



PhaseBio Doses First Patient in VANGARD Phase 2 Clinical Trial to Evaluate PB1046 for Hospitalized COVID-19 Patients

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Recently launched Phase 2 "VANGARD" trial to assess the efficacy and safety of PB1046 in hospitalized COVID-19 patients at high risk for rapid clinical deterioration and acute respiratory distress syndrome

PB1046, a long-acting analog of vasoactive intestinal peptide (VIP), has the potential to modulate several proinflammatory cytokines that are believed to be key drivers of the inflammatory response to COVID-19

MALVERN, Pa. & SAN DIEGO--(BUSINESS WIRE)--Jul. 16, 2020-- [PhaseBio Pharmaceuticals, Inc.](#) (Nasdaq: PHAS), a clinical-stage biopharmaceutical company focused on the development and commercialization of novel therapies for cardiopulmonary diseases, today announced that it has dosed the first patient in VANGARD, a potentially pivotal Phase 2 clinical trial to evaluate PB1046 as a treatment for hospitalized COVID-19 patients who are at high risk for rapid clinical deterioration and acute respiratory distress syndrome (ARDS). PB1046 is a novel, once-weekly, subcutaneously-injected VIP receptor agonist that targets VPAC receptors in the cardiovascular, pulmonary and immune systems. VIP is a neurohormone known to have anti-inflammatory, antifibrotic and potent bronchodilatory and immunomodulatory effects in the respiratory system. Specifically, VIP has been shown to regulate proinflammatory cytokines including TNF- α , IFN- γ , IL-12, IL-17A and IL-6. In animal models, treatment with VIP peptide prevented acute lung injury and inhibited cytokine-mediated inflammatory responses that are characteristic of ARDS.

"Having novel treatment options that could help prevent COVID-19 patients from requiring ventilator support is an important step in fighting against this global pandemic," said Dr. Andrew Catanzaro, an investigator in the VANGARD trial and head of Infectious Disease Medicine at Adventist Healthcare White Oak Medical Center in Silver Spring, Maryland. "The inflammatory response to COVID-19 has been an exceptionally challenging aspect of managing infected patients, and those who require ventilator support have an especially poor prognosis. The PB1046 mechanism of action has the potential to mitigate proinflammatory cytokines thought to be key drivers causing rapid decline in lung function observed in more severe COVID-19 cases. Through science, and with partners like PhaseBio, we hope to discover agents that will be active for the inflammatory response and this is another important step in this process."

The VANGARD trial (VIP Analogue, in hospitalized COVID-19 patients at hiGh risk for rapid clinical deterioration and ARDS) is a multi-center, randomized, double-blind, parallel group clinical trial that is assessing the efficacy and safety of once-weekly subcutaneous injections of PB1046 in hospitalized COVID-19 patients at high risk for rapid clinical deterioration and ARDS. Approximately 210 patients will be targeted to be enrolled at approximately 20 sites nationwide. The primary endpoint in the trial measures days alive and free of respiratory failure.

"We are pleased that the initial patient has been enrolled in our potentially pivotal Phase 2 trial of PB1046 in hospitalized COVID-19 patients who are facing rapid deterioration of lung function," said Jonathan Mow, Chief Executive Officer, PhaseBio Pharmaceuticals. "Physicians are in desperate need of new options to treat COVID-19 patients, and PhaseBio is working to be a key part of the solution to this global pandemic. To have initiated the VANGARD trial in the midst of a pandemic that has severely impacted the global healthcare system in an unprecedented manner is a testament to the resolve and determination of the PhaseBio team, trial investigators and our network of advisors. We remain on track to report trial results late in the fourth quarter of 2020."

As the COVID-19 pandemic unfolded around the world, PhaseBio moved rapidly to develop a trial protocol and submit an IND application to the FDA to evaluate the potential of PB1046 to help COVID-19 patients at high risk of progressing to ARDS. PhaseBio received FDA clearance in May to initiate the VANGARD trial and, subject to the pace of enrollment and any further impacts from the COVID-19 pandemic itself, the Company is targeting to report results late in the fourth quarter of 2020. Based on feedback from the FDA, PhaseBio believes that positive, clearly interpretable and clinically meaningful results from this trial may enable PhaseBio to submit a Biologics License Application.

More information about the VANGARD phase 2 trial is available at [ClinicalTrials.gov](#), using the identifier [NCT04433546](#).

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.

PB1046 is in Phase 2 development for the treatment of pulmonary arterial hypertension (PAH) and in a Phase 2 clinical trial for the treatment of hospitalized COVID-19 patients at high risk for rapid clinical deterioration and ARDS, which the Company refers to as the VANGARD trial. PhaseBio expects to report initial data from the VANGARD trial in the fourth quarter of 2020, while results from the Phase 2b trial in PAH are expected to be reported in 2021. To date, 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 United States. The FDA has granted PB1046 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 cardiopulmonary diseases. The company's pipeline includes: bentracimab (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 hospitalized COVID-19 patients at high risk for rapid clinical deterioration and ARDS; 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 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 VANGARD trial of PB1046 for the treatment of COVID-19 patients at high risk for rapid clinical deterioration and ARDS, or other product candidates in our pipeline, 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, including whether the FDA will accept the results of VANGARD for submission of a Biologics License Application, 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 filings, including in our Quarterly Report on Form 10-Q for the quarter ended March 31, 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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