Annovis Bio Announces Positive Phase 2 Data - Interim Data Shows ANVS401 Improves Speed and Coordination in Parkinson's Patients

Berwyn, Pennsylvania--(Newsfile Corp. - March 16, 2021) - Annovis Bio Inc. (NYSE American: ANVS), a clinical-stage drug platform company addressing Alzheimer's disease (AD), Parkinson's disease (PD) and other neurodegenerative diseases, today announced results of an interim analysis from a double-blind, placebo-controlled study of ANVS401, its lead drug candidate for the treatment of PD and AD. Patients' speed and coordination scores both improved following 25 days of ANVS401 treatment, with no serious adverse events.

Dr. Maria L. Maccecchini, CEO of Annovis Bio, explained: "We set up this study to measure the toxic cascade leading to nerve cell death and loss of function and its reversal. The study was powered to investigate a difference of 20 to 25 percent in biomarker levels, not to demonstrate efficacy, making this data that much more significant."

Before and after treatment, patients' cerebral spinal fluid and plasma were collected to measure biomarkers and a number of psychometric studies were conducted to measure function in PD patients.

Safety

The safety profile of ANVS401 in the interim analysis was consistent with prior safety data that shows it to be safe at 80 mg once a day in humans. There was one mild adverse event (dizziness) that could have been ascribed to the drug treatment, however, this side effect was experienced by only one person - a placebo patient.

Efficacy

In one test that measures speed of execution, the results were statistically significant ($p=0.04$), showing that while PD patients are slow in coding boxes, treatment with ANVS401 improves their performance. The statistical outcome difference was true whether the outcome was compared with baseline or with placebo.

In these same patients, another test that measures coordination showed an improvement in their movements and was almost statistically significant ($p=0.07$). The treated group had the same number of complications before and after one month of treatment, suggesting they were stable, while the placebo group had more complications, suggesting they got worse.

In all MDS-UPDRS tests performed, the placebo-treated group either stayed the same or performed worse than at baseline. Instead, the ANVS401-treated group either stayed the same or performed better than at baseline. MDS-UPDRS is a specific PD test that measures severity and progression of the disease.

"The results from this interim analysis are very encouraging," commented Dr. Maccecchini. "This brings us one step closer to evaluating whether our approach may translate into a novel treatment option for patients suffering from a range of neurodegenerative diseases."

Interim Analysis

Annovis Bio's ongoing Phase 2a study is designed to treat a combined total of 68 patients for four weeks with the Company's lead compound, ANVS401. The first 14 PD patients, whose data are reported here, have finished treatment and their biomarkers are being measured. The next 14 AD patients are finishing their treatment and again their biomarkers and cognition will be measured and reported. Finally, the last 40 patients will be given different doses to determine the optimal dose. The study compares in both patient populations how nerve cells die by measuring all the steps in the toxic cascade leading to nerve cell death and how ANVS401 might reverse the toxic cascade and recover normal brain and body function. Dosing of the first patients in the trial began in August 2020. Today's pre-planned interim analysis summarizes clinical data of the first 14 PD patients that have completed treatment, nine patients on drug and five patients on placebo, and have begun their evaluation.

Next Steps

Presently, the cerebral spinal fluid and plasma samples of the 14 PD patients who completed treatment are being analyzed to measure the reversal of the toxic cascade with interim data expected to be reported in April, while interim data measuring the same in 14 AD patients is expected to follow in May. The full study data, including a dose ranging analysis in 40 PD patients, is anticipated in June or July of this year.

Following completion of the Phase 2a trial, Annovis Bio will request a meeting with the FDA to present the results of the trial and its chronic toxicology study in animals. Annovis Bio believes today's data and prior clinical results support the potential advancement of ANVS401 into late-stage studies, which the Company is targeting in late 2021, assuming successful completion of its ongoing Phase 2a study.

About Annovis Bio

Headquartered in Berwyn, Pennsylvania, Annovis Bio, Inc. (Annovis) is a clinical-stage, drug platform company addressing neurodegeneration, such as Alzheimer's disease (AD), Parkinson's disease (PD) and Alzheimer's in Down Syndrome (AD-DS). We believe that we are the only company developing a drug for AD, PD and AD-DS that inhibits more than one neurotoxic protein and, thereby, improves the information highway of the nerve cell, known as axonal transport. When this information flow is impaired, the nerve cell gets sick and dies. We expect our treatment to improve memory loss and dementia associated with AD and AD-DS, as well as body and brain function in PD. We have two ongoing Phase 2a studies: one in AD patients and one in both AD and PD patients. For more information on Annovis, please visit the company's website: www.annovisbio.com.

Forward-Looking Statements

Statements in this press release contain "forward-looking statements" that are subject to substantial risks and uncertainties. Forward-looking statements contained in this press release may be identified by the use of words such as "anticipate," "expect," "believe," "will," "may," "should," "estimate," "project," "outlook," "forecast" or other similar words, and include, without limitation, statements regarding the timing, effectiveness, and anticipated results of ANVS401 clinical trials. Forward-looking statements are based on Annovis Bio, Inc.'s current expectations and are subject to inherent uncertainties, risks and

assumptions that are difficult to predict. Further, certain forward-looking statements are based on assumptions as to future events that may not prove to be accurate, including that clinical trials may be delayed and that the data reported herein is interim data, conclusions as to which may be superseded by subsequent data we expect to receive in connection with Phase 2a trials and/or subsequent clinical trials. These and other risks and uncertainties are described more fully in the section titled "Risk Factors" in the Annual Report on Form 10-K for the year ended December 31, 2020 filed with the Securities and Exchange Commission. Forward-looking statements contained in this announcement are made as of this date, and Annovis Bio, Inc. undertakes no duty to update such information except as required under applicable law.

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