PhaseBio Pharmaceuticals, Inc. Logo

PhaseBio Announces Completion of Phase 2a Clinical Trial of PB2452 for the Reversal of the Antiplatelet Activity of Ticagrelor

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Preliminary Results from Supratherapeutic-Dose Ticagrelor Cohort Are Consistent with Earlier Phase 2a Cohorts and Previously Published Phase 1 Trial

MALVERN, Pa. and SAN DIEGO, Sept. 24, 2019 (GLOBE NEWSWIRE) -- PhaseBio Pharmaceuticals, Inc. (Nasdaq: PHAS), a clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapies for cardiopulmonary orphan diseases, today announced the completion of its Phase 2a clinical trial of PB2452. Full data from the trial are planned to be presented at an upcoming medical congress.

In the trial, PB2452 achieved immediate and sustained reversal of ticagrelor in older (ages 50-64) and elderly (ages 65-80) 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. The older and elderly subjects in the Phase 2a trial resemble the patient population most likely to be treated with ticagrelor and to potentially benefit from PB2452, if approved.

Based on guidance provided by the U.S. Food and Drug Administration ("FDA") during the PB2452 End-of-Phase 1 meeting in July of this year, the Phase 2a trial also investigated a PB2452 regimen for the reversal of supratherapeutic doses of ticagrelor in healthy younger subjects. In the supratherapeutic-dose cohort, PB2452 demonstrated immediate and sustained reversal of ticagrelor and was well tolerated, consistent with the earlier cohorts in the Phase 2a and Phase 1 trials. Statistically significant reversal of the antiplatelet activity of supratherapeutic blood levels of ticagrelor was achieved within 5 minutes of initiation of PB2452 infusion and sustained for 24 hours. Platelet function was normalized by 30 minutes following initiation of PB2452 infusion and remained normal for 24 hours. Based on the preliminary results from this cohort, PhaseBio believes that it has identified an appropriate PB2452 regimen for use in patients who may have supratherapeutic blood levels of ticagrelor as a result of ticagrelor drug-drug interactions or overdosage.

"With the successful completion of our Phase 1 and 2a studies, we are excited to be moving forward into our registrational studies for PB2452," said John Lee, M.D., Ph.D., Chief Medical Officer of PhaseBio. "Our defined regulatory path for PB2452 remains on track as we prepare to advance the program into a Phase 2b trial in the fourth quarter of this year and a pivotal Phase 3 trial in the first quarter of 2020. We continue to be encouraged about 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."

Additional information on the trial can be found on www.ClinicalTrials.gov using the identifier NCT03928353.

About PB2452

PB2452 is a novel, recombinant, human monoclonal antibody antigen-binding fragment, or Fab, 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 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 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 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.

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1. Bhatt DL, Pollack CV, Weitz JI, et al. Antibody-Based Ticagrelor Reversal Agent in Healthy Volunteers. *N Engl J Med* 2019;Mar 17.

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