Source: *Annovis Bio Inc.*

April 30, 2020 06:45 ET

Annovis Bio Announces Plans for a New Phase II Clinical Trial to Treat 68 Parkinson's and Alzheimer's Patients

BERWYN, Pa., April 30, 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, announced today that the protocol for its Phase 2 clinical study in PD and AD patients was submitted to the U.S. Food and Drug Administration (FDA). The Company has received no comments from the FDA and is therefore able to proceed with the launch of the clinical trial.

The protocol is a two-part study designed to treat a combined total of 68 Alzheimer's and Parkinson's patients for one month with Annovis' 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 Annovis' drug candidate, ANVS401, might reverse the toxic cascade and recover normal brain function. As regards AD, there has been a string of clinical trial failures whose drugs were based on the belief that sticky brain plaques causes 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.

"We decided to add an Alzheimer's arm to our Parkinson's study because we want to treat patients the exact same way, monitor them the exact same way, and measure the exact same biomarkers, transport proteins, inflammatory markers, synaptic and degenerative markers. Although this is a short study, for safety purposes we will also measure cognition and function," commented Maria Maccecchini, Ph.D., CEO of Annovis Bio. "This study will allow us to compare neurodegeneration in two different diseases and show that ANVS 401 works in both neurodegenerative diseases the same way."

The clinical trial is expected to take place at 10 sites across the US. The Company expects to begin recruitment and enrollment in May, with treatment starting in June. The Company believes the study will be completed before the end of 2020, but due to the COVID-19 pandemic, the study's commencement may be delayed until later this summer and completion may be delayed until the first quarter of 2021.

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 plan to commence a second Phase 2a study in 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. 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.

Investor Relations:

Dave Gentry, CEO
RedChip Companies Inc.
407-491-4498
Dave@redchip.com

SOURCE: Annovis Bio Inc.