



PhaseBio Presents Data from Phase 1b/2a Trial of Pemziviaptadil for the Treatment of Pulmonary Arterial Hypertension at 15th Pulmonary Vascular Research Institute Virtual World Congress

January 27, 2021

New data for pemziviaptadil (PB1046) support continued evaluation as a potential novel therapy of once-weekly VIP analogue for adults with pulmonary arterial hypertension; novel agent observed to be well tolerated, with no drug-related serious adverse events resulting in study drug discontinuation

MALVERN, Pa. & SAN DIEGO--(BUSINESS WIRE)--Jan. 27, 2021-- [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 Phase 1b/2a pilot study highlighting three patients who received pemziviaptadil (PB1046), the company's first-in-class, sustained-release vasoactive intestinal peptide (VIP) analogue for the treatment of pulmonary arterial hypertension (PAH). The data, which were presented virtually at the 15th [Pulmonary Vascular Research Institute \(PVRI\) World Congress](#) on January 27, 2021, continue to highlight the favorable safety and tolerability profile of pemziviaptadil, as well as clinically-meaningful, long-term improvement of six-minute walk test (6MWT) distance for one patient after eighteen months of treatment. Additionally, the data demonstrate stability in functional status with no clinically-meaningful deterioration for two patients at two and six months after treatment. [Hemodynamic data](#) from this same trial were presented at the 14th PVRI World Congress in early 2020.

The patients participated in PhaseBio's Phase 1b/2a pilot study, which evaluated the multi-dose safety, pharmacokinetics (PK) and VIP-based pharmacodynamic effects of pemziviaptadil in three PAH patients who have a permanently implanted hemodynamic monitor (CardioMEMS™ HF System), a device placed in the pulmonary artery that continuously measures heart rate along with systolic and diastolic pressures. Pemziviaptadil was administered subcutaneously on a weekly basis for eight weeks (extended due to subjective improvements) at dose levels previously tested in Phase 1.

All three patients completed the study with no drug-related serious adverse events associated with study drug discontinuation and pemziviaptadil appeared to be well tolerated. New efficacy data in this analysis included 6MWT distance, which improved (by +78 meters, 17% change from baseline) after 18 months of treatment in one patient, a 29 year old, while showing no signs of clinically-meaningful deterioration in a 61 year old patient after two months of therapy (-9 meters, -2% change from baseline) or in a 74 year old patient after 6 months of treatment (+16 meters, 7% change from baseline). In an ongoing 16-week randomized, double-blind, Phase 2b clinical trial of pemziviaptadil in PAH patients (the VIP trial), PhaseBio is measuring pulmonary vascular resistance and 6MWT distance among other key efficacy endpoints in approximately 60 patients.

"Though these results are from a small number of patients in a pilot study of pemziviaptadil, we are encouraged to see that this novel therapeutic agent has provided symptomatic relief and meaningful clinical benefits while continuing to demonstrate a favorable safety and tolerability profile," said John Lee, M.D., Ph.D., Chief Medical Officer of PhaseBio Pharmaceuticals. "Having observed early signs of potential efficacy in PAH patients with once-weekly pemziviaptadil in this pilot study, we continue to be optimistic about the program and look forward to the results from the ongoing Phase 2b trial, which remains on track for a readout in the second half of this year."

"The successful development of a once-weekly treatment with a potentially disease-modifying mechanism of action would be a major advancement for patients with PAH, which remains a major life-threatening condition with no cure," added Dr. Raymond Benza, MD, FACC, Professor and Director, Division of Cardiovascular Medicine, the Ohio State University Wexner Medical Center, and National Principal Investigator for this trial.

A copy of the poster is available on the [company's website](#).

About Pemziviaptadil (PB1046)

Pemziviaptadil, 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 pemziviaptadil 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.

Pemziviaptadil is in Phase 2 development for the treatment of pulmonary arterial hypertension (PAH). PhaseBio expects to report initial data from the Phase 2b trial in PAH in the second half of 2021. To date, pemziviaptadil has been administered to more than 100 patients with cardiovascular or cardiopulmonary diseases in five clinical trials conducted in the United States. The FDA has granted pemziviaptadil orphan drug designation for the treatment of pulmonary arterial hypertension (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 cardiovascular and cardiopulmonary diseases. The company's pipeline includes: bentracimab (PB2452), a novel reversal agent for the antiplatelet therapy ticagrelor; pemziviaptadil (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 elastin-like polypeptide technology platform enables the development of therapies with potential for less-frequent dosing and improved pharmacokinetics, including pemziviaptadil, 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 our product candidates, the potential for these product candidates to receive regulatory approval from the FDA or equivalent foreign regulatory agencies, and whether, if approved, these product candidates will be successfully distributed and marketed. 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 ("SEC") filings, including in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2020. Such risks may be amplified by the impacts of the COVID-19 pandemic. 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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