Annovis Bio Begins Treatment of First Patients in its Phase 2a Alzheimer’s and Parkinson’s Trial

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BERWYN, Pa., Sept. 01, 2020 (GLOBE NEWSWIRE) -- 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 dosing of the first three patients in its new Phase 2a clinical trial targeting early AD and PD patients.

The two-part study, which received IRB approval in July 2020, is designed to treat a combined total of 28 AD and PD patients for four weeks with Annovis' lead compound, ANVS401. 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 function. In addition to target and pathway engagement, the Phase 2a study also examines safety and tolerability as well as the effect of ANVS401 on motor and non-motor symptoms in early PD patients and the effect on memory and cognitive function in early AD subjects. Initial data from this trial is expected in early 2021. This study will be followed by a dose response study in 40 PD patients with final data readout expected by late summer 2021.

“Beginning treatment in our second Phase 2a study is a major milestone for Annovis,” commented Maria Maccecchini, Ph.D., CEO of Annovis Bio. “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.”

Annovis Bio is following all FDA recommendations and taking appropriate precautions regarding COVID-19 and has selected the 15 sites for the study to be geographically dispersed throughout the U.S. The Company is initially targeting recruitment at sites in areas where COVID-19 is less rampant, while sites in high COVID-19 areas remain closed.

“While COVID-19 has previously delayed trials for most biopharma companies, including the start of this trial, having a diverse mix of study sites should afford us the opportunity to maintain recruitment and treatment schedules moving forward,” added Dr. Maccecchini.

There has been a string of clinical trial failures for drugs based on the belief that sticky brain plaques cause AD. With 500 failed drugs based on that hypothesis, Annovis has developed a new approach to treat AD as well as PD by attacking multiple neurotoxic proteins

simultaneously. In two animal models, ANVS401 reduced neurotoxic proteins, improved axonal transport, lowered inflammation, and restored healthy nerve cells in both AD and PD. Based on publicly available data, no other drug has been shown in animal studies to impede the whole toxic cascade and show preclinical efficacy in both AD and PD.

PD affects an estimated one million people in the U.S. and as many as 10 million globally. An estimated 5.8 million people in the U.S. have AD and there are approximately 44 million people worldwide living with the disease. AD and PD significantly impact quality of life for patients and their families.

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 an ongoing Phase 2a study in AD patients and have commenced a second Phase 2a study in 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. 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, 2019 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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