

# Annovis Bio Announces Positive FDA Notice For Buntanetap Phase 3 Clinical Trial In Parkinson's Disease



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**Annovis Bio** →

Jul 07, 2022, 07:30 ET

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*FDA indicates the Company may proceed with the Phase 3 clinical study of buntanetap for the treatment of Parkinson's disease*

BERWYN, Pa., July 7, 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 Company received notice from the FDA that the Phase 3 clinical study in early Parkinson's patients may proceed. The FDA accepted the final protocol and the clinical development plan, approved the use of the Company's new large-scale batch of good manufacturing practice material, and found the chronic toxicology in rats and dogs safe and adequate to support long-term human studies lasting decades compared to the previous restriction of one month.

Following a successful Type B meeting for the continued development of buntanetap in Parkinson's disease with the FDA earlier this year, the Company requested consideration from the FDA on amending the accepted development plan, finalizing the protocol for the Phase 3 study, and proceeding with longer duration clinical trials. The Company submitted all the



safety data in mice, rats, dogs and over 200 humans, the chemistry, manufacturing, and controls package for the new large-scale batch, and all the data accumulated over the years for the Company's Alzheimer's disease program that also pertained to Parkinson's disease program.

<b>PROTOCOL TITLE</b>	<b>A 6-month prospective, randomized, double-blind, placebo-controlled clinical trial investigating the efficacy, safety, and tolerability of two different doses of buntanetap or placebo in patients with early Parkinson's disease</b>
<b>STUDY DESIGN</b>	Placebo-controlled and double-blind in 100 sites in the US and EU
<b>INVESTIGATIONAL PRODUCT</b>	Buntanetap 10 mg, 20 mg, or placebo capsules, taken orally once a day for 6 months
<b>SUMMARY OF KEY ELIGIBILITY CRITERIA</b>	Diagnosis of idiopathic PD, Age 40 to 85, MMSE 22-30, Hoehn & Yahr = 1,2,3 and OFF-state < 2hrs per day
<b>PRIMARY OUTCOME MEASURES</b>	MDS-UPDRS Part II+III
<b>SECONDARY OUTCOME MEASURES</b>	<ul style="list-style-type: none"> <li>• Total MDS-UPDRS score</li> <li>• Participant Global Impression of Change (PGIC)</li> <li>• Clinical Global Impression of Severity of illness (CGIS)</li> </ul>

"We are pleased that the FDA has approved our clinical trial design in early PD patients and called it a well-designed study. The positive FDA review affirms the Company's path to securing approval for buntanetap to treat neurodegenerative diseases, including Parkinson's and Alzheimer's diseases, with longer treatment regimens," said Maria L. Maccicchini, Ph.D., Founder, President, and CEO of Annovis Bio. "With this FDA notice in hand, we are thrilled to start recruiting for the US clinical trial soon, expected later this summer."

## **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, the drug was 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.

## **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](http://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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