Aerovate Therapeutics to Present Patient Baseline Characteristics of the Phase 2b Portion of the Phase 2b/Phase 3 IMPAHCT Trial at the American Thoracic Society 2024 International Conference

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WALTHAM, Mass., March 27, 2024 (GLOBE NEWSWIRE) -- Aerovate Therapeutics, Inc. (Nasdaq: AVTE), a clinical stage biopharmaceutical company focused on developing drugs that improve the lives of patients with rare cardiopulmonary disease, today announced an upcoming poster presentation at the 2024 American Thoracic Society (ATS) International Conference taking place May 17-22, 2024, in San Diego, CA. The presentation will provide baseline characteristics from patients enrolled in the dose-ranging Phase 2b portion of the **I**nhaled i**M**atinib **P**ulmonary **A**rterial **H**ypertension **C**linical **T**rial (IMPAHCT), a Phase 2b/Phase 3, randomized, double-blind, placebo-controlled, multi-national trial evaluating the safety and efficacy of AV-101 in adults with pulmonary arterial hypertension.

“We look forward to presenting baseline characteristics of the Phase 2b portion of the IMPAHCT trial in our poster presentation at the upcoming ATS conference in May,” said Tim Noyes, Chief Executive Officer at Aerovate Therapeutics. “These data will provide insight into the IMPAHCT patient population as we continue Phase 3 trial recruitment globally and expect to present top line Phase 2b data in June.”

Details for the poster presentation are as follows:

Poster Session: C62. Top Gun: Novel Therapeutics And Outcomes In Pulmonary Arterial Hypertension
Date: Tuesday, May 21, 2024
Presentation Time: 11:30 a.m. – 1:15 p.m. PT
Location: Session Room TDP29
Abstract: Baseline characteristics from the IMPAHCT trial of AV-101, inhaled imatinib, in subjects with pulmonary arterial hypertension
Presenter: Hunter Gillies, MBChB

The poster abstract is available now on the 2024 ATS website. The abstract includes data from 147 patients, and the poster presentation on May 21st will include baseline characteristics for all 202 Phase 2b patients.

About AV-101
AV-101 is an investigational, proprietary dry powder inhaled formulation of the antiproliferative drug imatinib. Developed specifically for pulmonary arterial hypertension (PAH), AV-101 targets cellular hyperproliferation and resistance to apoptosis, driven by improper signaling in cells of the distal pulmonary arteries. By targeting the proliferation and accumulation of cells in the arteries of the lungs, we believe AV-101 has the potential to provide meaningful improvements for patients beyond the capabilities of currently approved therapies. 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. Phase 1 results published in *ERJ Open Research* showed that AV-101 delivered by dry powder inhalation was generally well-tolerated by healthy adult volunteers with no serious adverse events reported. Aerovate has completed enrollment in the Phase 2b portion of the IMPAHCT clinical trial and is currently enrolling patients in the Phase 3 portion to evaluate the safety and efficacy of AV-101 in adults with PAH.

About the IMPAHCT Trial
IMPAHCT (Inhaled iMatinib Pulmonary Arterial Hypertension Clinical Trial) is a multi-national, placebo-controlled Phase 2b/Phase 3 trial in adults with PAH that continuously enrolled patients from Phase 2b to Phase 3. The Phase 2b portion of the trial will evaluate three doses of AV-101 over 24 weeks, compared to placebo, to identify an optimal dose based on the primary endpoint, change in pulmonary vascular resistance (PVR), and safety, tolerability, and other clinical measures. The Phase 3 portion of the trial will compare patients taking the optimal dose of AV-101, selected from the Phase 2b data to placebo. The primary endpoint of the Phase 3 portion of the trial will be change in six-minute walk distance (6MWD) over 24 weeks versus placebo. More information about this trial is available at https://clinicaltrials.gov/ct2/show/NCT05036135.

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 disease. Aerovate's initial focus is on advancing AV-101, its proprietary dry powder inhaled formulation of the drug imatinib for the treatment of patients with PAH. Learn more at aerovatetx.com or follow the Company on X (formerly known as Twitter) and LinkedIn.

Available Information
Aerovate announces material information to the public about the Company, its products and services, and other matters through a variety of means, including filings with the U.S. Securities and Exchange Commission (SEC), press releases, public conference calls, webcasts, the investor relations section of the Company website at ir.aerovatetx.com, and the Company’s X (formerly known as Twitter) account @AerovateTx in order to achieve broad, non-exclusionary distribution of information to the public and for complying with its disclosure obligations under Regulation FD.

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,” 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 baseline patient characteristics from the Phase 2b portion of the IMPAHCT trial; our expectations regarding continuing patient enrollment for the Phase 3 portion of the IMPAHCT trial; and our anticipated timing for the release of topline data from the Phase 2b portion of our clinical trial.

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 and clinical benefits of AV-101; the timing associated with the identification and activation of clinical sites, patient enrollment, initiation, delivery of drug supply and continuation of our Phase 2b/Phase 3 trial of AV-101 in PAH patients; the impact of public health crises 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; as well as those risks and uncertainties set forth more fully under the caption “Risk Factors” in our most recent Annual Report on Form 10-K filed with the SEC 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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