Neurocrine Announces Data on the Real-World Patient Impact of TD from the RE-KINECT Study to be Presented at the 2017 Annual Psych Congress

September 15, 2017

SAN DIEGO, Sept. 15, 2017 /PRNewswire/ -- Neurocrine Biosciences Inc. (NASDAQ: NBIX) announced today upcoming poster presentations at the 2017 Annual Psych Congress featuring data from the RE-KINECT study outlining the real-world presence and impact of tardive dyskinesia (TD) on the lives of both patients and caregivers. Neurocrine will also present four posters regarding INGREZZA® (valbenazine) capsules, the first FDA-approved treatment for adults with tardive dyskinesia, including data on the effects of INGREZZA on tardive dyskinesia (TD) in different body regions and the safety profile of INGREZZA with respect to metabolic parameters.

"This year's Psych Congress serves as an excellent opportunity to dive deeper into the patient impact of TD, including demographics and healthcare utilization. The RE-KINECT study provides valuable insight into the complexities and needs of these patients and how INGREZZA can address the movements that may disrupt patient lives," said Chris O'Brien, M.D., Chief Medical Officer of Neurocrine. "We look forward to sharing this research with the community. Now that practicing physicians have access to an FDA approved treatment for tardive dyskinesia, it is important that we work toward a more in-depth understanding of the condition and patient experience."

The Psych Congress Annual Meeting is September 16-19, 2017, in New Orleans, Louisiana. Neurocrine's seven posters will be presented during the poster sessions on Sunday, September 17, 2017 from 1:30 – 2:30 pm ET and 5:30 – 7:30 pm ET, as well as Monday, September 18, 2017 from 1:30 – 2:30 pm ET:

- 227: Demographics and Real World Healthcare Utilization for Patients with Probable Tardive Dyskinesia
- 228: Evaluation of Potential Drug Interactions with Valbenazine
- 229: Tardive Dyskinesia: Patient and Caregiver Perspectives on Signs, Symptoms, and Impact
- 230: Effects of Once-Daily Valbenazine on Tardive Dyskinesia by Body Region as Measured by the Abnormal Involuntary Movement Scale
- 231: Effects of Once-Daily Valbenazine on Metabolic Parameters in Adults with Tardive Dyskinesia
- 243: RE-KINECT: A Prospective Real-World Dyskinesia Screening Study and Registry in Patients Taking Antipsychotic Agents: Patient Demographics
- 244: Estimation of an MCID for AIMS Total Score Change in Tardive Dyskinesia

About Tardive Dyskinesia (TD)

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

INGREZZA, a selective VMAT2 inhibitor, is the first approved product indicated for the treatment of adults with tardive dyskinesia. INGREZZA inhibits VMAT2 and 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 once-daily, and 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 (greater than or equal to 5% and twice the rate of placebo) is somnolence. Other adverse reactions (greater than or equal to 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.INGREZZA.com.

About Neurocrine Biosciences

Neurocrine Biosciences is a San Diego based biotechnology company focused on neurologic, psychiatric and endocrine related disorders. The Company markets INGREZZA® (valbenazine) 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; the value INGREZZA brings to patients and caregivers; 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 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 clinical trials may not be predictive of real-world results or of results in subsequent clinical trials; 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 June 30, 2017. The Company disclaims any obligation to update the statements contained in this press release after the date hereof.

View original content:http://www.prnewswire.com/news-releases/neurocrine-announces-data-on-the-real-world-patient-impact-of-td-from-the-re-kinect-study-to-be-presented-at-the-2017-annual-psych-congress-300520288.html

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