PhaseBio Announces Publication of Interim Results from Pivotal REVERSE-IT Phase 3 Trial of Bentracimab in NEJM Evidence

December 1, 2021

Results previously presented in a Late-Breaking Science Session at the American Heart Association's 2021 Scientific Sessions

Global Phase 3 trial of bentracimab achieved both primary reversal endpoint and co-primary endpoint of clinical hemostasis

Bentracimab had no drug-related serious adverse events

MALVERN, Pa. & SAN DIEGO--(BUSINESS WIRE)--Dec. 1, 2021-- PhaseBio Pharmaceuticals, Inc. (Nasdaq: PHAS), a clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapies for cardiopulmonary diseases, today announced the publication of the interim results from REVERSE-IT (**R**apid and Sustain**E**d Re**VERS**al of Ticagr**E**lor – **I**ntervention **T**rial) in the New England Journal of Medicine Evidence, a new digital journal from the NEJM (New England Journal of Medicine) Group. REVERSE-IT is PhaseBio's ongoing pivotal Phase 3 trial of its lead product bentracimab, which is designed to study the reversal of the antiplatelet effects of ticagrelor in patients who present either (i) with a need for urgent surgery or an invasive procedure or (ii) who are experiencing uncontrolled major or life-threatening bleeding.

The results of the prespecified interim analysis were previously presented on November 15, 2021, by Deepak L. Bhatt, M.D., M.P.H., Executive Director of Interventional Cardiovascular Programs at Brigham and Women's Hospital and professor at Harvard Medical School, during a Late-Breaking Science Session at the 2021 American Heart Association Scientific Sessions.

"We are pleased to see the publication of these highly positive interim Phase 3 results in a leading peer-reviewed scientific publication like NEJM Evidence," said John Lee, M.D., Ph.D., Chief Medical Officer of PhaseBio. "This first analysis of bentracimab in patients demonstrated a remarkable safety profile with no drug-related serious adverse events reported and a low thrombotic event rate. Importantly, the highly significant clinical efficacy demonstrated in the surgical patients suggests strongly that we will see similar efficacy in bleeding patients upon completion of the study. Both urgent surgery and major, uncontrolled bleeding represent clear unmet needs for patients on ticagrelor worldwide who lack an effective reversal agent. We remain on track to submit our planned Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) in mid-2022 and intend to seek approval for both urgent surgery and major bleeding indications."

REVERSE-IT Clinical Program

The REVERSE-IT trial is expected to enroll approximately 200 major bleeding or urgent surgery patients at sites in the United States, Canada, the European Union and China. Based on prior guidance from the FDA, to balance the two patient populations, the REVERSE-IT trial does not allow enrollment of more than approximately two-thirds of either the uncontrolled major or life-threatening bleeding population or urgent surgery or invasive procedure population. Because the total number of patients enrolled in the prespecified interim analysis included 142 patients who required urgent surgery or an invasive procedure, PhaseBio has determined that the surgery cohort of the trial has been fully enrolled. With the successful completion of enrollment in this surgery cohort, REVERSE-IT trial sites have shifted focus to enrolling patients with uncontrolled major or life-threatening bleeding events. PhaseBio is seeking to accelerate enrollment of patients with uncontrolled major or life-threatening bleeding, including by working to increase the number of enrolling clinical trial sites as it believes that a broader site footprint will increase the probability of enrolling these patients.

The FDA also previously indicated that an interim analysis of the first approximately 100 patients enrolled in the REVERSE-IT trial would be sufficient to support the submission of a BLA for accelerated approval of bentracimab. The FDA recommended that the 100 patients comprising the interim analysis include approximately 50 patients from each of the major or life-threatening bleeding population and urgent surgery or invasive procedure population, although the FDA noted that whether there are an adequate number of patients from either cohort would be a review issue and considered in the context of other data submitted with the BLA. PhaseBio is commencing preparation of the BLA and is targeting a BLA submission to the FDA in mid-2022.

