



Apnimed Announces Early Completion of Enrollment in Phase 3 SynAIRgy Study of AD109, the First Potential Oral Treatment Addressing the Neuromuscular Cause of Obstructive Sleep Apnea

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– The Milestone Marks the Completion of Patient Enrollment for All Phase 3 Studies for AD109, Which Include a Total of More Than 1,300 Participants

– Topline Phase 3 Data Expected in Mid-2025

CAMBRIDGE, Mass., September 19, 2024 – Apnimed, Inc., a pharmaceutical company focused on discovery, development, and commercialization of first-in-class oral therapies that address the neuromuscular dysfunction of obstructive sleep apnea (OSA) and other sleep-related breathing diseases, today announced the early completion of enrollment in its SynAIRgy Phase 3 Study. SynAIRgy is designed to examine the efficacy and safety of Apnimed's lead candidate AD109 (aroxybutynin/atomoxetine) compared to placebo at six months in adults living with mild, moderate and severe OSA.

Earlier this year, Apnimed also completed enrollment for its LunAIRo Phase 3 Study examining AD109 in OSA. Topline Phase 3 data for both the SynAIRgy and LunAIRo studies are expected in mid-2025.

AD109 has the potential to become the first pharmacological treatment to improve oxygenation during sleep by directly addressing the underlying neuromuscular cause of upper airway collapse in people with OSA.

"We believe the strong interest we have seen throughout the SynAIRgy Study is telling of the sleep community's desire for new treatment options," said Patrick Stollo, Jr, MD, Chairman of the SynAIRgy clinical study and Vice Chair of Medicine for Veterans Affairs at the University of Pittsburgh School of Medicine. "Millions of people living with OSA refuse, abandon, or are dissatisfied with their current treatment, and this Phase 3 trial offers them new hope."

OSA is a serious chronic sleep-related breathing disease, affecting more than 54 million people in the United States and nearly one billion worldwide. OSA is caused by two overlapping mechanisms: neuromuscular dysfunction and predisposing anatomic abnormalities. Failure to effectively treat OSA can impair daily function and increase one's risk for serious comorbidities like hypertension, diabetes, cardiovascular disease, and stroke. Yet, among the millions diagnosed, the majority of people with OSA refuse, abandon or underutilize existing treatment, underscoring the need for additional treatment options.

"We are deeply grateful to the patients who have chosen to participate in our Phase 3 studies. Their commitment brings us one step closer to a potential breakthrough in the treatment of OSA," said Larry Miller, CEO, Apnimed. "We believe that AD109 has the potential to become the first oral therapy to address the neuromuscular cause of OSA, which could redefine the standard of care and offer a new, simpler solution for millions of people living with this disease."

The SynAIRgy Study garnered strong attention with over 25,000 people expressing interest in trial participation. Apnimed's robust site selection process across the U.S. and Canada at centers of excellence and academic institutions facilitated diverse enrollment by race, gender, and location in 73 trial sites across both countries. To ensure diverse representation in its trials, Apnimed leveraged a variety of grassroots initiatives and engaged directly with patient advocacy groups and representatives of minority communities.

"There are millions of people living with OSA in the U.S. alone, myself included, yet current treatment options are limited," said Emma Cooksey, patient advocate and Sleep Apnea Program Manager at Project Sleep. "It is incredibly encouraging to see innovations like AD109 on the horizon with the potential to offer the OSA community a novel treatment option."

About the SynAIRgy Study

The SynAIRgy Study (clinicaltrials.gov identifier [NCT05813275](https://clinicaltrials.gov/ct2/show/study/NCT05813275)) is a randomized, double blind, placebo-controlled, parallel-arm 6-month study of a fixed dose combination of aroxybutynin/atomoxetine (AD109) in participants with OSA who are intolerant of or currently refuse continuous positive airway pressure (CPAP) therapy. Participants (n=646) had been randomized 1:1 to either AD109 or placebo, and instructed to take their assigned treatment nightly before bed. The primary endpoint is designed to evaluate AD109 compared to placebo in reduction of airway obstructions (AHI4). A key secondary endpoint is to evaluate AD109 compared 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 enrolled adult participants from 73 centers across the U.S. and Canada.

About AD109

AD109 could be the first pharmacological treatment to improve oxygenation during sleep by directly addressing the underlying

neuromuscular cause of upper airway collapse in people with obstructive sleep apnea. It is a first-in-class combination of aroxybutynin, a novel antimuscarinic, and atomoxetine, a selective noradrenaline reuptake inhibitor (NRI). Their combined pharmacological synergy targets the root neuromuscular cause of OSA. AD109 is a once-nightly oral pill that is designed to lower the complexity of intervention and may help more people benefit from effective, restorative sleep. In a disease characterized by complex and invasive treatment options, AD109 may be a simple solution to help improve oxygenation and health wellbeing for people living with OSA.

About Obstructive Sleep Apnea

Obstructive sleep apnea is a serious chronic sleep-related breathing disease where the upper airway repeatedly collapses during sleep, causing intermittent oxygen deprivation. It is caused by two overlapping mechanisms: neuromuscular dysfunction during sleep and predisposing anatomic abnormalities. The impact of OSA spans age, sex, and body type—there is no single face of the disease. Every night, greater than 54 million people in the U.S. and 1 billion people worldwide with OSA stop breathing, exposing them to serious, long-term health risks. An individual with OSA can experience hundreds of sleep apnea events in a single night. Each sleep apnea event reduces blood oxygen levels and deprives cells of the energy they need to perform vital functions. Ultimately, failure to effectively treat OSA increases the risk of long-term health consequences and quality of life impacts, including daytime fatigue, impaired judgement, premature death, and severe and potentially life-threatening health complications, such as high blood pressure, cardiovascular disease, and type 2 diabetes. Yet, even after being diagnosed, the majority of people with OSA either refuse, abandon, or underutilize treatment. In addition, no currently available treatments address the underlying neuromuscular dysfunction present in all OSA cases.

About Apnimed

Apnimed is a pharmaceutical company dedicated to breathing new life into the sleep-related breathing disease treatment landscape. The company envisions a new era where novel oral therapies simplify intervention, expand the reach of diagnosis and treatment, and elevate the health and expectations of everyone in the sleep-related breathing disease community. Based in Cambridge, Mass., Apnimed is advancing a focused pipeline of oral pharmaceutical product candidates designed to help improve oxygenation for people living with obstructive sleep apnea and beyond, to other sleep-related breathing diseases, including several that are part of our joint venture with Shionogi & Co., Ltd, Shionogi Apnimed Sleep Science (SASS). Learn more at apnimed.com or follow us on [X](#) and [LinkedIn](#).

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