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Neurocrine Biosciences announces positive data from NBI-98854 Phase III trial in tardive dyskinesia

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Neurocrine Biosciences, Inc. (NASDAQ: NBIX) announced today that NBI-98854, a highly selective small molecule VMAT2 inhibitor, showed a statistically significant reduction in tardive dyskinesia during the six weeks of placebo-controlled treatment in the Kinect 3 clinical trial. This Phase III trial included moderate to severe tardive dyskinesia patients with underlying schizophrenia, schizoaffective disorder, bipolar or major depressive disorder.

The pre-specified primary efficacy endpoint was the change-from-baseline in the Abnormal Involuntary Movement Scale (AIMS) at Week 6 in the 80mg once-daily dosing group compared to placebo as assessed by central blinded video raters. The AIMS ratings at Week 6 for the 80mg once-daily NBI-98854 intention-to-treat (ITT) population was reduced 3.1 points (Least-Squares Mean) more than placebo ($p<0.0001$).

"We are very pleased with the outstanding efficacy and side effect profile demonstrated by NBI-98854 in the Kinect 3 study. The efficacy data from this pivotal Phase III study completes our placebo-controlled dataset for NBI-98854 in tardive dyskinesia," said Kevin C. Gorman, President and Chief Executive Officer of Neurocrine. "We will now turn our focus to completing the open-label safety portion of the studies in tardive dyskinesia patients and compiling the data for both doses of NBI-98854 to be included in the New Drug Application we intend to file with the FDA in 2016."

"The results of this Kinect 3 study demonstrate the potential of NBI-98854 to be a safe and effective treatment for patients suffering from the debilitating effects of tardive dyskinesia and we look forward to sharing additional details of this important study at upcoming scientific meetings starting in mid-2016," said Christopher F. O'Brien, Chief Medical Officer of Neurocrine. "We want to thank the trial participants and investigators who contributed to this successful placebo-controlled portion of the Kinect 3 study and we look forward to continuing our work with them in the open-label safety assessment of NBI-98854 in patients suffering from tardive dyskinesia, as well as completing the initial Tourette syndrome study later this year."

In addition to the primary efficacy endpoint, the AIMS rating for the 40mg once-daily dose and the Clinical Global Impression of Change (CGI-TD) for both doses were also evaluated. The table below summarizes the results of the AIMS ratings and CGI-TD at Week 6 for both the ITT population and a preliminary pre-specified per-protocol (PP) population. The PP population excluded subjects whose plasma concentrations of NBI-98854 were below the lower limit of quantitation (i.e., not detectable). Given the timing of plasma samples collections and the pharmacokinetic profile of NBI-98854, it was determined that these subjects had not ingested the study drug.

Safety Profile

During the six-week placebo-controlled treatment period NBI-98854 was generally well tolerated. The frequency of adverse events was similar among all treatment groups and treatment emergent adverse effects were consistent with those of prior studies.

Participants were also assessed utilizing the Barnes Akathisia Ratings Scale (BARS) for akathisia and the Simpson-Angus Scale (SAS) for parkinsonism. Both of these scales documented minimal symptoms at baseline and there was no worsening during the six weeks of treatment. Clinical hematology, chemistry and ECG monitoring indicated no emergent safety signals.

There were no drug-drug interactions identified in subjects who were utilizing a wide range of psychotropic and other concomitant medications.

Kinect 3 Study Design

The Kinect 3 study (ClinicalTrials.gov Identifier NCT02274558) is a randomized, parallel-group, double-blind, placebo-controlled, Phase III clinical trial utilizing the capsule formulation of NBI-98854 in moderate to severe tardive dyskinesia patients with underlying schizophrenia, schizoaffective disorder or mood disorder (including bipolar disorder or major depressive disorder). The Kinect 3 study randomized 234 subjects to either placebo, once-daily 40mg of NBI-98854 or once-daily 80mg of NBI-98854 for six weeks. Subsequent to the completion of the six

week placebo-controlled dosing, all subjects are placed on once-daily 40mg or once-daily 80mg of NBI-98854 through Week 48.

The Kinect 3 study, along with the previous efficacy studies of NBI-98854, is designed to complete the placebo-controlled clinical efficacy evaluation of NBI-98854 in tardive dyskinesia. In addition to Kinect 3, a separate one-year open-label safety study of NBI-98854, Kinect 4, has also been initiated to support the anticipated 2016 filing of a New Drug Application in tardive dyskinesia.

Source:
Neurocrine Biosciences, Inc.
