PhaseBio Pharmaceuticals, Inc. Logo

PhaseBio Announces Case Study Highlighting PB1046 Hemodynamic Data Presented at the 14th Pulmonary Vascular Research Institute World Congress

February 4, 2020

Data continue to support potential of once-weekly VIP analogue for adults with pulmonary arterial hypertension

MALVERN, Pa. and SAN DIEGO, Calif., Feb. 04, 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 presentation of data from a patient who received more than 18 months of treatment with PB1046, the company's first-in-class, sustained-release vasoactive intestinal peptide (VIP) analogue being evaluated for the treatment of patients with pulmonary arterial hypertension (PAH). The data, which were presented at the 14th Pulmonary Vascular Research Institute (PVRI) World Congress held in Lima, Peru, from January 30th through February 2nd 2020, demonstrate clinically-meaningful improvements in all of the hemodynamic parameters assessed, which were sustained for up to three months after the last dose was administered.

The patient was part of PhaseBio's Phase 1b/2a pilot study which evaluated the multi-dose safety, pharmacokinetics (PK) and VIP-based pharmacodynamic effects of PB1046 in three PAH patients who have a permanently implanted hemodynamic monitor (CardioMEMS™ HF System), a device placed in the pulmonary artery (PA) which continuously measures heart rate along with systolic and diastolic pressures. PB1046 was administered subcutaneously on a weekly basis for eight weeks at dose levels previously tested and observed to have a favorable safety profile. All three patients completed the eight-week study with no drug-related serious adverse events and PB1046 appeared to be well tolerated with only mild injection site erythema. In one patient, the subject of the case study, treatment was extended for a total of 18 months, based on continued improvements in hemodynamic parameters. The CardioMEMS monitoring system detected reductions in mean PA pressure and total pulmonary resistance and increases in stroke volume and cardiac output without an increase in heart rate with PB1046.

"We were pleased to see sustained positive long-term effects in an adult patient with PAH who had been treated with PB1046," said Raymond Benza, MD, cardiologist at the Allegheny Health Network in Pittsburgh, Pennsylvania. "We believe these data validate the continued evaluation of PB1046 in the ongoing Phase 2b clinical trial and underscore its potential to be a once-weekly treatment for PAH, a progressive and life-threatening orphan disease with no known cure."

About PB1046

PB1046, a novel, subcutaneously-injected vasoactive intestinal peptide (VIP) analogue, is a recombinant fusion protein composed of VIP and PhaseBio's proprietary elastin-like polypeptide (ELP) biopolymer.

Based on the pharmacokinetic profile of PB1046 observed in clinical trials, the fusion of VIP to ELP results in both a prolonged absorption profile and a longer circulating half-life, enabling once-weekly dosing. In addition to VIP-mediated vasodilation, PB1046 may suppress the adverse remodeling of blood vessels and increase cardiac contractility and relaxation. PB1046 has been administered to more than 70 patients with hypertension or a history of cardiovascular disease in three Phase 1/2 clinical trials conducted in the U.S., with no drug-related serious adverse events to date.

The U.S. Food and Drug Administration has granted PB1046 orphan drug designation for the treatment of PAH (WHO Group 1 Pulmonary Hypertension) and cardiomyopathy associated with dystrophinopathies.

About PhaseBio

PhaseBio Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapies for cardiopulmonary diseases. The company's pipeline includes: PB2452, a novel reversal agent for the antiplatelet therapy ticagrelor; PB1046, a once-weekly vasoactive intestinal peptide receptor agonist for the treatment of pulmonary arterial hypertension; and PB6440, an oral agent for the treatment of resistant hypertension. PhaseBio's proprietary ELP technology platform enables the development of therapies with potential for less-frequent dosing and improved pharmacokinetics, including PB1046, 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.

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 PB1046 and the potential for PB1046 to be disease-modifying. 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.

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