PhaseBio Pharmaceuticals and SFJ Pharmaceuticals® Announce Approval of IND Application in China for Bentracimab

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Enrollment in the REVERSE-IT global Phase 3 trial from clinical sites in China expected to begin later in 2021

MALVERN, Pa. & SAN DIEGO--(BUSINESS WIRE)--Aug. 10, 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 the Investigational New Drug (IND) application for bentracimab submitted to the Center for Drug Evaluation (CDE) of the China National Medical Products Administration (NMPA) in collaboration with development partner, SFJ Pharmaceuticals (SFJ), has been approved. 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®/Brilique® (ticagrelor).

With approval of the IND, PhaseBio and SFJ are authorized to begin enrolling patients in China into REVERSE-IT, the ongoing global 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 an invasive procedure. PhaseBio and SFJ anticipate enrolling the first patients at sites in China later in 2021, after the REVERSE-IT trial has reached its interim enrollment milestone expected in mid-2021. Patients enrolled in China are expected to contribute to the completion of full enrollment of the trial, post interim analysis.

“The approval of the IND in China for bentracimab is a significant step forward for the bentracimab development program as it opens a path to approval in China based upon the REVERSE-IT trial,” said John Lee, M.D., Ph.D., Chief Medical Officer of PhaseBio. “China has the largest population of patients treated with $P2Y_{12}$ inhibitors in the world, and with both branded and generic formulations available, the use of ticagrelor continues to grow rapidly. With no approved reversal agents to help manage the bleeding complications associated with the $P2Y_{12}$ inhibitor class of drugs, the unmet need for bentracimab is clear. I’d like to thank our collaborators at SFJ Pharmaceuticals and the team at PhaseBio for their diligent efforts leading up to this important milestone in the development of bentracimab.”

In January 2020, PhaseBio announced a financing and co-development partnership with SFJ Pharmaceuticals, and since this time, SFJ has been leading clinical development efforts in China. PhaseBio retains commercial rights to bentracimab in China and is pursuing prospective commercial partners to license the marketing rights in China and other countries in the Asia-Pacific region.

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 U.S. 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.

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 (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.

About the SFJ Pharmaceuticals Group

SFJ is a global drug development company, which provides a unique and highly customized co-development partnering model for the world's top pharmaceutical and biotechnology companies. SFJ provides at-risk funding and the global clinical development management and oversight necessary for regulatory submission for some of the most promising drug development programs of Pharmaceutical and Biotechnology companies. SFJ’s mission is to leverage its financial strength and global team of pharmaceutical development experts to accelerate the development of life-saving and life-enhancing drugs for the benefit of physicians and the patients they serve.

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, including those with SFJ, 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 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 filings, including in our Quarterly Report on Form 10-Q for the quarter ended March 31, 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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PhaseBio Investor Contact:
John Sharp
PhaseBio Pharmaceuticals, Inc.
Chief Financial Officer
(610) 981-6506
john.sharp@phasebio.com

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

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