Annovis Bio Receives Institutional Review Board Approval to Initiate 15 Site Phase 2 Study in 68 Parkinson's and Alzheimer's Patients

July 07, 2020 06:45 ET

BERWYN, Pa., July 07, 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, reported that it has received Central Institutional Review Board (IRB) approval to begin its Phase 2 clinical study in early PD and early AD patients at 15 sites across the US.

An IRB is a committee that applies research ethics by reviewing the methods proposed for research to ensure that they are ethical. Such boards are formally designated to approve or reject, monitor, and review biomedical and behavioral research involving humans. The purpose of the IRB is to assure that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in a research study.

The two-part study is designed to treat a combined total of 68 PD and AD patients for 4 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 2 study will also examine safety and tolerability as well as the effect of ANVS401 on motor impairment and non-motor symptoms in early PD patients and the effect on memory and cognitive function in early AD subjects.

"We are excited to receive IRB approval to move forward with this Phase 2 study in PD and AD," commented Maria Maccecchini, Ph.D., CEO of Annovis Bio. "While the original initiation of the trial was delayed due to COVID-19, we believe we remain on track to complete the study by 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 and AD 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 and the approval of any allowances or additional patents. 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.