Neurocrine Biosciences Announces Results from the Real-World RE-KINECT™ Study Published in the Journal of Patient-Reported Outcomes Demonstrating the Effects of Possible Tardive Dyskinesia (TD) on Patient Health and Social Functioning

March 9, 2023

SAN DIEGO, March 9, 2023 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) announced today that new data from RE-KINECT ™, the largest real-world, observational, multicenter study of antipsychotic-treated patients with possible tardive dyskinesia (TD), was published in the *Journal of Patient-Reported Outcomes*.[1] The analysis assessed the effects of possible TD, defined as clinician-confirmed presence of abnormal involuntary movements, on patient health and social functioning. It demonstrated that it's important for clinicians to not only assess possible presence and severity of TD, but to also assess patient awareness of their own abnormal movements and the impact of these symptoms on the patients' overall wellness and ability to function to determine optimal management strategies.

The data demonstrated physical wellness and social functioning were diminished, as observed in the study, particularly among patients with possible TD who were aware of their involuntary movements and rated those movements as having "a lot" of impact on daily activities. In addition, severity terms or standardized assessments that label movements as "mild" and "severe" are inherently subjective and patients who are aware of their movements might find even "milder" movements to be disruptive, debilitating, or embarrassing.

"Insights from RE-KINECT suggest clinician-rated severity of TD may not always correlate with patient perceptions on the impact of TD on their daily lives," said Eiry W. Roberts, M.D., Chief Medical Officer at Neurocrine Biosciences. "In addition to assessing the presence and severity of patients' abnormal movements, clinicians should ask patients about how their uncontrollable movements affect their daily activities and consider these impacts when making treatment plans."

"While awareness around the impact of TD has increased among healthcare providers, patients, and caregivers, there are limited comprehensive, quantitative assessments specifically measuring the health-related quality of life impact the condition has on patients," said Stanley N. Caroff, M.D., Professor of Psychiatry at the University of Pennsylvania Perelman School of Medicine. "The findings from this RE-KINECT analysis are useful for understanding the impact of TD on patients' overall health, physical wellbeing and social functioning beyond subjective measures."

This real-world analysis included a total of 1,148 patients who were screened from outpatient psychiatry clinics. Cohort 1 included patients with no abnormal involuntary movements or whose movements were not consistent with possible TD based on clinician assessment (n=450). Cohort 2A included patients with clinician-confirmed possible TD who also self-reported having abnormal involuntary movements within the past 4 weeks and had self-rated severity as "some" or "a lot" in at least 1 of 4 body regions, including head/face, neck/trunk, upper extremities, and/or lower extremities (n=110). Cohort 2NA included patients with possible TD based on clinician assessment, but who self-reported having no abnormal involuntary movements in the past 4 weeks (n=94).

Assessments included: EuroQoL's EQ-5D-5L utility (health); Sheehan Disability Scale (SDS) total score (social functioning); patient- and clinician-rated severity of possible TD ("none", "some", "a lot"); and patient-rated impact of possible TD ("none", "some", "a lot"). Key results from the study include:

- Analyses of EQ-5D-5L utility and SDS total scores by clinician/patient-rated severity and patient-rated impact further confirmed patients with possible TD had worse physical wellness and social functioning than those with no abnormal involuntary movements.
- Among patients who were aware of their possible TD (Cohort 2A), self-reported severity ("some" or "a lot") was associated with standard patient-reported outcomes (EQ-5D-5L utility and SDS total).
    - A higher percentage of patients in Cohort 2A reported having moderate to extreme problems in all EQ-5D-5L dimensions including mobility, self-care, usual activities, pain/discomfort, and/or anxiety/depression.
    - Patient-rated impact (not severity) of possible TD had the greatest association with EQ-5D-5L utility across five activities (self-care, usual activities, being productive, socializing, and eating).
    - Similarly, patient-rated impact of possible TD on 4 activities (self-care, usual activities, being productive, and socializing) had the largest association with SDS total score.
- Clinician ratings of TD severity were less likely to be associated with EQ-5D-5L and SCS scores, underscoring the importance of assessing the patient's perspective.

