PhaseBio Pharmaceuticals, Inc. Logo

PhaseBio Announces Dosing of First Patient in Phase 2b Clinical Trial of PB1046 in Pulmonary Arterial Hypertension

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MALVERN, Pa. and SAN DIEGO, Calif., Nov. 27, 2018 (GLOBE NEWSWIRE) -- PhaseBio Pharmaceuticals, Inc. (Nasdaq: PHAS), a clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapies for orphan diseases, with an initial focus on cardiopulmonary disorders, today announced that the first patient in a Phase 2b clinical trial of PB1046 for the treatment of pulmonary arterial hypertension (PAH) has been dosed by Murali Chakinala, M.D., Professor of Medicine at the Washington University School of Medicine (WUSM) and Director of the WUSM and Barnes-Jewish Hospital Pulmonary Hypertension Care Center. PB1046 is a sustained-release analogue of human vasoactive intestinal peptide (VIP) fused to PhaseBio's proprietary ELP half-life extension technology.

The randomized, double-blinded, parallel-group Phase 2b trial will assess the safety, tolerability and efficacy of PB1046 injected subcutaneously once weekly in approximately 60 PAH patients. The trial will evaluate the effects of PB1046 on pulmonary hemodynamics and exercise tolerance as measured by the six-minute walk test, an important clinical endpoint that the U.S. Food and Drug Administration has used as the basis for approval of other PAH drugs.

"PB1046 leverages our ELP technology to harness the positive therapeutic effects and extend the half-life of native human VIP, which has previously been limited in its application as a therapeutic by its rapid degradation and potential for gastrointestinal side effects," said John Lee, M.D., Ph.D., Chief Medical Officer of PhaseBio. "PB1046 has been generally safe and well tolerated in early clinical trials and we are excited to investigate its potential benefits in PAH, a rare disease with high unmet need for innovative therapies. We look forward to reporting results from the Phase 2b trial in the first half of 2020."

The Phase 2b trial of PB1046 in PAH is supported in part by a Fast-Track Small Business Innovation Research grant from the National Heart, Lung, and Blood Institute of the National Institutes of Health under Award Number R44HL140690. The content of this press release is solely the responsibility of PhaseBio and does not necessarily represent the official views of the National Institutes of Health.

Additional information on the trial can be found on www.clinicaltrials.gov using the identifier NCT03556020.

About Pulmonary Arterial Hypertension

Pulmonary arterial hypertension (PAH) is a progressive and life-threatening orphan disease caused by abnormal constriction and adverse remodeling of the arteries in the lungs, leading to chronically elevated blood pressure in the pulmonary arteries. This increased pressure restricts blood circulation through the lungs, resulting in poor oxygenation, abnormal strain on the heart's right ventricle and underfilling of the left ventricle. Over time, the remodeling worsens as inflammatory cells are recruited. This leads to tissue scarring and fibrosis, which results in severe restriction of blood flow, increasing the risk of developing life-threatening blood clots, heart failure and premature death. None of the approved treatment options is curative and long-term prognosis remains poor.

About PB1046

PB1046, a novel, subcutaneously-injected VIP analogue, is a recombinant fusion protein composed of VIP and PhaseBio's proprietary 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 60 patients with hypertension or a history of cardiac 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 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 (PAH).

PhaseBio is located in Malvern, PA and San Diego, CA. For more information, please visit www.phasebio.com.

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