

PhaseBio Pharmaceuticals, Inc. Logo

PhaseBio Receives FDA Breakthrough Therapy Designation for PB2452 for the Reversal of the Antiplatelet Activity of Ticagrelor

April 8, 2019

In Phase 1 clinical trial, PB2452 provided immediate and sustained reversal of ticagrelor antiplatelet effects

MALVERN, Pa. and SAN DIEGO, April 08, 2019 (GLOBE NEWSWIRE) -- PhaseBio Pharmaceuticals, Inc. (Nasdaq: PHAS), a clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapies for orphan diseases, today announced that the U.S. Food and Drug Administration ("FDA") has granted Breakthrough Therapy designation for PB2452, a novel reversal agent for the antiplatelet drug ticagrelor.

Breakthrough Therapy designation is designed to expedite the development and review of promising new drugs for serious or life-threatening conditions, when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. With all the features of the Fast Track program, Breakthrough Therapy designation also offers companies the opportunity for increased communication with FDA and an organizational commitment involving more intensive guidance from FDA senior managers. Companies may also be eligible for Accelerated Approval and Priority Review, if relevant criteria are met.

The Breakthrough Therapy designation for PB2452 was supported by Phase 1 trial results, in which PB2452 achieved immediate and sustained reversal of ticagrelor's antiplatelet effects. The results from this trial were recently published in the *New England Journal of Medicine* and presented in a featured clinical research session at the American College of Cardiology's 68th Scientific Session (ACC.19).

"Breakthrough Therapy designation for PB2452 highlights the critical unmet need for a therapy to reverse the antiplatelet activity of ticagrelor, which is widely prescribed to patients with acute coronary syndrome or a history of heart attack," said John Lee, M.D., Chief Medical Officer of PhaseBio. "The results from the Phase 1 clinical trial of PB2452 demonstrated immediate and sustained reversal of the antiplatelet activity of ticagrelor, which could mitigate bleeding concerns associated with use of ticagrelor. Breakthrough Therapy designation supports our goal of making the first approved reversal agent for ticagrelor available to patients and physicians as soon as possible. We look forward to working closely with the FDA throughout the expedited development process."

About PB2452

PB2452 is a novel, recombinant, human monoclonal antibody antigen-binding fragment, or Fab fragment, designed to reverse the antiplatelet activity of ticagrelor in major bleeding and urgent surgery situations. In Phase 1 clinical and preclinical studies, PB2452 achieved immediate and sustained reversal of ticagrelor's antiplatelet activity, demonstrating the potential to bring life-saving therapeutic benefit by increasing the safety of ticagrelor and mitigating concerns regarding the bleeding risk associated with antiplatelet drugs. There are currently no approved reversal agents for ticagrelor or any other antiplatelet drugs.

About PhaseBio

PhaseBio Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapies to treat orphan diseases, with an initial focus on cardiopulmonary disorders. The company's lead development candidate is PB2452, a novel reversal agent for the antiplatelet therapy ticagrelor. PhaseBio is also leveraging its proprietary elastin-like polypeptide ("ELP") technology platform to develop therapies with the potential for less-frequent dosing and improved pharmacokinetics. PhaseBio's second product candidate PB1046, which is based on ELP, is a once-weekly vasoactive intestinal peptide receptor agonist for the treatment of pulmonary arterial hypertension.

PhaseBio is located in Malvern, PA and San Diego, CA. For more information, please visit www.phasebio.com.

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The logo for PhaseBio, featuring the word "PHASE" in a bold, sans-serif font above the word "Bio" in a lighter, sans-serif font.

Source: PhaseBio Pharmaceuticals, Inc.