Neurocrine Biosciences Presents New Data Analyses at AAN Annual Meeting Demonstrating INGREZZA® Improved Tardive Dyskinesia Symptoms Across Body Regions

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Additional Long-Term Data Show INGREZZA Sustained Improvement of Tardive Dyskinesia Symptoms Through 48 Weeks of Treatment and was Well-Tolerated

SAN DIEGO, April 25, 2018 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ: NBIX) today announced that once-daily INGREZZA® (valbenazine) capsules, the first U.S. Food and Drug Administration (FDA) approved treatment for adults with tardive dyskinesia (TD), improved TD symptoms regardless of body region. These new data analyses, along with long-term efficacy and tolerability data analyses, were presented at the 70th Annual Meeting of the American Academy of Neurology (AAN).

TD is characterized by uncontrollable, abnormal and repetitive movements of the trunk, extremities and/or face and is estimated to affect at least 500,000 people in the U.S. TD is associated with the prolonged use of drugs, such as antipsychotics, that help control dopamine, a chemical in the brain, to treat conditions like depression, bipolar disorder and schizophrenia.

"At Neurocrine, we are committed to serving patients with neurological diseases, in particular those who struggle with tardive dyskinesia as part of their neuropsychiatric condition," said Eiry W. Roberts, M.D., Chief Medical Officer at Neurocrine. "We are pleased to share new data on the effectiveness of INGREZZA in providing sustained improvement in the symptoms of TD, irrespective of the body region impacted by the disorder. We believe these data are important since patients' experience with tardive dyskinesia can be highly variable in terms of the body region impacted by uncontrollable movements. In addition, data analyses from our open-label long-term study show improvement in clinician and patient-reported outcomes, further demonstrating the effectiveness and tolerability of INGREZZA for the treatment of tardive dyskinesia."

Results from the KINECT 3 Phase III study, including data from the long-term extension phase, showed that for each body region, greater than or equal to 50% of participants who had moderate/severe abnormal movements at baseline improved to mild/minimal/none movements after 48 weeks of treatment with INGREZZA (80 mg and/or 40 mg). At the week 52 assessment, when participants had been off INGREZZA treatment for approximately 4 weeks, the percentage of participants experiencing continued benefit was substantially reduced, although some participants continued to experience clinically meaningful shifts.

Researchers also presented data analyses demonstrating long-term effectiveness of INGREZZA from the KINECT 4 open-label Phase III study. Consistent with previous trials, long-term improvements in TD severity were observed in participants receiving once-daily INGREZZA, based on change in mean Abnormal Involuntary Movement Scale (AIMS) total scores from baseline to week 48. Data also showed improvement based on clinician and patient-reported outcomes with more than 85% of participants in each INGREZZA dose group having a Clinical Global Impression of Change (CGIC) and Patient Global Impression of Change (PGIC) score indicating "much improved" or "very much improved" at 48 weeks. INGREZZA was generally well tolerated with no new safety signals detected.

About the KINECT 3 Phase III Study

KINECT 3 is a Phase III, randomized, double-blind, placebo-controlled, parallel-group, fixed-dose study, in which 234 participants with moderate to severe TD and underlying schizophrenia, schizoaffective disorder or mood disorder (including bipolar disorder or major depressive disorder) received six weeks of once-daily INGREZZA (40 mg or 80 mg capsules) or placebo (participants randomized to 80 mg started on 40 mg for 1 week). Subsequent to the completion of the six-week placebo-controlled dosing, participants receiving INGREZZA continued on their current dose and placebo participants were randomized to receive either once-daily 40 mg or once-daily 80 mg of INGREZZA, through week 48 (42-week blinded treatment extension period; placebo participants randomized to 80 mg started on 40 mg for 1 week), followed by a 4-week drug-free washout. Dose reduction to 40 mg was allowed for participants who were unable to tolerate the 80 mg dose.

The study met its primary endpoint of change-from-baseline in AIMS at week six in the 80 mg 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 80 mg once-daily group as compared to -0.1 in the placebo group (p>0.0001). Sustained TD improvements were seen with INGREZZA 40 mg and 80 mg through week 48.

INGREZZA was generally well tolerated throughout 48 weeks of treatment. The most common adverse reactions (≥5% and twice the rate of placebo) during the 6-week double-blind, placebo-controlled phase was somnolence with the frequency of adverse events being similar among all treatment groups. Treatment emergent adverse events (TEAEs) were consistent with those of prior studies. There were no drug-drug interactions identified in participants who were utilizing a wide range of psychotropic and other concomitant medications and participants generally remained psychiatrically stable throughout the study.

About the KINECT 4 Phase III Study
KINECT 4 is a Phase III, open-label study, in which 163 participants with moderate to severe TD and underlying schizophrenia, schizoaffective disorder or mood disorder (including bipolar disorder or major depressive disorder) received 48 weeks of open-label treatment with once-daily INGREZZA (40 mg or 80 mg capsules) followed by a 4-week washout. Dosing was initiated at 40 mg/day in all participants, with escalation to 80 mg/day at week 4 based on effectiveness and tolerability. Dose reduction to 40 mg was allowed in participants who could not tolerate the 80 mg dose.

