PhaseBio Announces Dosing of First Patient in European Union as Part of REVERSE-IT Global Phase 3 Trial of Bentracimab for Reversal of Antiplatelet Effects of Ticagrelor

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Cardiovascular disease remains a leading cause of mortality in both the European Union and globally, with antiplatelet therapy being a core treatment to prevent cardiovascular events

The lack of reversal agents for patients taking antiplatelet therapies who require urgent surgery or experience a major bleeding event remains a critical unmet need

Bentracimab (PB2452) has demonstrated immediate and sustained reversal of the antiplatelet effects of ticagrelor in both Phase 1 and Phase 2 clinical trials

MALVERN, Pa. & SAN DIEGO--(BUSINESS WIRE)--Jan. 28, 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 that in conjunction with its financing and co-development partner for the European Union and China, SFJ Pharmaceuticals, PhaseBio has expanded its pivotal Phase 3 REVERSE-IT trial for its lead product candidate bentracimab into the European Union, having opened trial sites for enrollment and begun dosing its first patients. Bentracimab is a novel, human monoclonal antibody fragment that in earlier clinical trials has shown immediate and sustained reversal of the antiplatelet effects of Brilinta® (ticagrelor).

"We are pleased to announce the expansion of our global Phase 3 study of bentracimab into a number of European Union countries. The first patient dosed in the European Union is a significant milestone for the global development of bentracimab, given that the largest population of patients on $P2Y_{12}$ inhibitors like ticagrelor reside in Europe," said Jonathan Mow, President & CEO of PhaseBio Pharmaceuticals. "To help better manage patients who benefit from antiplatelet therapy, physicians across the globe need a reversal agent that can immediately intervene in the case of a spontaneous bleeding event or before an urgent surgery. We are confident in the clinical profile of bentracimab and pleased to expand its clinical development into the European Union as we work to develop the first ticagrelor-specific antiplatelet reversal agent."

John Lee, M.D., Ph.D., Chief Medical Officer of PhaseBio Pharmaceuticals, added, "The successful development of a novel, specific reversal agent for patients on ticagrelor antiplatelet therapy has the potential to change the way the healthcare system currently manages patients with acute coronary syndrome (ACS), a history of myocardial infarction or established coronary artery disease. With the potential to eliminate procedure delays due to pre-operative washout periods that may increase thrombotic risk and prolong in-hospital stays, an effective reversal agent such as bentracimab could enable surgeons to perform necessary surgical procedures on these patients without waiting the currently-recommended 5-7 days prior to surgery. Additionally, having the ability to immediately restore platelet function in patients who are experiencing a major spontaneous bleeding event would represent a paradigm shift in how these patients are managed, given that currently available options are limited to blood transfusions and supportive care. We are excited to be able to bring this important investigational therapy to our investigators in Europe and are looking forward to the continued expansion of the global REVERSE-IT Phase 3 trial, with sites in China expected to open later this year."

Bentracimab has been studied in Phase 1 and Phase 2 clinical trials and has demonstrated the potential to bring life-saving therapeutic benefit through immediate and sustained reversal of the antiplatelet activity of ticagrelor, potentially mitigating concerns regarding bleeding risks associated with the use of this antiplatelet drug. Additionally, in a translational study, bentracimab achieved equivalent reversal of branded ticagrelor and multiple ticagrelor generics. Estimates from IQVIA® for 2019 suggest nearly 450,000 patients on Brilinta® (ticagrelor) in the United States, and approximately 1.2 million patients on Brilinta®/Brilique® (ticagrelor) in the 27 countries comprising the European Union, plus the United Kingdom, Switzerland, and Norway.

REVERSE-IT (Rapid and SustainEd ReVERSal of TicagrElor – Intervention Trial) is a Phase 3, multi-center, open-label, prospective single-arm trial designed to study reversal of the antiplatelet effects of ticagrelor with bentracimab in patients who present with uncontrolled major or life-threatening bleeding or who require urgent surgery or invasive procedure. Approximately 200 patients are being targeted to be enrolled from major health centers worldwide. Patients with reported use of ticagrelor within the prior 3 days who require urgent ticagrelor reversal will be eligible for enrollment.

More information about the REVERSE-IT Phase 3 trial is available at ClinicalTrials.gov, using the identifier NCT04286438.

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. 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 Food and Drug Administration (FDA). Breakthrough Therapy Designation may be granted by the FDA when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapy. In September 2019, PhaseBio completed a Phase 2a trial in which bentracimab was investigated in 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 both arms of the trial, 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 the REVERSE-IT trial, a pivotal Phase 3 clinical trial of bentracimab, in March 2020 to support a Biologics License Application for bentracimab in both major bleeding and urgent 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 for cardiovascular and cardiopulmonary diseases. The company's pipeline includes: bentracimab (PB2452), a novel reversal agent for the antiplatelet therapy ticagrelor; pemziviptadil (PB1046), a once-weekly vasoactive intestinal peptide 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.

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," "projects," 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 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 and marketed. 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 ("SEC") filings, including in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2020. 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.

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