect 3 Phase III study of INGREZZA (valbenazine) for the treatment of tardive dyskinesia (TD) were published online by the American Journal of Psychiatry (DOI: 10.1176/appi.ajp.2017.16091037). Once-daily INGREZZA, a novel, selective vesicular monoamine transporter 2 (VMAT2) inhibitor, demonstrated a significant and meaningful reduction in TD symptoms compared with placebo in participants with underlying schizophrenia, schizoaffective disorder or mood disorder. INGREZZA was found to be generally well tolerated with adverse events consistent with those of prior studies.

Tardive dyskinesia is thought to affect at least 500,000 people in the U.S. and is characterized by uncontrollable, abnormal and repetitive movements of the trunk, extremities and/or face. These symptoms are associated with chronic exposure to dopamine receptor blockers such as antipsychotic medications and can be severe, persistent and irreversible. In some cases, they can even interfere with speech, walking, swallowing and breathing.

"The unprecedented results from the Kinect 3 study demonstrate the potential of INGREZZA to fill a significant unmet need in this underserved patient population," said Kevin C. Gorman, Chief Executive Officer of Neurocrine. "This novel, new chemical entity was developed by Neurocrine chemists and biologists who devoted themselves to identifying a treatment for those living with the disruptive impact of tardive dyskinesia."

"There are currently no medications indicated for the treatment of tardive dyskinesia approved by the U.S. Food and Drug Administration. A common approach to address the condition has been to discontinue antipsychotic treatment or reduce the dosage, which may often have a negative impact on the psychiatric status of individuals suffering from TD," said Christopher F. O'Brien, Chief Medical Officer of Neurocrine. "The results of the Kinect 3 study indicate that INGREZZA significantly reduced tardive dyskinesia symptoms while maintaining stability of psychiatric status during treatment."

Neurocrine has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for INGREZZA and has been granted Priority Review with a Prescription Drug User Fee Act (PDUFA) action date of April 11, 2017. Neurocrine received Breakthrough Therapy Designation from the FDA in 2014 for INGREZZA for the treatment of TD.

Kinect 3 Study Results

The study met its primary endpoint of change-from-baseline in the Abnormal Involuntary Movement Scale (AIMS) at week six in the 80mg once-daily dosing group compared to placebo as assessed by expert central blinded video raters. The mean change from baseline to week six in the AIMS rating was -3.2 for the 80mg once-daily group as compared to -0.1 in the placebo group ($p>0.0001$).

In addition, the percentage of participants who achieved an AIMS response (defined in the study as a reduction greater than or equal to 50 percent from baseline in dyskinesia score) was higher in the INGREZZA 80mg/day group compared to placebo at all study visits. At week six, 40 percent ($p<0.001$) of participants receiving 80mg/day of INGREZZA had at least a 50% improvement in AIMS dyskinesia score as compared to only 8.7 percent of those who received placebo.

The Kinect 3 study was a Phase III, randomized, double-blind, placebo-controlled, parallel-group, fixed-dose study in which 234 subjects with TD and underlying schizophrenia, schizoaffective disorder or mood disorder (including bipolar disorder or major depressive disorder) receive six weeks of once-daily INGREZZA (40mg or 80mg capsules) or placebo. Subsequent to the completion of the six week placebo-controlled dosing, all subjects were placed on once-daily 40mg or once-daily 80mg of INGREZZA through week 48.

Safety Profile

During the six-week placebo-controlled treatment period INGREZZA was generally well tolerated and the most common adverse reactions were somnolence and drooling. The frequency of adverse events was similar among all treatment groups and treatment emergent adverse effects were consistent with those of prior studies. There were no drug-drug interactions identified in subjects who were utilizing a wide range of psychotropic and other concomitant medications.

About Tardive Dyskinesia

Tardive dyskinesia is caused by treatments that block dopamine receptors in the brain, such as antipsychotics and other medications. In patients with TD, these treatments are thought to result in excessive dopamine signaling in the region of the brain that controls movement. Tardive dyskinesia is characterized by uncontrollable, abnormal and repetitive movements of the trunk, extremities and/or face. These can include hand or foot movements, rocking of the trunk, lip smacking, grimacing, tongue protrusion, facial movements or blinking, as well as puckering and pursing of the lips. Tardive dyskinesia can cause significant impairment and may lead to social withdrawal, reduced workplace productivity or loss of employment, feeling embarrassed in public, or making others feel uncomfortable.

