PhaseBio Pharmaceuticals, Inc. Logo

PhaseBio Announces Acquisition of Novel Oral Aldosterone Synthase Inhibitor to Develop for Treatment-Resistant Hypertension

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PhaseBio to be responsible for all development, manufacturing and commercialization

MALVERN, Pa. and SAN DIEGO, Jan. 13, 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 that it has signed an agreement with Viamet Pharmaceuticals Holdings, LLC and its wholly-owned subsidiary, Selenity Pharmaceuticals (Bermuda), Ltd., to acquire all of the assets and intellectual property rights related to certain novel aldosterone synthase inhibitors, including the company's lead development compound formerly known as SE-6440 or VT-6440. PhaseBio will designate the lead development compound as PB6440, which PhaseBio plans to develop for treatment-resistant hypertension. Terms of the agreement include an upfront payment by PhaseBio, development, approval, and net sales milestones and tiered royalties on global net sales.

PhaseBio will be responsible for all development, manufacturing and commercialization of PB6440. In preclinical studies completed to date, PB6440 was observed to be a highly potent and selective inhibitor of aldosterone synthase (CYP11B2) versus the closely-related steroid 11β-hydroxylase enzyme (CYP11B1). PB6440 demonstrated dose-dependent aldosterone reduction without a significant increase in 11-deoxycorticosterone or deoxycortisol in both rodent and primate models. The oral bioavailability and pharmacokinetic profiles appear suitable for once-daily dosing in humans. To date, no evidence of toxicity has been observed in either *in vitro* toxicity studies or in animal models, including primates. PhaseBio is planning to initiate clinical development of PB6440 pending the completion of nonclinical Investigational New Drug Application ("IND")-enabling studies planned for 2020, which are expected to be followed by an IND filing and a first-in-human study in early 2021.

"Hypertension is one of the key risk factors for cardiovascular disease and has been linked to significant morbidity and mortality," said Jonathan Mow, Chief Executive Officer of PhaseBio. "Despite a broad array of therapeutic options available to manage blood pressure, a significant proportion of hypertensive patients are still not achieving the increasingly stringent blood-pressure goals set by the American College of Cardiology and the American Heart Association. PB6440 represents an exciting, new potential treatment option for patients with treatment-resistant hypertension, and we believe it is an excellent strategic fit with PhaseBio's pipeline of novel therapies for specialty cardiovascular diseases with high unmet need."

John Lee, M.D., Ph.D., Chief Medical Officer of PhaseBio, said, "Over the past decade, the dramatic decline in research and development focused on novel treatment options for hypertension, coupled with an alarming increase in global obesity rates, has led to a very high unmet need for novel approaches to blood pressure management. Recent draft guidance from the U.S. Food and Drug Administration highlights this unmet need and describes a streamlined regulatory path for novel drugs to treat resistant hypertension without the need for large outcomes studies.[1] Based on data seen to date, we believe targeting elevated aldosterone levels in patients with hypertension who are not adequately controlled on a background of multiple antihypertensive drugs represents a promising new approach. We are excited to have the opportunity to advance PB6440 as part of our growing portfolio of novel cardiovascular therapies."

About PB6440

PB6440 is a highly selective aldosterone synthase inhibitor being developed for treatment-resistant hypertension. PB6440 modulates the renin-angiotensin-aldosterone system, which plays a critical role in regulation of systemic blood pressure. Despite the broad range of currently available antihypertensive therapies, approximately 10 million, or 20%, of drug-treated U.S. hypertension patients have not achieved target blood-pressure lowering while on three or more antihypertensive medications.[2] These patients with treatment-resistant hypertension are at a significantly greater risk for major adverse cardiovascular events, including heart attack, stroke, and heart failure, as well as peripheral artery disease and kidney failure.[3]

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 for the treatment of resistant hypertension. PhaseBio's proprietary elastin-like polypeptide ("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 preclinical studies and clinical trials, timelines for regulatory submissions and our research, development and regulatory plans for PB2452, PB1046, PB6440 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 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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1. U. S. Food and Drug Administration. Center for Drug Evaluation and Research. (2018) Hypertension: Conducting Studies of Drugs to Treat Patients on a Background of Multiple Antihypertensive Drugs Guidance for Industry. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/hypertension-conducting-studies-drugs-treat-patients-background-multiple-antihypertensive-drugs

2. Carey RM, Sakhuja S, Calhoun DA, Whelton PK, Muntner P. Prevalence of apparent treatment-resistant hypertension in the United States: comparison of the 2008 and 2018 American heart association scientific statements on resistant hypertension. Hypertension. 2019; 73: 424- 431.

3. Muntner P, Davis BR, Cushman WC, et al. Treatment-resistant hypertension and the incidence of cardiovascular disease and end-stage renal disease: results from the Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT) Hypertension. 2014;64:1012–1021.

Source: PhaseBio Pharmaceuticals, Inc.