Apnimed Announces FDA Acceptance of New Drug Application for AD109, An Investigational Oral Pill to Treat Adults with Obstructive Sleep Apnea

July 14, 2026

- *The FDA assigned a PDUFA target action date of February 28, 2027*
- *If approved, AD109 has the potential to become the first oral pharmacologic therapy designed to address the neuromuscular root cause of upper airway collapse for the millions of people living with OSA*

CAMBRIDGE, Mass., July 14, 2026 – Apnimed, Inc., a late stage clinical pharmaceutical company dedicated to the discovery, development, and commercialization of novel oral therapies that address the neurobiology of sleep-related breathing diseases, today announced that the U.S. Food and Drug Administration ("FDA") has accepted for review the New Drug Application ("NDA") filing of AD109 (aroxybutynin 2.3 mg/atomoxetine 75 mg) for the treatment of adults with obstructive sleep apnea ("OSA"). The FDA has assigned a Prescription Drug User Fee Act ("PDUFA") target action date of February 28 , 2027.

"The FDA acceptance of our NDA is an important milestone for Apnimed as we advance toward our goal of expanding treatment options for people with OSA who continue to need more accessible solutions," said Kevin Lind, Chief Executive Officer of Apnimed. "The NDA is supported by a clinical data package that reflects years of scientific innovation focused on a major unmet need. We believe AD109 has the potential to offer an important new treatment option for adults with OSA, if approved, and we look forward to engaging with the FDA during its review."

The NDA submission is supported by data from Apnimed's Phase 3 clinical program, including the SynAIRgy and LunAIRo randomized, double-blind, placebo-controlled trials evaluating AD109 in adults with mild, moderate, and severe OSA. Across both trials, AD109 demonstrated statistically significant reductions in apnea-hypopnea index (AHI), along with improvements in oxygenation metrics, including hypoxic burden and oxygen desaturation index. AD109 was generally well-tolerated in its Phase 3 clinical program, and the most common adverse events were dry mouth, insomnia and nausea, which were consistent with earlier AD109 clinical trials.

About AD109
AD109 is investigational and is designed to be the first potential pharmacological treatment to improve oxygenation during sleep and target the neuromuscular root cause of upper airway collapse in people with OSA. It is a potentially first-in-class combination of aroxybutynin, a novel antimuscarinic, and atomoxetine, a selective norepinephrine reuptake inhibitor. AD109 is a once-daily oral pill taken at bedtime that is designed to lower the complexity of intervention and may help more people benefit from effective, restorative sleep. In a disease treatment landscape characterized by complex and invasive treatment options, AD109, if approved, may offer a convenient oral solution to help improve oxygenation and health for people living with OSA.

About Obstructive Sleep Apnea
OSA is a serious, chronic sleep-related breathing disease in which the upper airway repeatedly collapses during sleep, leading to intermittent oxygen deprivation. It is caused by two overlapping mechanisms: neuromuscular dysfunction during sleep and predisposing anatomic abnormalities. OSA affects individuals across all walks of life, impacting both males and females of all age groups, ethnicities, and weight classes, including those with or without obesity. An estimated 80 million people in the United States and one billion people worldwide suffer from OSA.

An individual with OSA can experience hundreds of sleep apnea events in a single night, each one reducing the blood oxygen levels and negatively impacting cellular functions vital to normal health and function. Failure to effectively treat OSA increases the risk of serious long-term health consequences, including cardiovascular, neurocognitive and cardiometabolic damage and heightened mortality. Yet, many patients diagnosed with OSA remain untreated.

About Apnimed
Apnimed is a privately held late stage clinical pharmaceutical company dedicated to the discovery, development and commercialization of novel oral therapies that address the neurobiology of sleep-related breathing diseases. We believe the introduction of once-nightly oral drugs has the potential to expand diagnosis and the reach of treatment for people with OSA. We believe that people with OSA would benefit from having multiple drugs with differing mechanisms to more fully address the heterogeneity of OSA's disease pathophysiology. Apnimed envisions a new era where novel oral therapies simplify intervention, expand the reach of diagnosis and treatment, and help more people get the oxygen and restorative sleep needed to thrive.

Based in Cambridge, Massachusetts, Apnimed is advancing its product candidate, AD109, designed to improve oxygenation in individuals living with OSA. We believe that AD109 could become the catalyst for a new oral treatment paradigm for OSA that has been historically limited to cumbersome devices or invasive surgeries. AD109 has completed two Phase 3 clinical trials for the treatment of mild, moderate and severe OSA. Apnimed's NDA for AD109 was assigned a PDUFA target action date of February 28, 2027. There can be no assurances that AD109 will be approved by the PDUFA target action date, or at all.

Learn more at apnimed.com or follow us on X and LinkedIn.

Media Contact:
media@apnimed.com

Investor Contact:
ir@apnimed.com