Annovis Bio Announces Update on Phase II Clinical Trial for Alzheimer's Disease

BERWYN, Pa., Feb. 13, 2020 (GLOBE NEWSWIRE) -- Annovis Bio Inc. (NYSE American: ANVS), a clinical-stage drug platform company addressing Alzheimer's, Parkinson's and other neurodegenerative diseases, announced today that the Data Safety Monitoring Board has reviewed the safety data, enrollment, participant status, demographic data and vital signs of patients enrolled in their Phase II clinical trial for the treatment of Alzheimer's disease and unanimously supported that the study, which is named DISCOVER, continue without modification.

The clinical trial taking place at six sites, including the University of California, San Diego, Johns Hopkins, Indiana University, Washington University, the Cleveland Clinic and Columbia University, is a 24-patient study. To date, 11 patients have been enrolled. No adverse effects have been reported in any of the enrolled patients. The clinical trial is expected to conclude in the spring of 2021 with interim data expected later in 2020.

The clinical trial was designed to test the effects of ANVS401, the Company's lead compound, on neurotoxic proteins in human spinal fluid by stable isotope labeling kinetics (SILK) for the treatment of Alzheimer's disease.

Howard Feldman, MD, Director of the Alzheimer's Disease Cooperative Study (ADCS), and Martin Farlow, MD, Professor and Vice Chairman of Research, Indiana University School of Medicine, are serving as Project Directors for the study. Funding for this research came through the National Institute on Aging ADCS grant.

This study is breaking new ground in the Alzheimer's field. It combines state-of-the-art SILK to evaluate the effects of ANVS401 on neurotoxic proteins in spinal fluid with safety, pharmacokinetics, pharmacodynamics and efficacy.

Maria Maccecchini, Ph.D., CEO of Annovis, commented, "We are extremely pleased that the Data Safety Monitoring Board has unanimously supported that the study continues without modification. This trial will provide proof of mechanism and proof of concept for ANVS401. It will also provide the necessary dose range and safety

information we need to progress our drug development into pivotal phase II/III clinical efficacy studies.

"We believe our approach to the treatment of Alzheimer's is unique. There have been over 500 failed attempts at developing Alzheimer's drugs. But we have taken a different approach by focusing on improving the information highway of the nerve cell. Our lead compound, ANVS401, is the only drug to improve axonal transport, the information highway of the nerve cell, by attacking multiple neurotoxic proteins simultaneously. We look forward to receiving interim results in the fourth quarter of this year."

About ADCS: ADCS was formed in 1991 as a cooperative agreement between the National Institute on Aging (NIA) and the University of California, San Diego. The ADCS is part of the NIA Division of Neuroscience program's effort to facilitate the discovery, development and testing of new drugs for the treatment of AD.

About Annovis Bio, Inc.

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 (ADDS). 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 proof-of-concept study in AD patients and plan to commence a second Phase 2a study in PD patients. For more information about Annovis Bio, please visit the company's website: www.annovisbio.com

Forward Looking-Statements

This press release contains "forward-looking statements" about the company's current expectations about future results, performance, prospects and opportunities. Statements that are not historical facts, such as "anticipates," "believes" and "expects" or similar expressions, are forward-looking statements. These statements are subject to a number of risks, uncertainties and other factors that could cause actual results in future periods to differ materially from what is expressed in, or implied by, these statements. The factors which may influence the company's future performance include the company's ability to obtain additional capital to expand operations as planned, success in achieving regulatory approval for clinical protocols, enrollment of adequate numbers of patients in clinical trials, unforeseen difficulties in showing efficacy of the company's biopharmaceutical products, success in attracting additional

customers and profitable contracts, and regulatory risks associated with producing pharmaceutical grade and food products. These and other risk factors are described from time to time in the company's filings with the Securities and Exchange Commission, including, but not limited to, the company's reports on Forms 10-K and 10-Q. Unless required by law, the company assumes no obligation to update or revise any forward-looking statements as a result of new information or future events.

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