Participants experienced TD improvements during long-term treatment as demonstrated by mean change from baseline to week 48 in AIMS total score (sum of items 1-7, evaluated by site raters) with INGREZZA 40 mg/day (-10.2) or 80 mg/day (-11.0). Consistent with previous studies, INGREZZA was generally well-tolerated. From week 4 to week 48, TEAEs that occurred in ≥5% of all participants (combined dose groups) were urinary tract infection (8.5%) and headache (5.2%). Change from baseline in vital signs, electrocardiogram parameters, and laboratory test values were generally small and not clinically significant.

About Tardive Dyskinesia (TD)
Tardive dyskinesia (TD) is characterized by uncontrollable, abnormal and repetitive movements of the trunk, extremities and/or face. The condition is associated with treatments that block dopamine receptors in the brain, such as antipsychotics commonly prescribed to treat mental illnesses such as schizophrenia, bipolar disorder and depression and certain anti-nausea medications. In patients with TD, these treatments are thought to result in irregular dopamine signaling in a region of the brain that controls movement. The symptoms of TD may be severe and are often persistent and irreversible. TD is estimated to affect at least 500,000 people in the U.S.

About INGREZZA® (valbenazine) Capsules
INGREZZA, a selective vesicular monoamine transporter 2 (VMAT2) inhibitor, is the first FDA approved product indicated for the treatment of adults with tardive dyskinesia, a condition associated with uncontrollable, abnormal and repetitive movements of the trunk, extremities and/or face.

INGREZZA is thought to work by reducing the amount of dopamine released in a region of the brain that controls movement and motor function, helping to regulate nerve signaling in adults with tardive dyskinesia. VMAT2 is a protein in the brain that packages neurotransmitters, such as dopamine, for transport and release in presynaptic neurons. INGREZZA, developed in Neurocrine's laboratories, is novel in that it selectively inhibits VMAT2 with no appreciable binding affinity for VMAT1, dopaminergic (including D2), serotonergic, adrenergic, histaminergic, or muscarinic receptors. Additionally, INGREZZA can be taken for the treatment of tardive dyskinesia as one capsule, once-daily, together with psychiatric medications such as antipsychotics or antidepressants.

Important Safety Information
Warnings & Precautions
Somnolence
INGREZZA can cause somnolence. Patients should not perform activities requiring mental alertness such as operating a motor vehicle or operating hazardous machinery until they know how they will be affected by INGREZZA.

QT Prolongation
INGREZZA may prolong the QT interval, although the degree of QT prolongation is not clinically significant at concentrations expected with recommended dosing. INGREZZA should be avoided in patients with congenital long QT syndrome or with arrhythmias associated with a prolonged QT interval. For patients at increased risk of a prolonged QT interval, assess the QT interval before increasing the dosage.

Adverse Reactions
The most common adverse reaction (≥5% and twice the rate of placebo) is somnolence. Other adverse reactions (≥2% and >placebo) include: anticholinergic effects, balance disorders/falls, headache, akathisia, vomiting, nausea, and arthralgia.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit MedWatch at www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see INGREZZA full Prescribing Information at www.INGREZZAHCP.com

About Neurocrine Biosciences, Inc.
Neurocrine Biosciences is a San Diego based biotechnology company focused on neurologic, psychiatric and endocrine related disorders. The Company markets INGREZZA® (valbenazine) capsules in the United States for the treatment of adults with tardive dyskinesia. INGREZZA is a novel, selective vesicular monoamine transporter 2 (VMAT2) inhibitor, and is the first FDA approved product indicated for the treatment of adults with tardive dyskinesia. The Company's three late-stage clinical programs are:

elagolix, a gonadotropin-releasing hormone antagonist for women's health that is partnered with AbbVie Inc.; opicapone, a novel, once-daily, peripherally-acting, highly-selective catechol-o-methyltransferase inhibitor under investigation as adjunct therapy to levodopa in Parkinson's patients; and INGREZZA, a novel, once-daily, selective VMAT2 inhibitor under investigation for the treatment of Tourette syndrome.

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 benefits to be derived from INGREZZA and whether results from INGREZZA's clinical trials are indicative of real-world results. 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 the commercialization of INGREZZA; risks that INGREZZA clinical trials results may not be predictive of real-world results or of results in subsequent clinical trials; risks and uncertainties relating to competitive products and technological changes that may limit demand for INGREZZA; risks associated with the Company's dependence on third parties for development and manufacturing activities related to INGREZZA and the ability of the Company to manage these third parties; risks that the FDA or other regulatory authorities may make adverse decisions regarding INGREZZA; risks that INGREZZA may be alleged to infringe upon the proprietary rights of third parties, or have unintended side effects, adverse reactions or incidents of misuse; and other risks described in the Company's periodic reports filed with the Securities and Exchange Commission, including without limitation the Company's annual report on Form 10-K for the year ended December 31, 2017. Neurocrine disclaims any obligation to update the statements contained in this press release after the date hereof.

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