Neurocrine Biosciences Presents New Quality of Life Data from RE-KINECT, the Largest Real-World Screening Study of Possible Tardive Dyskinesia in Patients Treated with Antipsychotics

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- Nearly 28 Percent of Patients Treated with Antipsychotics in the RE-KINECT Study Had Clinician-Confirmed Possible Tardive Dyskinesia

- Over Half of Patients with Possible Tardive Dyskinesia Experienced Uncontrollable Movements in Two or More Body Regions

- New Data from KINECT 4 Study Show Long-Term Treatment with INGREZZA® (valbenazine) Capsules Provided Sustained, Clinically Meaningful Improvement in Tardive Dyskinesia and was Well-Tolerated

SAN DIEGO, May 8, 2018 /PRNewswire/ -- Neurocrine Biosciences, Inc. (NASDAQ: NBIX) today announced new data from RE-KINECT, the largest real-world screening study to date of patients with clinician-confirmed possible tardive dyskinesia (TD), providing valuable insight into the impact of involuntary movements on the quality of life of patients taking antipsychotic medication. TD is a condition that is characterized by uncontrollable, abnormal and repetitive movements of the trunk, extremities and/or face, which may be disruptive and negatively impact patients. Results from the RE-KINECT study showed that nearly 28 percent of patients treated with an antipsychotic had clinician-confirmed possible TD. Over half of patients with clinician-confirmed possible TD were affected by uncontrollable movements in two or more body regions. These data, along with new data from the KINECT 4 study, were presented at the American Psychiatric Association (APA) Annual Meeting in New York City.

"The results of the RE-KINECT study are the first-of-their kind and offer healthcare practitioners invaluable insights into the disease burden and impact of possible tardive dyskinesia in patients," said Stanley Caroff, M.D., Professor of Psychiatry at the University of Pennsylvania and the Corporal Michael J. Crescenz VA Medical Center in Philadelphia. "It is important that psychiatrists and neurologists take these findings into consideration when managing patients treated with antipsychotic medications. Now that we have approved treatment options for tardive dyskinesia, it is important to proactively screen patients for the symptoms of tardive dyskinesia and diagnose patients living with this condition."

TD is associated with the prolonged use of medications that help control dopamine (a chemical in the brain), such as antipsychotics, used to treat conditions like depression, bipolar disorder and schizophrenia. The symptoms of TD can be severe and are often persistent and irreversible and it is estimated to affect at least 500,000 people in the U.S.

"We are pleased to share the initial findings from our RE-KINECT study as these data provide valuable insight into the impact of involuntary movements on the quality of life of patients," said Eiry W. Roberts, M.D., Chief Medical Officer at Neurocrine Biosciences. "We are committed to better understanding the potentially broad reaching impact of TD symptoms on patients treated with antipsychotic medicines and how to best address this underdiagnosed and underserved patient population."

Researchers also presented data analyses from the long-term, open-label, Phase III KINECT 4 study demonstrating sustained and clinically meaningful TD improvement in participants with schizophrenia/schizoaffective disorder or mood disorder who had received INGREZZA® (valbenazine) capsules once-daily for up to 48 weeks. Participants diagnosed with schizophrenia/schizoaffective disorder receiving INGREZZA 40 mg or 80 mg once-daily showed a mean improvement, at week 48, from baseline in the Abnormal Involuntary Movement Scale (AIMS) of 10.1 and 10.7 points, respectively, while participants diagnosed with mood disorder showed an improvement of 10.2 and 11.6 points, respectively. Consistent with prior studies, INGREZZA was well tolerated with a safety profile consistent with previous studies.

Additionally, researchers presented baseline characteristics of participants enrolled in the open-label KINECT 4 study. Seventy-three percent of participants in the study had a primary psychiatric diagnosis of schizophrenia/schizoaffective disorder while 27 percent of participants had a mood disorder. Most participants were being treated with one or more concomitant medication(s), including antipsychotics (88 percent), antidepressants (65 percent), and anticholinergics (27 percent).

About the RE-KINECT Study

RE-KINECT is a prospective real-world screening study that included 739 patients from 37 outpatient psychiatry practices in the United States. The study objective was to assess the presence and impact of possible tardive dyskinesia (TD) and describe the associated disease burden in a cohort of patients with one or more psychiatric disorders and a cumulative lifetime exposure to antipsychotic medication of three months or more. Patients were clinically evaluated for abnormal involuntary movements in general body regions (head/face, neck/trunk, upper/lower limbs) as well as for possible TD. Demographics, psychiatric history and medication history were captured as part of a 12-month retrospective chart review. Health-related quality of life was evaluated using the EuroQoL 5 Dimensions (EQ-5D-5L) questionnaire, which includes 5 domains that are each scored on a scale of 1 ("no problems") to 5 ("unable to perform") and the Sheehan Disability Scale (SDS), which is a brief patient-rated measure for disability and impairment, that includes 3 domains that are scored on a scale of 0 "not at all" to 10 "extremely."

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, treatment emergent adverse events 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 caused by 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 can 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 neurological 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.

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. 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 quarterly report on Form 10-Q for the quarter ended March 31, 2018. Neurocrine disclaims any obligation to update the statements contained in this press release after the date hereof.

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