# Annovis Bio Announces Positive FDA Feedback for Buntanetap Phase 3 Clinical Development in Parkinson's Disease

## FDA gives guidance for two Phase 3 clinical trials of Buntanetap in Parkinson's Disease

Berwyn, Pennsylvania--(Newsfile Corp. - January 25, 2022) - Annovis Bio, Inc. (https://www.newsfilecorp.com/redirect/aVY8jfoyjj) (NYSE: ANVS) ("Annovis" or the "Company"), a clinical-stage drug platform company addressing neurodegenerative diseases, today announced that the company held a successful Type B meeting with the U.S. Food and Drug Administration (FDA) with regard to the Company's planned Phase 3 clinical studies of Buntanetap for the treatment of Parkinson's Disease (PD) as an offshoot of the Company's clinical program in Alzheimer's Disease (AD).

Following the Company's submission of the Phase 2 clinical data and the chronic toxicology data in animals, the Company requested directions to further pursue the development of Buntanetap in PD. The FDA provided guidance on the initiation of the Phase 3 clinical studies of Buntanetap for PD in parallel with the 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.

"We appreciate the thoughtful and clear feedback from the FDA regarding our clinical program, and we are thrilled with the acceptance of our proposed development plan for Buntanetap in Parkinson's Disease," said Maria L. Maccecchini, Ph.D., Founder, President, and CEO of Annovis Bio. "Now we can continue with all necessary steps to begin the Phase 3 trials in PD."

Additionally, the FDA provided guidance on updating the existing Investigational New Drug Application (IND) for AD based on the result of the successful Phase 2 study and in preparation for an End of Phase 2 meeting on the AD indication.

**About Buntanetap**

Buntanetap (previously known as ANVS401 or Posiphen) is an oral translational inhibitor of neurotoxic aggregating proteins (TINAPs), which mode of action leads to a lower level of neurotoxic proteins, and consequently less toxicity in the brain. Buntanetap is currently being developed for Alzheimer's Disease (AD), Parkinson's Disease (PD) and AD in Down Syndrome (AD-DS). In the Phase 2a clinical trial in AD and PD patients, Buntanetap was shown to be well-tolerated and safe, and its pharmacokinetics were found to be in line with levels measured earlier in humans, meeting both the primary and secondary endpoints. Additionally, exploratory endpoints were also met, as treatment with Buntanetap resulted in statistically significant improvement in motor function in PD patients and cognition in AD patients.

**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 (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 improvement in memory loss and dementia associated with AD, as well as body and brain function in PD.

For more information on Annovis Bio, please visit the Company's website www.annovisbio.com (https://www.newsfilecorp.com/redirect/2JeayTvebb) and follow us on LinkedIn (https://www.newsfilecorp.com/redirect/MZNweSX48N) and Twitter (https://www.newsfilecorp.com/redirect/bA8WvIzqXz).

**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, 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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