Annovis Bio Announces Third Quarter 2022 Results and Provides Corporate Update

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Annovis Bio →
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BERWYN, Penn., Nov. 8, 2022 /PRNewswire/ -- Annovis Bio, Inc. (NYSE: ANVS) ("Annovis" or the "Company"), a clinical-stage drug platform company addressing neurodegenerative diseases, today announced third quarter financial results for the quarter ended September 30, 2022, and reviewed recent accomplishments.

Maria L. Maccecchini, Ph.D., Founder, President, and CEO of Annovis, commented: "This quarter, we have made significant advances in the clinical development of buntanetap as we began to dose patients in our Phase 3 trial for early Parkinson's Disease and received FDA authorization to proceed with a Phase 2/3 trial in moderate Alzheimer's Disease. Additionally, we have seen that buntanetap works in numerous acute and chronic neurodegenerative conditions through its ability to inhibit multiple neurotoxic proteins, improve axonal transport and preserve nerve cell function in various neurodegenerative conditions. As a result, we have pursued and made significant strides this quarter in expanding our intellectual property portfolio as it relates to buntanetap and additional neurodegenerative conditions."

Third Quarter Highlights and New Developments

- **Receipt of Positive U.S. Food and Drug Administration (FDA) Notice for Buntanetap Phase 3 Clinical Trial in Parkinson's Disease (PD):** The Company received notice from the FDA that the Phase 3 clinical study in early PD patients may proceed. The FDA accepted the final protocol and the clinical development plan, approved the use of the Company's new large-scale batch of good manufacturing practice material, and found the chronic toxicology in rats and dogs safe and adequate to support long-term human studies. The Phase 3 trial is a randomized, double-blind, placebo-controlled trial investigating the efficacy, safety, and tolerability of buntanetap. The trial will enroll a total of 450 early PD patients to be treated with 10mg buntanetap, 20mg buntanetap or a placebo, 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.

- **Dosed First Patient for the Phase 3 Trial in Patients with Early Parkinson's Disease:** Annovis announced that the first patient in the Phase 3 clinical trial evaluating buntanetap in early PD has been dosed.

- **Receipt of FDA Authorization to Proceed with Phase 2/3 Trial for Buntanetap in Alzheimer's Disease (AD):** The Company announced that the FDA authorized the Phase 2/3 clinical study of buntanetap in moderate AD. The Phase 2/3 study is a randomized, double-blind, placebo-controlled trial investigating the efficacy, safety, and tolerability of buntanetap in moderate AD patients. The trial will enroll a total of 320 AD patients to be treated with 7.5mg buntanetap, 15mg buntanetap, 30mg buntanetap or a placebo, on top of their standard of care, for three months.

- **Publication of Phase 2a Clinical Data in *The Journal of Prevention of Alzheimer's Disease***: The published study, titled '*Buntanetap, a Novel Translational Inhibitor of Multiple Neurotoxic Proteins, Proves to Be Safe and Promising in Both Alzheimer's and Parkinson's Patients*', evaluated safety, pharmacokinetics, biomarkers, and efficacy of buntanetap in treating early AD and PD patients. The study demonstrated that buntanetap was well tolerated, safe and significantly improved cognition in AD patients

and motor function in PD patients.

- **Appointment of Henry Hagopian III as Chief Financial Officer:** Mr. Hagopian comes to Annovis with 30 years of finance and accounting experience, including 15 years at Organogenesis, a leading publicly traded regenerative medicine company. Mr. Hagopian has an extensive background in corporate accounting, financial reporting, treasury operations, financial planning & analysis, and investor relations.

- **Publication of Patents Covering the Treatment of Amyloid Lateral Sclerosis, Huntington's Disease and Prion Diseases:** Annovis announced the publication of three granted US patents – US11400075, US11376238, and US11382893. The patents cover methods of treating amyloid lateral sclerosis, Huntington's disease, and prion diseases by administering buntanetap. The patents provide intellectual property protection through 2031 and strengthen and expand the Company's intellectual property portfolio. The Company now has issued patents covering a wide range of neurodegenerative diseases, including AD, alpha-synucleopathies, such as PD, tauopathies, such as frontotemporal dementia, chronic traumatic encephalopathy and acute injuries, such as stroke and traumatic brain injury.

- **Presented at the Alzheimer's Association International Conference:** Maria Maccecchini, Ph.D., Founder, President, and CEO of Annovis, participated on the Systems Biology of Alzheimer's Disease Panel at the Alzheimer's Association International Conference. The panel was moderated by Jeffrey Cummings, MD, ScD, and Krista Lanctôt, Ph.D. The discussion focused on the need and underpinning rationale for advancing novel therapeutic approaches for AD and featured a panel of industry thought leaders and experts.

Financial Results for the Third Quarter of 2022

Cash, cash equivalents, and marketable securities were $32.0 million as of September 30, 2022. Research and development expenses for the quarter ended September 30, 2022 were $5.3 million, compared to $1.4 million for the same period in 2021. The increase was primarily the result of an increase of $2.4 million in clinical expenses, as the Company incurred costs related to its Phase 3 study in early PD patients, an increase of $1.0 million for the cost of materials and

an increase of $0.4 million in stock-based compensation expense. General and administrative expenses for the quarter ended September 30, 2022 were $2.4 million, compared to $1.5 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.

For the quarter ended September 30, 2022, Annovis reported a net loss of $7.6 million, compared to a net loss of $2.9 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 and follow us on LinkedIn and Twitter.

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 expected effectiveness of buntanetap and 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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