About the RE-KINECT Study

RE-KINECT, a prospective real-world screening study that included 1,148 patients from 37 outpatient psychiatry clinics in the U.S. and was conducted with support from Neurocrine Biosciences, Inc. The study objective was to assess the effects of possible tardive dyskinesia (TD) on patient health and social functioning. Analyses were conducted in Cohort 1 (patients with no abnormal involuntary movements or whose movements were not consistent with possible TD based on clinician assessment), Cohort 2A (patients with clinician-confirmed possible TD who also self-reported having abnormal involuntary movements), and Cohort 2NA (patients with possible TD based on clinician assessment, but who self-reported having no abnormal involuntary movements). Assessments included: EuroQoL's EQ-5D-5L utility (health); Sheehan Disability Scale (SDS) total score (social functioning); patient- and clinician-rated severity of possible TD ("none", "some", "a lot"); and patient-rated impact of possible TD ("none", "some", "a lot"). Regression models were used to analyze the following: associations between higher (worse) severity/impact scores and lower (worse) EQ-5D-5L utility (indicated by negative regression coefficients); and associations between higher (worse) severity/impact scores and higher (worse) SDS total score (indicated by positive regression coefficients).

About Neurocrine Biosciences
Neurocrine Biosciences is a 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*).

About Tardive Dyskinesia (TD)
Tardive dyskinesia (TD) is a movement disorder that is characterized by uncontrollable, abnormal, and repetitive movements of the face, torso and/or other body parts, which may be disruptive and negatively impact patients. The condition is associated with taking certain kinds of mental health medicines (like antipsychotics) that help control dopamine receptors in the brain. Taking antipsychotics commonly prescribed to treat mental illnesses such as depression, bipolar disorder, schizophrenia and schizoaffective disorder, and certain medications to treat upset stomach, nausea, and vomiting are associated with TD. 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 approximately 600,000 people in the U.S.

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 the RE-KINECT study. 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 the commercialization of our products; risks that clinical trial activities may not be predictive of real-world results or of results in subsequent clinical trials; risks that our products may be precluded from commercialization by the proprietary rights of third parties, or have unintended side effects or adverse reactions; risks and uncertainties relating to competitive products and technological changes that may limit demand for our products; risks associated with our dependence on third parties for development and manufacturing activities related to our products and our product candidates, and our ability to manage these third parties; risks that the FDA or other regulatory authorities may make adverse decisions regarding our products or product candidates; risks that our products, and/or our product candidates may be precluded from commercialization by the proprietary or regulatory rights of third parties, or have unintended side effects, adverse reactions or incidents of misuse; risks associated with potential generic entrants for our products; risks and uncertainties associated with the scale and duration of the COVID-19 pandemic and resulting global, national, and local economic and financial disruptions; 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, 2022. Neurocrine disclaims any obligation to update the statements contained in this press release after the date hereof.

References:

1. Tanner, C.M., Caroff, S.N., Cutler, A.J. et al. Impact of possible tardive dyskinesia on physical wellness and social functioning: results from the real-world RE-KINECT study. *J Patient Rep Outcomes 7, 21 (2023).* *https://doi.org/10.1186/s41687-023-00551-5*

View original content to download multimedia:https://www.prnewswire.com/news-releases/neurocrine-biosciences-announces-results-from-the-real-world-re-kinect-study-published-in-the-journal-of-patient-reported-outcomes-demonstrating-the-effects-of-possible-tardive-dyskinesia-td-on-patient-health-and-social-functio-301768390.html

SOURCE Neurocrine Biosciences, Inc.

Neurocrine Biosciences, Inc., Aimee White (Media), 858-617-7578, media@neurocrine.com; Todd Tushla (Investors), 858-617-7143, ir@neurocrine.com