Aerovate Therapeutics Announces Initiation of IMPAHCT Phase 2b/Phase 3 Trial of AV-101 In Pulmonary Arterial Hypertension

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WALTHAM, Mass., Dec. 15, 2021 (GLOBE NEWSWIRE) -- Aerovate Therapeutics, Inc. (Nasdaq: AVTE), a clinical-stage biopharmaceutical company focused on developing drugs that meaningfully improve the lives of patients with rare cardiopulmonary diseases, today announced the initiation of its **I**nhaled I**m**atinib **P**ulmonary **A**rterial **H**ypertension **C**linical **T**rial (IMPAHCT) Phase 2b/Phase 3 trial to evaluate the safety and efficacy of AV-101 (dry powder inhaled imatinib) in adult patients with Pulmonary Arterial Hypertension (PAH).

“There is a real need for new treatment options for PAH patients that work differently from our currently approved therapies,” said Dr. Nicholas Hill, Chief, Pulmonary, Critical Care and Sleep Division, Tufts Medical Center and Chair of the IMPAHCT clinical advisory board. “Imatinib has shown promise as a therapy for PAH and if AV-101 can deliver improvements for patients with fewer of the systemic adverse events associated with oral imatinib in PAH, it could represent a real advancement for patients.”

“We are excited and humbled to initiate this Phase 2b/Phase 3 trial of AV-101,” said Tim Noyes, Chief Executive Officer at Aerovate. “Starting enrollment represents an important milestone for Aerovate Therapeutics and advances our goal of improving the lives of patients suffering from rare cardiovascular diseases.”

Aerovate expects to report top-line results from the Phase 2b portion of IMPAHCT in mid-2023.

More information about this trial is available at https://clinicaltrials.gov/ct2/show/NCT05036135.

About the IMPAHCT Trial
IMPAHCT is a multi-national, placebo-controlled Phase 2b/Phase 3 trial in adults with pulmonary arterial hypertension (PAH) that will continuously enroll patients as the study progresses from Phase 2b to Phase 3. The Phase 2b portion of the trial will evaluate three doses of AV-101 compared to placebo to identify an optimal dose based on the primary endpoint, change in pulmonary vascular resistance (PVR) over 24 weeks versus placebo, and safety, tolerability, and other clinical measures. The Phase 3 portion of the trial will compare patients taking the optimal dose selected in Phase 2b of AV-101 with placebo. The primary endpoint of the Phase 3 portion of the trial will be change in 6-minute walk distance (6MWD) over 24 weeks versus placebo.

About Pulmonary Arterial Hypertension (PAH)
Pulmonary arterial hypertension (PAH) is a rare, progressive disease characterized by cellular hyperproliferation of the pulmonary vasculature that affects approximately 70,000 people in the United States and Europe. The disease process involves remodeling, constriction and occlusion of the small pulmonary arteries resulting in elevated blood pressure in the pulmonary circulation. PAH can cause strain on the heart, leading to limitation of physical activity, heart failure and reduced life expectancy. Existing vasodilator drugs fail to treat the underlying cellular proliferation causing the disease.

About AV-101
AV-101 is a proprietary dry powder inhaled formulation of the anti-proliferative drug imatinib. Dosed specifically for PAH, AV-101 is designed for delivery by an easy-to-use dry powder inhaler, directly into the lungs to maximize potential clinical benefit and limit systemic adverse effects. In a recent Phase 1 clinical trial, AV-101 was generally well-tolerated by healthy adult volunteers with no serious adverse events associated with AV-101.

About Aerovate Therapeutics, Inc.
Aerovate is a clinical stage biopharmaceutical company focused on developing drugs that meaningfully improve the lives of patients with rare cardiopulmonary diseases. Aerovate's initial focus is on advancing AV-101, its dry powder inhaled formulation of the drug imatinib for the treatment of PAH.

Cautionary Note Regarding Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements can be identified by words such as “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “future,” “goal,” “intend,” “look forward to,” “may,” “plan,” “potential,” “predict,” “project,” “potential,” seek,” “strategy,” “should,” “target,” “will,” “would” and similar expressions regarding future periods. These forward-looking statements include, but are not limited to, statements regarding the therapeutic potential of AV-101; our expectations regarding patient enrollment for the Phase 2b portion of our Phase 2b/Phase 3 trial of AV-101 in PAH; our business plans and objectives for AV-101, including expectations regarding timing and success of the our Phase 2b/Phase 3 clinical trial, including the timing of top-line results, the therapeutic potential and clinical benefits of AV-101 and potential regulatory submissions and approvals for AV-101; and our growth and goals as a company.

Any forward-looking statements in this press release are based on management’s current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, those risks and uncertainties related to the therapeutic potential of AV-101, and the timing associated with patient recruitment, initiation and continuation of our Phase 2b/Phase 3 trial of AV-101 in PAH patients and timing of top-line results, the impact of the COVID-19 pandemic on our business, clinical trials, operations and goals, positive results from a clinical study may not necessarily be predictive of the results of future or ongoing clinical studies, regulatory developments in the United States and foreign countries, and other risks identified in our filings with the Securities and Exchange Commission (“SEC”), including our Registration Statement on Form S-1, and subsequent filings with the SEC. We caution you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. We disclaim any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set

forth in the forward-looking statements. Any forward-looking statements contained in this press release represent our views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date.

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