

PhaseBio Pharmaceuticals, Inc. Logo

PhaseBio Announces First Patient Dosed in Phase 2b Clinical Trial of PB2452 for Reversal of the Antiplatelet Activity of Ticagrelor

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MALVERN, Pa. and SAN DIEGO, Oct. 15, 2019 (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 that the first patient has been dosed in a Phase 2b clinical trial of PB2452, a novel, recombinant, human monoclonal antibody antigen-binding fragment designed to reverse the antiplatelet activity of ticagrelor in major bleeding and urgent surgery situations.

The Phase 2b multi-center, randomized, double-blind, placebo-controlled trial is designed to evaluate the safety and efficacy of PB2452 in reversing the antiplatelet effects of ticagrelor as part of a dual antiplatelet regimen including low-dose aspirin. Additionally, the Phase 2b trial marks the beginning of United States Food and Drug Administration ("FDA")-aligned registrational trials to support the submission of a Biologics License Application ("BLA") for potential accelerated approval of PB2452. Approximately 200 older and elderly (ages 50-80) subjects are expected to be enrolled, resembling the patient population most likely to be treated with ticagrelor and potentially benefit from PB2452, if approved. Subjects will be randomized in a ratio of 3:1 and will receive either PB2452 or placebo, with approximately 150 subjects receiving PB2452. The primary endpoint of the trial is reversal of the antiplatelet effects of ticagrelor with intravenous infusion of PB2452 or placebo, as measured by the VerifyNow® PRUtest® biomarker.

"We are pleased that the first patient has been dosed in the registrational Phase 2b clinical trial of PB2452, as it signifies continued progress on our Accelerated Approval pathway discussed with the FDA at our End-of-Phase 1 meeting," said John Lee, M.D., Ph.D., Chief Medical Officer of PhaseBio. "We continue to be encouraged by the potential of PB2452 to address a significant unmet need for patients by reversing the antiplatelet activity of ticagrelor in major bleeding and urgent surgery situations. Our plans to initiate our Phase 3 trial in the first quarter of 2020 and potentially submit a BLA for PB2452 in the second half of 2022 remain on track."

PhaseBio recently completed a Phase 2a trial in which PB2452 achieved immediate and sustained reversal of the antiplatelet effects of ticagrelor in older and elderly subjects on dual antiplatelet therapy of ticagrelor and low-dose aspirin. PB2452 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. Additionally, the Phase 2a trial investigated a PB2452 regimen for the reversal of supratherapeutic doses of ticagrelor in healthy younger subjects, which demonstrated immediate and sustained reversal of the antiplatelet effects of ticagrelor and was well tolerated, consistent with the earlier cohorts in the Phase 2a trial and the Phase 1 trial.

Additional information on the trial can be found on <https://clinicaltrials.gov/> using the identifier [NCT04122170](#).

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 Biologics License Application 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 orphan diseases, with an initial focus on cardiopulmonary disorders. 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.

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, timelines for regulatory submissions 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 June 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.

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

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



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