Annovis Bio Announces First Quarter 2022 Results and Provides Corporate Update

Berwyn, Pennsylvania--(Newsfile Corp. - May 4, 2022) - Annovis Bio, Inc.

(https://www.newsfilecorp.com/redirect/Z42vzSYxyN) (NYSE: ANVS) ("Annovis" or the "Company"), a clinical-stage drug platform company addressing neurodegenerative diseases, today announced first quarter financial results for the quarter ended March 31, 2022, and provided a corporate update.

Maria L. Maccecchini, Ph.D., Founder, President, and CEO of Annovis, commented, "we have made significant progress advancing buntanetap in Parkinson's disease and Alzheimer's disease this quarter. We received positive feedback from the U.S. Food and Drug Administration (FDA) for two Phase 3 clinical trials with buntanetap in early and late Parkinson's disease. As our clinical trials advance, we have continued to build out our diverse team of highly motivated industry experts as we move to the next stage of clinical development."

Recent Highlights and New Developments

- <u>Clinical Advancement of buntanetap for PD</u>: The Company held a successful Type B meeting with the FDA with regard to the Company's planned Phase 3 clinical studies of buntanetap for the treatment of Parkinson's Disease (PD). The FDA provided feedback on the initiation of the Phase 3 clinical studies of buntanetap for PD in parallel with the Alzheimer's disease (AD) program. The agency detailed guidance on the specific endpoints, entry criteria, and further study parameters for two Phase 3 studies that would support a broad indication for both early and late PD.
- <u>Announced Phase 3 Trial Design for PD:</u> The Company announced the trial design of the upcoming Phase 3 trial evaluating buntanetap in early PD. The study is designed to enroll 450 PD patients with Hoehn & Yahr scale scores of 1, 2 and 3 and randomize them at 1:1:1 ratio into placebo, 10mg or 20mg buntanetap once daily on top of their standard of care for six months. Movement Disorder Society-Sponsored Revision of the Unified Parkinson's Disease Rating Scale (MDS-UPDRS) Part II and III will be used as primary endpoints, while total MDS-UPDRS and Participant Global Impression of Change will be secondary endpoints. In addition, Wechsler Adult Intelligence Scale, plasma biomarkers and Mini-Mental State Examination will be evaluated as exploratory endpoints.
- <u>Expansion of the leadership team</u>: The Company announced the appointment of Eve Damiano, MS, RAC, as Senior Vice President of Regulatory Operations to advance the Company's regulatory objectives. Eve joins Annovis with more than 35 years of experience in the biotechnology sector with a focus on the definition and execution of regulatory strategies. Additionally, the Company announced the promotion of Cheng Fang, Ph.D., to Senior Vice President of Research & Development to advance the Company's clinical objectives. Cheng is an experienced neuroscientist with over a decade of experience studying neurodegenerative diseases.
- <u>Receipt of USAN Assigned Name</u>: The Company announced receipt of the United States Adopted Names Council assigned name "buntanetap" for the Company's lead drug candidate previously known as ANVS401/Posiphen.

Financial Results for the First quarter of 2022

Cash, cash equivalents, and marketable securities were \$42.7 million as of March 31, 2022. Research and development expenses for the quarter ended March 31, 2022, were \$2.8 million, compared to \$2.4 million for the same period in 2021. The increase was primarily the result of an increase of \$1.2 million in stock-based compensation expense, partially offset by a decrease of \$0.7 million in expenses related to the Company's two Phase 2a clinical trials which were completed in

2021. General and administrative expenses for the quarter ended March 31, 2022, were \$3.1 million, compared to \$0.8 million for the same period in 2021. The increase was primarily the result of increases of \$2.2 million in stock-based compensation expense and \$0.1 million in professional fees.

For the quarter ended March 31, 2022, Annovis reported a net loss of \$5.9 million, compared to a net loss of \$3.2 million for the same period in 2021.

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 other chronic neurodegenerative diseases, including 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. Annovis conducted two Phase 2 studies: one in AD patients and one in both AD and PD patients. In the AD/PD study buntanetap showed improvements in cognition and memory in AD as well as body and brain function in PD patients.

For more information on Annovis Bio, please visit the Company's website www.annovisbio.com (https://www.newsfilecorp.com/redirect/QrKp0sX3Y1) and follow us on LinkedIn (https://www.newsfilecorp.com/redirect/mowxbieMXq) and Twitter (https://www.newsfilecorp.com/redirect/kz2Y3c1nDb).

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 buntanetap 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, 2021, 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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