

PhaseBio Pharmaceuticals, Inc. Logo

## PhaseBio Announces Positive Preliminary Results from Phase 2a Clinical Trial of PB2452 for the Reversal of the Antiplatelet Activity of Ticagrelor in Older and Elderly Subjects

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### Top-Line Data Are Consistent with Previously Published Phase 1 Trial

MALVERN, Pa. and SAN DIEGO, June 17, 2019 (GLOBE NEWSWIRE) -- [PhaseBio Pharmaceuticals, Inc.](#) (Nasdaq: PHAS), a clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapies for orphan diseases, today announced preliminary data from its Phase 2a clinical trial of PB2452, which is the first trial of PB2452 to include older (ages 50-64) and elderly (ages 65-80) subjects on dual antiplatelet therapy of ticagrelor and low-dose aspirin. Subjects in the trial resemble the patient population most likely to be treated with ticagrelor and potentially benefit from PB2452, if approved. In the trial, statistically significant reversal of ticagrelor was achieved within 5 minutes of initiation of PB2452 infusion and sustained for over 20 hours. Platelet function was normalized by 15 minutes following initiation of PB2452 infusion and remained normal for over 20 hours. To date, PB2452 has been generally well tolerated in the Phase 2a trial, with only minor adverse events reported. These new data are consistent with results from PhaseBio's previously published Phase 1 trial conducted in healthy younger volunteers treated with ticagrelor alone and not aspirin. Efficacy of PB2452 in the Phase 2a trial is measured using the same three assays that were utilized in the Phase 1 trial, with results from all three assays showing a high degree of correlation in both trials.

"For patients taking antiplatelet therapies such as ticagrelor, it is currently recommended that they stop their antiplatelet regimen for at least five days prior to undergoing surgery to reduce the risk of major bleeding," said John Lee, M.D., Ph.D., Chief Medical Officer of PhaseBio. "This isn't an option for patients requiring urgent or emergency surgery. For patients experiencing major bleeding, there are currently no proven methods to reverse the effects of antiplatelet agents. If approved, PB2452 could help address these critical unmet medical needs by enhancing the safety profile of ticagrelor, which has the potential to become the only antiplatelet therapy on the market with a specific reversal agent. We look forward to reporting full results from the Phase 2a trial at an upcoming medical congress."

Additional information on the trial can be found on [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov) using the identifier [NCT03928353](#).

#### About PB2452

PB2452 is a novel, recombinant, human monoclonal antibody antigen-binding fragment, or Fab 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 selected as a late-breaking, oral presentation at The American College of Cardiology's Annual Scientific Session<sup>1</sup> and published simultaneously in the *New England Journal of Medicine* in March 2019.<sup>2</sup> In April 2019, PB2452 received Breakthrough Therapy designation from the U.S. Food and Drug Administration ("FDA"). Breakthrough Designation may be granted by FDA when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapy. 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](http://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 March 31, 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. <https://www.acc.org/latest-in-cardiology/clinical-trials/2019/03/15/21/37/ticagrelor-reversal-agent>
2. Bhatt DL, Pollack CV, Weitz JI, et al. Antibody-Based Ticagrelor Reversal Agent in Healthy Volunteers. [\*N Engl J Med\* 2019;Mar 17.](#)



Source: PhaseBio Pharmaceuticals, Inc.