PhaseBio Pharmaceuticals, Inc. Logo

PhaseBio Announces Financing and Co-Development Collaboration with SFJ Pharmaceuticals® for PB2452

January 10, 2020

PhaseBio to receive up to $120 million in development funding

PhaseBio retains exclusive worldwide commercial rights to PB2452

MALVERN, Pa. and SAN DIEGO, Jan. 10, 2020 (GLOBE NEWSWIRE) -- PhaseBio Pharmaceuticals, Inc. (Nasdaq: PHAS), a clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapies for cardiopulmonary diseases, today announced a financing and co-development collaboration with SFJ Pharmaceuticals to support the development of PB2452, a reversal agent for the antiplatelet therapy ticagrelor. SFJ Pharmaceuticals is a global drug development company backed by Blackstone Life Sciences and Abingworth.

The collaboration between SFJ and PhaseBio will support the global development of PB2452, which is designed to reverse the antiplatelet activity of ticagrelor in major bleeding and urgent surgery situations. Under the terms of the agreement, SFJ has agreed to fund up to $120 million to support the clinical development of PB2452 and to assume a central role in global clinical development and regulatory activities for PB2452 outside the United States. SFJ will fund up to $90 million of development expenses through the end of 2021 and up to an additional $30 million based on PhaseBio meeting specific, pre-defined clinical milestones for PB2452.

“This innovative collaboration with SFJ provides PhaseBio with substantial funding to continue the rapid advancement of our lead program, PB2452, and enables us to efficiently extend our global reach,” said Jonathan P. Mow, Chief Executive Officer of PhaseBio. “SFJ’s global drug development and regulatory expertise, coupled with a track record of success in accelerating and advancing late-stage development programs for large, multi-national pharmaceutical companies, make it an ideal partner. The collaboration provides PhaseBio with financial flexibility while allowing us to retain full commercial rights and mitigate our global development risk.”

Under the terms of the PB2452 agreement, PhaseBio will pay SFJ a series of annual payments over seven to eight years following receipt of regulatory approvals in the United States, the European Union and either China or Japan, with the majority of payments to SFJ due in years three to seven following each respective regulatory approval. If PB2452 does not receive regulatory approval in a specific territory, PhaseBio will not owe any payments linked to that territory. In general, the amount to be repaid by PhaseBio will not exceed five times the amount funded by SFJ. PhaseBio will retain exclusive worldwide commercial rights to PB2452.

“We are excited to be partnering with PhaseBio under this novel co-development agreement,” said Bob DeBenedetto, Chief Executive Officer of SFJ. “Based on the clinical data generated to date and following an extensive diligence process conducted in conjunction with our partners at Blackstone Life Sciences and Abingworth, we believe that PB2452 has great potential to address a significant unmet need. We look forward to supporting its continued development and working closely with the PhaseBio team.”

About PB2452

PB2452 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, 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 FDA. Breakthrough Therapy designation may be granted by FDA when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapy. PhaseBio plans to initiate a single pivotal Phase 3 clinical trial of PB2452 in the first quarter of 2020 to support a BLA for PB2452 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 to treat cardiopulmonary diseases. 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.

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,” “projects,” and “future” or similar expressions are intended to identify forward-looking statements.

Forward-looking statements include statements concerning or implying the success of our collaboration with SFJ, including whether we will receive all

of the contemplated funding under the co-development agreement, the conduct or timing of our clinical trials, timelines for regulatory submissions, the potential for PB2452 to receive regulatory approval from the FDA or equivalent foreign regulatory agencies and whether, if approved, PB2452 will be successfully distributed and marketed and our research, development and regulatory plans for PB2452, PB1046 and our ELP research programs. 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, 2019. 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.

[1] Bhatt DL, Pollack CV, Weitz JI, et al. Antibody-Based Ticagrelor Reversal Agent in Healthy Volunteers. N Engl J Med 2019; 380:1825-1833

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

Media Contact:
Gina Cestari
6 Degrees
(917) 797-7904
gcestari@6degreespr.com

Source: PhaseBio Pharmaceuticals, Inc.