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Aerami Therapeutics Announces Pharmacokinetic Data Demonstrating the Potential of AER-901 (Inhaled Imatinib) to Achieve Therapeutic Levels at Low Inhaled Doses for Treatment of Pulmonary Hypertension

DURHAM, N.C., May 24, 2023 (GLOBE NEWSWIRE) -- Aerami Therapeutics ("Aerami"), a clinical stage biopharmaceutical company dedicated to breathing life into the treatment of serious and rare cardiopulmonary conditions, today announced results from studies of AER-901 (inhaled imatinib) that support progression into a Phase 2 clinical trial in both pulmonary hypertension associated with interstitial lung disease (PH-ILD) and pulmonary arterial hypertension (PAH).

The data, presented at the 2023 American Thoracic Society (ATS) International Conference, included nonclinical pharmacokinetic (PK) findings in rats receiving a single dose of oral imatinib mesylate or pulmonary administration of AER-901. In addition, preliminary safety findings from the completed AER-901 Phase 1 clinical trial (NCT04903730) were presented.

Key findings included:

- **Lung exposure was nearly 10-fold higher with pulmonary administration of AER-901 compared with equivalent doses of oral imatinib:** By targeting the lung, the data from the nonclinical study suggest that the effective dose of AER-901 is potentially 10-fold lower than the 200 to 400 mg oral imatinib doses previously studied in pulmonary hypertension.
- **The completed Phase 1 trial evaluated the safety, tolerability, and PK of low inhaled doses of AER-901 vs placebo in more than 80 participants:** The randomized, double-blind, placebo-controlled, dose escalation trial included single and multiple ascending dose studies and evaluated doses from 5 mg to 80 mg.
- **AER-901 demonstrated a predominantly mild and transient adverse event profile consistent with inhalation products:** Safety and tolerability findings from the completed Phase 1 study in healthy volunteers demonstrated that AER-901 was generally well-tolerated with a mild and transient treatment-emergent adverse event profile after single and multiple doses. The most frequent adverse events, such as cough and throat irritation, were consistent with inhaled products.

AER-901 is in development to address critical unmet medical need for people with two serious and rare forms of pulmonary hypertension – PAH and PH-ILD. Pulmonary

hypertension is a serious complication of ILD for more than 80,000 people in the U.S. and Europe. Only one treatment for PH-ILD is currently approved by the United States Food and Drug Administration (FDA), but estimated survival remains less than 5 years.

PAH, which disproportionately impacts women and frequently during the middle part of their lives, is a rare and progressive disease that affects approximately 70,000 patients in the U.S. and Europe. Despite advances in therapy, there is no cure for PAH and median survival remains approximately 5-7 years.

“These important data presented at ATS and the full results of Aerami’s completed Phase 1 of AER-901 study mark significant steps forward in the development of AER-901 with the ultimate goal of addressing the critical unmet medical need for patients with PH-ILD and PAH,” said Anne Whitaker, Executive Chairwoman of the Board of Directors at Aerami. “The positive results strongly support our path forward into Phase 2.”

Aerami plans to update the open Investigational New Drug (IND) application with the FDA to initiate a Phase 2 proof-of-concept clinical trial that will enroll patients with either PAH or PH-ILD in mid-2023. Full results for the Phase 1 study in healthy volunteers will be presented at a future meeting.

About AER-901
AER-901 is a drug-device combination that is designed to deliver potentially reverse-remodeling imatinib therapy deeply and efficiently throughout the diseased tissue of the lung. AER-901 is delivered via a high-performance, handheld, smart nebulizer that controls flow rate and provides patients with real-time feedback to help optimize lung deposition of imatinib. AER-901 is being developed for patients with PH and PH-ILD, two areas with high unmet medical need for improved treatment options.

About Pulmonary Arterial Hypertension (PAH)
PAH (World Health Organization [WHO] Group 1 PH) is a rare and progressive form of pulmonary hypertension characterized by high blood pressure in the arteries of the lungs due to their narrowing or a blockage. PAH, which disproportionately impacts women and frequently during the middle part of their lives, affects approximately 70,000 patients in the United States and Europe. Pulmonary vascular remodeling leads to narrowing and obstruction of small pulmonary arteries resulting in increased pulmonary arterial pressure, which requires the heart to work harder as it pumps blood through the lungs, eventually leading to right heart failure and, ultimately, death. Currently approved therapies primarily mediate vasodilation, and despite advances in therapy, median survival remains approximately 5-7 years.

About Pulmonary Hypertension Associated with Interstitial Lung Disease (PH-ILD)
Interstitial lung disease (ILD) is an umbrella term for a number of conditions that cause inflammation and scarring (fibrosis) of the lung tissue. Pulmonary hypertension is a serious complication of ILD for more than 80,000 patients in the U.S. and Europe. Like PAH, PH-ILD is a serious condition characterized by high blood pressure in the arteries of the lungs. Similarly, pulmonary vascular remodeling, associated with proliferation, fibrosis, and inflammation, is believed to play an important role in PH-ILD development and progression. There is only one FDA-approved treatment for PH-ILD and estimated survival is less than 5 years.

About Aerami Therapeutics
Aerami is a clinical stage biopharmaceutical company dedicated to breathing life into the treatment of serious and rare cardiopulmonary conditions. Aerami's mission-driven approach to product development seeks to help patients live longer and live better by combining precision medicines and advanced administration platforms to support ease-of-use and quality-of-life.

This press release contains "forward-looking statements" concerning the development and commercialization of Aerami's product candidates, timing of clinical trials, the company's business development efforts and its expectations regarding its prospects, including, but not limited to, the timing and outcome of current and planned clinical trials. Forward-looking statements are subject to risks, assumptions and uncertainties that could cause actual future events or results to differ materially from such statements, including, but not limited to, uncertainties associated with the clinical development process, including, among other things, the timing, expense, and results of clinical trials and regulatory processes, the company's ability to financially support its drug-device product candidate clinical development programs, and the timing and outcome of the company's anticipated interactions with regulatory authorities. These statements are made as of the date of this press release. Actual results may vary. Aerami undertakes no obligation to update any forward-looking statements for any reason.

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