About INGREZZA

VMAT2 is a protein concentrated in the human brain that is primarily responsible for re-packaging and transporting monoamines (dopamine, norepinephrine, serotonin, and histamine) in pre-synaptic neurons. INGREZZA (valbenazine) capsules, developed in the Neurocrine laboratories, is a novel, selective VMAT2 inhibitor that modulates dopamine release during nerve communication, showing little or no affinity for VMAT1, other receptors, transporters and ion channels. INGREZZA is designed to provide low, sustained, plasma and brain concentrations of active drug to allow for once-daily dosing. The proprietary name INGREZZA has been conditionally accepted by the FDA.

Modulation of neuronal dopamine levels in diseases such as tardive dyskinesia, Tourette syndrome, Huntington's chorea, schizophrenia, and tardive dystonia, which are characterized, in part, by a hyperdopaminergic state, may provide symptomatic benefits for patients with these diseases.

The Company has a pending NDA under review by the FDA to utilize INGREZZA for the treatment of tardive dyskinesia. The Company also has another ongoing placebo-controlled Phase II Tourette syndrome study evaluating INGREZZA in pediatrics, the T-Force GREEN study. Additionally, the Company has an ongoing open-label, fixed-dose rollover study of INGREZZA in up to 180 subjects with Tourette syndrome.

About Neurocrine Biosciences

Neurocrine Biosciences, Inc. discovers and develops innovative and life-changing pharmaceuticals in diseases with high unmet medical needs through its novel R&D platform, focused on neurologic, psychiatric and endocrine based diseases and disorders. The Company's three late-stage clinical programs are: INGREZZA, a VMAT2 inhibitor for the treatment of movement disorders; elagolix, a gonadotropin-releasing hormone antagonist for women's health that is partnered with AbbVie Inc.; and opicapone, a novel, once-daily, peripherally-acting, highly-selective catechol-o-methyltransferase inhibitor under investigation as adjunct therapy to levodopa in Parkinson's patients. Neurocrine plans to commercialize INGREZZA in the United States upon approval by the FDA.

Neurocrine Biosciences, Inc. news releases are available through the Company's website via the internet at http://www.neurocrine.com.

Forward Looking Statements

In addition to historical facts, this press release contains forward-looking statements that involve a number of risks and uncertainties. Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are risks and uncertainties associated with Neurocrine's business and finances in general, as well as risks and uncertainties associated with INGREZZA development for both tardive dyskinesia and/or Tourette syndrome. Specifically, the risks and uncertainties the Company faces include risks that the INGREZZA NDA may not obtain regulatory approval from the FDA for tardive dyskinesia or such approval may be delayed or conditioned; risks that additional regulatory submissions, for Tourette syndrome or otherwise, may not occur or be submitted in a timely manner; risks that the FDA or regulatory authorities outside the U.S. may make adverse decisions regarding INGREZZA; risks that INGREZZA development activities may not be completed on time or at all; risks that ongoing INGREZZA development activities may be delayed for regulatory or other reasons; risks that ongoing or future INGREZZA clinical trials may not be successful or replicate previous clinical trial results, may fail to demonstrate that INGREZZA is safe, tolerable or effective, or may not be predictive of real-world results or of results in subsequent clinical trials; risks that INGREZZA may be precluded from commercialization by the proprietary rights of third parties, or 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 INGREZZA; risks that the Company will be unable to raise additional funding, if required, to complete development of or commercialize INGREZZA; risks and uncertainties relating to competitive products and technological changes that may limit demand for INGREZZA; risks that the Company may not successfully commercialize INGREZZA; and other risks described in the Company's annual report on Form 10-K for the year ended December 31, 2016. Neurocrine disclaims any obligation to update the statements contained in this press release after the date hereof.

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/neurocrine-announces-american-journal-of-psychiatry-publication-of-positive-results-from-kinect-3-phase-iii-study-of-ingrezza-tm-valbenazine-for-the-treatment-of-tardive-dyskinesia-300426923.html

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