ANNOVIS BIO FILES FOR FDA ORPHAN DRUG DESIGNATION FOR ANVS401 FOR THE TREATMENT OF ALZHEIMER'S DISEASE IN PERSONS WITH DOWN SYNDROME

Thu, 13 May 2021

BERWYN, PA. – May 13, 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 it has filed an application with the U.S. Food and Drug Administration (FDA) to receive orphan drug designation for its lead drug candidate, ANVS401, for the treatment of AD in persons with Down syndrome (DS), referred to as DS-AD.

DS occurs in about 1 in 700 newborns and approximately 200,000 people in the U.S. have the condition. People with DS often experience a gradual decline in cognition as they age, which can lead to AD. Newer screening methods and publications estimate DS-AD begins in people in their late thirties, with measurable decline starting before 40 years of age. Remarkably, over 80% of those with DS over age 65 are demented due to AD. There are approximately 17,000 people living with DS-AD in the United States, making the condition an orphan indication.

With improved healthcare, the DS population is both growing and aging. However, with improved longevity comes a very high risk of AD. The percentage of DS patients with AD is growing faster than the percentage of AD patients in general. The condition results in significant suffering and financial burden for those who care for people with DS.

ANVS401 is being tested in Phase 2a trials designed to show that it lowers levels of amyloid precursor protein, alpha-synuclein and tau and by doing so can increase axonal transport, lower inflammation, and protect nerve cells from dying. In seven animal models it fully restored the affected function back to normal, including four models of memory and learning: trisomic DS mice, transgenic AD mice, stroke mice and traumatic brain injury rats. Based on these and other data, the Company believes that ANVS401 can change the course of AD in DS patients. Subject to the approval of the orphan drug designation by the FDA, Annovis Bio hopes to initiate a Phase 3 trial in DS-AD patients by the end of 2021.

Maria Maccecchini, Ph.D., CEO of Annovis Bio, commented, "The FDA orphan drug application for ANVS401 to treat DS-AD is an important milestone for Annovis as we focus on building a robust

product pipeline focused on novel uses of AVNS401 to treat significant unmet medical needs. We are currently evaluating ANVS401 in two Phase 2a clinical trials targeting AD and PD. The data from these studies will guide us in the continuing development of ANVS401 for chronic neurodegenerative diseases – specifically in DS-AD and in PD."

The Orphan Drug Act grants special status to a drug or biological product to treat a rare disease or condition upon request of a sponsor. This status is referred to as orphan designation (or sometimes "orphan status"). The FDA grants orphan status to products that treat rare diseases, providing incentives to sponsors developing drugs or biologics. The FDA defines rare diseases as those affecting fewer than 200,000 people in the United States at any given time. The incidence of DS-AD is well within the limit of 200,000 for orphan indication status. Orphan drug designation would qualify ANVS401 for certain benefits and incentives, including seven years of marketing exclusivity if regulatory approval is ultimately received for the designated indication, potential tax credits for certain clinical drug testing costs, activities, eligibility for orphan drug grants, and the waiver of the FDA New Drug Application filing fee of approximately $2.4 million.

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 (DS-AD). We believe that we are the only company developing a drug for AD, PD and DS-AD 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 DS-AD, 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. 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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