

Annovis Bio Announces Approval for European Union Clinical Trial Sites for the Phase 3 Study of Buntanetap for the Treatment of Parkinson's Disease



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Annovis Bio →

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The Company was Granted Approval for an Additional 48 sites Across Five European Union Countries

Annovis Currently has 50 Clinical Trial Sites Open in the United States

BERWYN, Pa., Feb. 8, 2023 /PRNewswire/ -- Annovis Bio, Inc. (NYSE: ANVS) ("Annovis" or the "Company"), a clinical-stage drug platform company addressing neurodegenerative diseases, today announced approval for additional European clinical trial sites for the ongoing Phase 3 study of buntanetap for the treatment of Parkinson's disease ("PD").

Annovis is actively recruiting for the ongoing Phase 3 study with 50 clinical trial sites open and currently enrolling in the United States. The approval adds an additional 48 sites in five European Union ("EU") countries, including Italy, Spain, Hungary, Poland and Germany, for the Company's Phase 3 study of buntanetap for the treatment of Early PD.



Maria L. Maccacchini, Ph.D., Founder, President, and CEO of Annovis, commented: "We are pleased to significantly expand our geographic reach with the addition of these EU sites that gives us the ability to efficiently enroll European patients in our study."

The locations will enroll the initial cohort of early PD patients. 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 interim analysis will be used 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.

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.

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-UPRDS 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.

¹ Fang et al: Buntanetap Proves Promising in Both Alzheimer's and Parkinson's Patients; J Prevention Alzheimer Disease 10-2022

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



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