Annovis Bio Announces FDA Authorization to Proceed with Phase 2/3 Trial for Buntanetap in Alzheimer's Disease

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Annovis Bio →
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BERWYN, Pa., Oct. 6, 2022 /PRNewswire/ -- Annovis Bio, Inc. (NYSE: ANVS) ("Annovis" or the "Company"), a late-stage clinical drug platform company addressing neurodegenerative diseases, announced today that the U.S. Food and Drug Administration (FDA) has authorized the Phase 2/3 clinical study of buntanetap in moderate Alzheimer's Disease (AD).

Following the submission of the Phase 2a clinical safety data and the chronic toxicology data in animals, the Company requested approval to further pursue the development of buntanetap in AD. The FDA approved the Company's development plan, study protocol and authorized the initiation of the Phase 2/3 clinical study of buntanetap in AD.

"We are very pleased with the clinical progress of buntanetap," said Maria L. Maccecchini, Ph.D., Founder, President, and CEO of Annovis Bio. "In a Phase 2a clinical trial in AD and PD, treatment with buntanetap resulted in statistically significant improvement in motor function in PD patients and cognition in AD patients. With this promising data, we have progressed buntanetap into a Phase 3 trial for the treatment of early PD, and now with FDA authorization,

into a Phase 2/3 trial for the treatment of moderate AD. We are on a clinical development pathway to bring forward a promising treatment for both far reaching neurodegenerative indications."

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. In a 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. Presently buntanetap is being studied in a phase 3 early PD study and will enter a phase 2/3 study in AD patients later in the year.

About Annovis Bio, Inc.

Headquartered in Berwyn, Pennsylvania, Annovis Bio, Inc. is a clinical-stage, drug platform company developing transformative therapies that treat neurodegenerative disorders such as Alzheimer's disease (AD), Parkinson's disease (PD) and other chronic and acute neurodegenerative diseases. The Company believes that it is the only company developing a drug that inhibits more than one neurotoxic protein, improves the information highway of the nerve cell, known as axonal transport, reduces inflammation and protects nerve cells from dying in chronic and acute neurodegeneration. 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 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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