



Apnimed Announces First Patient Dosed in LunAIrO, the First Phase 3 Clinical Study of AD109, a Potential Nighttime Oral Treatment for Obstructive Sleep Apnea

September 21, 2023

– LunAIrO Compares AD109 to Placebo Over 6 and 12 Months in People with OSA who Are Intolerant of or Refuse Positive Airway Pressure (PAP) Therapy, the Current Standard of Care

– Second registrational Phase 3 study, SynAIRgy, to begin enrollment in 4th quarter

CAMBRIDGE, Mass. September 19, 2023 – Apnimed, Inc., a clinical-stage pharmaceutical company focused on developing oral pharmacologic therapies for the treatment of obstructive sleep apnea (OSA) and related disorders, today announced the first patient dosed in its LunAIrO Phase 3 study designed to examine the efficacy and safety of AD109 (aroxybutynin/atomoxetine) compared to placebo at six-months and one year. AD109 has the potential to be the first nighttime oral pharmacologic treatment for people with OSA who are either intolerant of or refuse to use positive airway pressure (PAP) therapy.

“There is an urgent need for new treatment options for people with OSA, particularly those who cannot tolerate currently available therapies,” said Sanjay Patel, M.D., primary investigator in the LunAIrO clinical study and Director, UPMC Comprehensive Sleep Disorders Clinical Program in Pittsburgh, Pennsylvania. “It’s vital to discover and test alternative treatments for people with OSA to potentially help improve their quality of life both at night and during the day. Based on the results, AD109 has the potential to be a major game changer in how we treat OSA.”

Currently, fewer than half of the people using PAP therapy are compliant long-term, leaving many people at risk from the consequences of untreated OSA, including a higher risk for stroke and heart attack.

“LunAIrO and SynAIRgy, our second registrational study expected to begin enrollment in the fourth quarter, represent the largest ever prospective evaluations of a novel pharmacologic for OSA,” said Larry Miller, M.D., Chief Executive Officer of Apnimed.

“These trials are a major step in developing a potential treatment that meets the needs of patients who have limited or no other options. Topline results are expected by early 2025, and with positive results, we anticipate submitting our new drug application to the FDA in the second half of 2025.”

About the LunAIrO study

The LunAIrO Study (clinicaltrials.gov identifier [NCT05811247](#)) is a randomized, double blind, placebo-controlled, parallel-arm 1-year study of a fixed dose combination of aroxybutynin/atomoxetine (AD109) in participants with OSA who are intolerant of or currently refuse positive airway pressure (PAP) therapy. Participants (n=640) will be randomized 1:1 to either AD109 or placebo. The primary endpoint is designed to show that AD109 is safe and superior to placebo in reduction of airway obstructions (AHI4). A key secondary endpoint is determining whether AD109 is superior to placebo for OSA symptoms based on the PROMIS-Fatigue scale. Other standard objective and subjective metrics of OSA will also be evaluated. The trial will include up to 65 enrolling centers across the US.

About AD109

AD109 has the potential to be the first oral pharmacologic that could both treat the underlying nighttime airway obstruction and hypoxia that characterize OSA, as well as improve the daytime consequences of OSA, such as fatigue. It is a first-in-class, novel, investigational combination dosed once daily at bedtime and is designed to treat OSA patients across a broad spectrum of disease severity. AD109 combines Apnimed’s novel selective antimuscarinic (aroxybutynin) with a selective norepinephrine reuptake inhibitor (atomoxetine). AD109 targets key neurological pathways in OSA that activate upper airway dilator muscles to maintain an open airway during sleep. AD109 has the potential to become a safe, effective, and convenient treatment for OSA, addressing some of the key limitations of current standard of care treatments that can be poorly tolerated (e.g., CPAP and oral devices) and/or invasive (e.g., surgery or implanted devices).

AD109 has been granted Fast Track designation by the FDA and is currently in Phase 3..

About Obstructive Sleep Apnea

Obstructive Sleep Apnea is one of the most common and serious sleep disorders. It is estimated to affect more than 45 million Americans, though underdiagnosis continues to be a serious problem and the number of affected Americans may be far greater. OSA is characterized by partial or complete upper airway closure that occurs during sleep, which can cause dramatic reductions in overnight oxygen saturation and often leads to poor sleep, and in the long term, has been shown to exacerbate hypertension, diabetes, cardiovascular disease, and stroke. Additionally, OSA can impair work productivity, reduce daytime functional abilities,

and lower quality of life. Sleep-related muscular relaxation driven by the central nervous system is the key neurologic mechanism that causes OSA. In patients with OSA, a reduction in neuromuscular control of the upper airway during sleep leads to a corresponding relaxation of the upper airway dilator muscles. The vast majority of diagnosed patients are prescribed positive air pressure therapy devices such as continuous positive airway pressure, or CPAP, but many patients are dissatisfied with these mechanical nighttime devices and fewer than half are compliant long term, leaving a significant population untreated, undertreated and at risk.

About Apnimed

Apnimed is a clinical-stage pharmaceutical company working to transform the treatment of sleep apnea based on a simple idea – patients with obstructive sleep apnea could benefit from treatment with a safe and effective oral medication dosed once daily at bedtime. Apnimed's lead development program targets the neurologic control of upper airway muscles to maintain an open airway during sleep. Based in Cambridge, Mass., the company is developing a portfolio of novel pharmacologic therapies for sleep apnea and related disorders. Learn more at apnimed.com or follow us on [X](#) and [LinkedIn](#).

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