PhaseBio Pharmaceuticals Announces Bentracimab Manufacturing Update

March 8, 2022

Manufacturing of bentracimab drug substance and drug product Process Performance Qualification (PPQ) batches has been completed

PhaseBio remains on track to submit bentracimab Biologics License Application (BLA) in mid-2022

MALVERN, Pa. & SAN DIEGO--(BUSINESS WIRE)--Mar. 8, 2022-- 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 completion of the bentracimab drug substance and drug product Process Performance Qualification (PPQ) campaign. The PPQ campaign consisted of multiple commercial scale runs required for the validation of the bentracimab manufacturing process and the demonstration of batch-to-batch manufacturing consistency, at commercial scale.

"We are pleased with the exceptional efforts of our manufacturing partners, BIOVECTRA Inc. (Windsor, Nova Scotia) and Berkshire Sterile Manufacturing (Lee, MA)," said Susan Arnold, Ph.D., SVP, Technical Operations at PhaseBio. "The completion of our drug substance and drug product PPQ manufacturing runs is a critical milestone in the development of bentracimab, which will form the basis of the Chemistry, Manufacturing and Controls (CMC) sections of the Biologics License Application (BLA) that we plan to submit to the U.S. Food and Drug Administration (FDA) later this year."

"Establishing a commercial-scale manufacturing process early in the development of bentracimab has been a key strategic imperative for PhaseBio," said Jonathan Mow, Chief Executive Officer at PhaseBio. "The inclusion of commercial-scale material in our completed Phase 2b trial and ongoing Phase 3 trial for bentracimab, coupled with the completion of the PPQ campaign, has positioned PhaseBio to be ready to supply global demand for bentracimab at launch, once approved."

Bentracimab, PhaseBio's lead drug candidate, is currently in late-stage clinical development in the REVERSE-IT (Rapid and SustainEd ReVERSal of TicagrElor – Intervention Trial) trial. REVERSE-IT 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. In November 2021, PhaseBio presented positive interim results from the REVERSE-IT trial during a Late-Breaking Science Session at the 2021 American Heart Association Scientific Sessions. In December 2021, the REVERSE-IT interim results were subsequently published in NEJM Evidence, a new digital journal from the NEJM (New England Journal of Medicine) Group. The Company is targeting a BLA submission to FDA in mid-2022.

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.

About Bentracimab (PB2452)

Bentracimab is a novel, recombinant, human monoclonal antibody antigen-binding fragment designed to reverse the antiplatelet activity of ticagrelor in patients who present with uncontrolled bleeding or require surgery. 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 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 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 uncontrolled bleeding and surgery indications. Interim results from the Phase 3 REVERSE-IT trial were presented in November 2021 and subsequently published in NEJM Evidence in December 2021.

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, including having sufficient product supply at launch. 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.

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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

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