Annovis Bio Announces First Patient Dosed in Phase 3 Trial in Patients with Early Parkinson's Disease

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Annovis Bio →
Aug 24, 2022, 07:30 ET

BERWYN, Pa., Aug. 24, 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 first patient in the Phase 3 clinical trial evaluating buntanetap in early Parkinson's Disease (PD) has been dosed.

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.

The Company previously reported results from its Phase 2a study of buntanetap in PD patients, which were treated with 5mg, 10mg, 20mg, 40mg or 80mg daily with no clinically significant adverse events. Additionally, treatment with buntanetap resulted in statistically significant improvement in motor function and its pharmacokinetics were found to be in line with levels measured earlier in humans, meeting both the primary and secondary endpoints.

Maria L. Maccecchini, Ph.D., Founder, President, and CEO of Annovis Bio said: "Buntanetap has shown promising preliminary safety data in all clinical work to date. Just as encouraging is the significant improvement in speed of movement, motor function and cognitive function observed in early to moderate PD patients treated with buntanetap in the Phase 2a trial. Now, as we officially advance buntanetap into a Phase 3 trial, with a longer treatment duration and a dose range shown to be efficacious in early studies, we are one step closer to delivering a solution that can transform the lives of patients with Parkinson's Disease."

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 lower levels of neurotoxic proteins and consequently less toxicity in the brain. In a Phase 2a clinical trial in AD and PD patients, treatment with buntanetap resulted in statistically significant improvement in motor function in PD patients and cognition in AD patients. Additionally, buntanetap was shown to reduce biomarkers associated with AD or PD, it was well-tolerated and safe, and its pharmacokinetics were found to be in line with levels measured earlier in humans, meeting primary, secondary and exploratory endpoints.

About Annovis Bio, Inc.

Headquartered in Berwyn, Pennsylvania, Annovis Bio, Inc. is a late-stage clinical 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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