FOR IMMEDIATE RELEASE
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Altesa BioSciences Enrolls First Patient in Phase 2b CARDINAL Clinical Trial Evaluating Vapendavir as Transformational Treatment for Patients with COPD Impacted by Rhinovirus, the Leading Cause of Exacerbations

Study objective is to demonstrate that treatment with vapendavir can mitigate or prevent worsening of respiratory symptoms caused by rhinovirus that often lead to increased need for medical interventions

Atlanta, GA – Altesa BioSciences, a clinical-stage pharmaceutical company dedicated to improving the lives of people with chronic lung diseases including COPD and asthma, today announced the enrollment of the first patient in its Phase 2b CARDINAL multinational trial. The trial is designed to demonstrate that treatment of rhinovirus respiratory infections with vapendavir can improve upper and lower airway symptoms, reduce illness duration, and better maintain small airways lung function compared to placebo.

“CARDINAL is designed to answer a fundamental question in COPD care: can directly targeting rhinovirus change the trajectory of the disease, including exacerbations? Enrolling our first patient brings us meaningfully closer to that answer—and to a potential new option for patients who urgently need one,” said Dr. Katharine Knobil, Chief Medical Officer of Altesa BioSciences and former Chief Medical Officer of GSK. “Launching this trial just over ten weeks after closing our Series B financing is a testament to our team’s preparation and expertise and also reflects our urgency to deliver better outcomes for patients.”

The CARDINAL clinical trial is a randomized placebo-controlled study in COPD patients experiencing rhinovirus infections that will enroll 900 people with COPD in the US and UK. The trial is specifically designed to reflect real-world care models, proactively identifying and supporting those at greatest risk. Participants will be closely monitored over time and, upon development of rhinovirus infection, will be randomized to receive one of two doses of vapendavir or placebo. The trial’s primary objective is to assess improvement in respiratory symptoms using established patient-reported outcomes, with additional endpoints evaluating time to symptom resolution, quality of life, healthcare resource utilization, and lung function as well as to identify a dose for future study in Phase 3.

"Rhinovirus is responsible for roughly half of all acute COPD exacerbations, yet today, the ability to target this underlying cause falls short," said Dr. Knobil. “Care has largely focused on managing symptoms after the inflammatory cascade has already begun—vapendavir was developed to directly target rhinovirus to interrupt this cycle earlier. This transformational, disruptive approach to the treatment status quo represents an opportunity to provide a better approach for respiratory infections in vulnerable patients who want and need better options."

Dr. Knobil is leading the Phase 2b CARDINAL study, which builds on Altesa’s recently completed rhinovirus Phase 2a Challenge Study in COPD patients. The Challenge study data demonstrated vapendavir improved upper and lower airway symptoms, reduced illness duration and better maintained small airway lung function compared to placebo.

About Vapendavir

Vapendavir, taken orally in pill form, is a broad-spectrum, antiviral, investigational drug—preventing the virus from both entering human cells as well as reproducing. It exhibits potent clinical activity across all three types of rhinoviruses, including RV-C, and other respiratory enteroviruses. While the immediate focus is on evaluating vapendavir as a treatment for patients with COPD, vapendavir has potential for broader application in other high-risk respiratory populations, including people with asthma and other chronic lung diseases.

About the CARDINAL Study

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About Altesa BioSciences, Inc.

Altesa BioSciences is a clinical-stage pharmaceutical company led by global experts in respiratory medicine and infectious diseases. We are dedicated to improving the lives of people with chronic lung diseases like COPD and asthma, by treating the principal cause of exacerbations and pathological inflammation–viral respiratory infections. ***www.altesa.com***

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