Bentracimab has been studied in Phase 1 and Phase 2 clinical trials and demonstrated immediate and sustained reversal of the antiplatelet activity of ticagrelor. If these data are reproduced in the final results from the Phase 3 study, bentracimab may have the potential to bring life-saving therapeutic benefit to patients by potentially mitigating concerns regarding bleeding risks associated with the use of ticagrelor. Additionally, in a translational study, bentracimab achieved equivalent reversal of branded ticagrelor and multiple ticagrelor generics.

About Bentracimab (PB2452)

Bentracimab is a novel, recombinant, human monoclonal antibody antigen-binding fragment designed to reverse the antiplatelet activity of ticagrelor in major bleeding and urgent surgery situations. In a Phase 1 clinical trial, bentracimab 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 this antiplatelet drug. Data from the Phase 1 clinical trial of bentracimab in healthy volunteers was published in the New England Journal of Medicine in March 2019. In April 2019, bentracimab received Breakthrough Therapy Designation from the FDA. In September 2019, PhaseBio completed a Phase 2a trial in which bentracimab was investigated in healthy, older and elderly subjects on dual antiplatelet therapy of ticagrelor and low-dose aspirin. Additionally, the Phase 2a trial investigated a bentracimab regimen for the reversal of supratherapeutic doses of ticagrelor in healthy younger subjects. In November 2021, PhaseBio completed a Phase 2b trial in which bentracimab was investigated in healthy, older and elderly subjects on dual antiplatelet therapy of ticagrelor and low-dose aspirin. In all active treatment arms in both the Phase 2a and Phase 2b trials, bentracimab achieved immediate and sustained reversal of the antiplatelet effects of ticagrelor and was generally well-tolerated, with only minor adverse events reported. These results are consistent with the results observed in healthy younger subjects treated with ticagrelor in the previously published Phase 1 trial. PhaseBio initiated REVERSE-IT, a pivotal Phase 3 clinical trial of bentracimab, in March 2020 to support a potential Biologics License Application for bentracimab in both major bleeding and urgent surgery indications.

About PhaseBio

PhaseBio Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapies for cardiovascular and cardiopulmonary diseases. PhaseBio's pipeline includes: bentracimab (PB2452), a novel reversal agent for the antiplatelet therapy ticagrelor; pemziviptadil (PB1046), a once-weekly vasoactive intestinal peptide (VIP) receptor agonist for the treatment of pulmonary arterial hypertension; and PB6440, an oral agent for the treatment of resistant hypertension. PhaseBio's proprietary elastin-like polypeptide technology platform enables the development of therapies with potential for less-frequent dosing and improved pharmacokinetics, including pemziviptadil, and drives both internal and partnership drug-development opportunities.

PhaseBio is located in Malvern, PA, and San Diego, CA. For more information, please visit www.phasebio.com, and follow us on Twitter @PhaseBio and LinkedIn.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "anticipates," "believes," "expects," "intends," "potential," "projects," "target," "will," "would" and "future" or similar expressions are intended to identify forward-looking statements.

Forward-looking statements include statements concerning or implying the conduct or timing of our clinical trials and our research, development and regulatory plans for our product candidates, the timing of availability or disclosure of data from those clinical trials and the timing of planned regulatory submissions, the potential for these product candidates to receive regulatory approval from the FDA or equivalent foreign regulatory agencies, and whether, if approved, these product candidates will be successfully distributed, marketed and commercialized. Forward-looking statements are based on management's current expectations and are subject to various risks and uncertainties that could cause actual results to differ materially and adversely from those expressed or implied by such forward-looking statements. Accordingly, these forward-looking statements do not constitute guarantees of future performance, and you are cautioned not to place undue reliance on these forward-looking statements.

Risks regarding our business are described in detail in our Securities and Exchange Commission filings, including in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2021. These forward-looking statements speak only as of the date hereof, and PhaseBio Pharmaceuticals, Inc. disclaims any obligation to update these statements except as may be required by law.

View source version on businesswire.com: https://www.businesswire.com/news/home/20211201006179/en/

Investor Contact:
John Sharp
PhaseBio Pharmaceuticals, Inc.
Chief Financial Officer
(610) 981-6506
john.sharp@phasebio.com

Media Contact:
Will Zasadny
Canale Communications, Inc.
(619) 961-8848
will.zasadny@canalecomm.com

Source: PhaseBio Pharmaceuticals, Inc.