PhaseBio Pharmaceuticals, Inc. Logo

Pharmacodynamics Evaluation of PhaseBio's Novel Ticagrelor Reversal Agent Presented at ESC Congress 2019

September 3, 2019

Results from three different assays, including VerifyNow® PRUTest®, demonstrate a high degree of correlation

MALVERN, Pa. and SAN DIEGO, Sept. 03, 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 data from an evaluation of the pharmacodynamics of PB2452, a novel reversal agent for the antiplatelet drug ticagrelor, were presented by Lisa K. Jennings, Ph.D., Professor of Medicine, University of Tennessee Health Science Center, at ESC Congress 2019 in Paris on September 1.

"Utilizing multiple assays of platelet function provided a wider range of understanding of the pharmacodynamics of PB2452 in the first-in-human clinical trial," said Dr. Jennings. "PB2452 provided immediate and sustained reversal of ticagrelor antiplatelet activity, which could reduce the bleeding risk associated with ticagrelor. The Phase 1 data support further evaluation of PB2452 for the reversal of the antiplatelet effects of ticagrelor in emergency situations involving major bleeding and to enable emergent or urgent surgery in patients."

The first-in-human, randomized, double-blind, placebo-controlled Phase 1 clinical trial evaluated the safety, efficacy and pharmacokinetics of intravenous PB2452 as a ticagrelor reversal agent in 64 healthy volunteers aged 18 to 50 years. Platelet function was assessed using light transmission aggregometry, VerifyNow PRUTest and vasodilator stimulated phosphoprotein (VASP) assays. VerifyNow PRUTest is considered to be the gold standard for point-of-care assessments of platelet function. The data demonstrated that complete reversal by all measurements occurred within 15 minutes of administration and was sustained for over 20 hours.

PhaseBio has continued to use the same three assays to demonstrate the efficacy of PB2452 in a Phase 2a trial and has continued to see a high degree of correlation among the assays in both trials.

"These primary measures of efficacy in our clinical trials are a key feature of the Accelerated Approval program that will help streamline the defined regulatory path for PB2452, coupled with its Breakthrough Therapy designation," said John Lee, M.D., Ph.D., Chief Medical Officer of PhaseBio. "The U.S. Food and Drug Administration recently acknowledged that there is a clear unmet need for reversal of bleeding events related to $P2Y_{12}$ inhibitors, including ticagrelor. As we move PB2452 into Phase 2b development by year's end and initiate our Phase 3 trial in the first quarter of 2020, we believe that we are well-positioned to execute on our strategy to deliver this potentially life-saving therapy to patients in need."

Additional information including the abstract can be found on the ESC Congress website here.

About PB2452

PB2452 is a novel, recombinant, human monoclonal antibody antigen-binding fragment, or Fab, designed to reverse the antiplatelet activity of ticagrelor in major bleeding and urgent surgery situations. In a Phase 1 clinical trial, PB2452 demonstrated the potential to bring life-saving therapeutic benefit through immediate and sustained reversal of ticagrelor's antiplatelet activity, mitigating concerns regarding bleeding risks associated with the use of antiplatelet drugs. The Phase 1 clinical trial of PB2452 in healthy volunteers was published in the *New England Journal of Medicine*in March 2019.[1] In April 2019, PB2452 received Breakthrough Therapy designation from the U.S. Food and Drug Administration ("FDA"). Breakthrough Designation may be granted by FDA when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapy. In the first quarter of 2020, PhaseBio plans to initiate a single pivotal Phase 3 clinical trial of PB2452 which will support a Biologics License Application for both major bleeding and surgery indications. 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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[1] Bhatt DL, Pollack CV, Weitz JI, et al. Antibody-Based Ticagrelor Reversal Agent in Healthy Volunteers. *N Engl J Med* 2019;Mar 17.

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