

ANNOVIS BIO ANNOUNCES PATIENT ENROLLMENT UPDATE FOR PHASE 3 STUDY OF BUNTANETAP FOR THE TREATMENT OF PARKINSON'S DISEASE



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Annovis Bio →

Jan 25, 2023, 07:30 ET

*Strong enrollment in Phase 3 trial demonstrates continued execution
Interim analysis expected in 2Q 2023*

BERWYN, Pa., Jan. 25, 2023 /PRNewswire/ -- [Annovis Bio, Inc.](#) (NYSE: ANVS) ("Annovis" or the "Company"), a clinical-stage drug platform company addressing neurodegenerative diseases, today provided a patient enrollment update for the Company's ongoing Phase 3 study of buntanetap for the treatment of Parkinson's disease ("PD").

Maria L. Maccacchini, Ph.D., Founder, President, and CEO of Annovis, commented: "We are very pleased with the pace of enrollment in our Phase 3 study, which is designed to assess the safety and efficacy of buntanetap in early-stage Parkinson's patients. Buntanetap is a highly differentiated and potentially ground-breaking therapy that has been designed to inhibit the production of multiple neurotoxic proteins which are associated with several



neurodegenerative conditions, including Parkinson's disease and Alzheimer's disease. We look forward to providing an interim data analysis from the study in the second quarter of 2023, which will enable us to optimize our patient enrollment for the study."

Based on the current enrollment, the Company anticipates having a sufficient number of patients who have received two months of therapy to conduct an interim analysis in the second quarter of 2023. The purpose of the interim analysis is to determine if the Company's original estimates for patient enrollment in the Phase 3 trial (150 patients per arm) will be sufficient to observe a statistically significant treatment effect in both scales between the active arms and the control arm of the study after six months of treatment.

More specifically, the interim analysis could confirm that 150 patients is the optimal number, or it could inform that less patients are needed (the efficacy is better than expected) or that more patients are needed (the efficacy is less than expected). The boundaries of the extent to which we will decrease or increase the number of patients is +/- 25% or between 112 and 200 patients per arm.

The ongoing Phase 3 trial is a randomized, double-blind, placebo-controlled trial investigating the efficacy, safety, and tolerability of buntanetap in patients with early-stage Parkinson's disease. Patients are being treated with 10mg buntanetap, 20mg buntanetap or 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's Phase 3 trial in PD builds upon earlier, proof-of-concept data from a Phase 2a study which demonstrated that patients treated with buntanetap showed statistically significant improvements in both motor function and coding speed, as measured by MDS-UPDRS Part III and WAIS Coding scores.¹ Additionally, no clinically significant adverse events were observed in the Phase 2a study and its pharmacokinetics were found to be in line with levels measured earlier in humans.

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 Alzheimer's disease (AD) and Parkinson's disease (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 in a Phase 2/3 study 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 other chronic neurodegenerative diseases. We believe that we are the only company developing a drug for AD and PD 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](#).

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This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements relate to all information other than historical matters, such as expectations or forecasts of future events. Forward-looking statements may be identified by the use of words such as "forecast," "intend," "seek," "target," "anticipate," "believe," "expect," "estimate," "plan," "outlook," and "project" and other similar expressions that predict or indicate future events or trends or that are not statements of historical matters. Forward-looking statements with respect to the operations, strategies, prospects and other aspects of the business of Annovis Bio are based on current expectations that are subject to known and unknown risks and uncertainties, which could cause actual results or outcomes to differ materially from expectations expressed or implied by such forward-looking statements. These risks and uncertainties include but are not limited to: that clinical trials may be delayed and that the data reported herein is from a Phase 2a study. These and other risks and uncertainties are described more fully in the section titled "Risk Factors" in Annovis Bio's Annual Report on Form 10-K for the year ended December 31, 2021, and other periodic reports filed with the Securities and Exchange Commission. You are cautioned not to place undue reliance upon any forward-looking statements, which speak only as of the date made. Although it may voluntarily do so, from time to time, Annovis Bio undertakes no commitment to update or revise the forward-looking statements contained in this presentation, whether as a result of new information, future events or otherwise, except as required under applicable law.

Media Contact:

Nic Johnson

Russo Partners, LLC

(303) 482-6405

nic.johnson@russopartnersllc.com

Investors Contact:

Chris Calabrese

+1 (917) 680-5608

ccalabrese@lifesciadvisors.com

LifeSci Advisors, LLC

Kevin Gardner

+1 (617) 283-2856

kgardner@lifesciadvisors.com

LifeSci Advisors, LLC

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