



Apnimed to Present Positive Phase 2b Results on AD109, an Investigational Oral Treatment for Obstructive Sleep Apnea, at ATS 2023

May 15, 2023

– New MARIPOSA Data Showing AD109 Had Statistically Significant Improvement in Both Objective and Subjective Outcomes to Be Featured as an Oral Presentation in the Breaking News in OSA: New Approaches and New Trials Mini Symposium

– Data Supporting Use of Specific Patient-Reported Outcomes in Future Phase 3 Clinical Studies Will Also Be Presented

CAMBRIDGE, Mass. May 15, 2023 – Apnimed, a clinical-stage pharmaceutical company focused on developing oral pharmacologic therapies for the treatment of obstructive sleep apnea (OSA) and related disorders, announced that data from the MARIPOSA Phase 2b trial, an efficacy, safety and dose-finding study of one-month duration, will be featured in both an oral presentation and a poster presentation at The American Thoracic Society's ATS 2023 International Conference in Washington, DC.

"ATS 2023 will be our first opportunity to present data from MARIPOSA, a study that found patients treated with the company's lead candidate for OSA, AD109 (aroxybutynin + atomoxetine), had a statistically significant reduction in Apnea-Hypopnea Index (AHI) scores, improved daytime symptoms caused by OSA and was well-tolerated," said Larry Miller, M.D., Chief Executive Officer of Apnimed. "These data support the dose and endpoint selection we have discussed with the U.S. Food and Drug Administration (FDA) for our Phase 3 studies scheduled to start in the second half of 2023."

PRESENTATION DETAILS

Oral: [Abstract 6336](#)

Title: The Oral Agent AD109 Improves Objective and Subjective Outcomes in Obstructive Sleep Apnea Patients. Results from the MARIPOSA Study, a Randomized, Controlled Clinical Trial

Session: A18 – BREAKING NEWS IN OSA: NEW APPROACHES AND NEW TRIALS Mini Symposium

Time: Sunday, May 21, 10:00 – 10:12 AM ET

Location: Walter E. Washington Convention Center, Room 202 B (Level 2)

Presenter: Paula Schweitzer, Ph.D., Director of Research at St. Luke's Sleep Medicine and Research Center, Chesterfield, MO

Poster: [Abstract 8755](#)

Title: Comparison of Night-to-Night and Inter-scorer Variability of Different Indices of Obstructive Sleep Apnea Severity in the MARIPOSA Trial

Session: C110 – ADVANCED SIGNAL ANALYSIS: NEW DIAGNOSTICS AND PHYSIOLOGIC INSIGHTS, FOR SDB Poster Discussion Session

Time: Tuesday, May 23, 2:15 – 4:15 PM ET

Location: Walter E. Washington Convention Center, Room 144 A-C (Street Level)

Presenter: Huy Pho, Clinical Data Scientist, Apnimed

MARIPOSA Study Design

MARIPOSA was a randomized, double-blind, placebo-controlled dose-finding study of one-month duration. A total of 294 participants with a wide range of OSA severity, from mild to severe (AHI of 10-45), were enrolled at 25 sites across the United States. Participants were randomized to parallel arms comparing two doses of AD109, two doses of AD504 (a second candidate in an earlier phase of development), atomoxetine alone, and placebo. Enrollment was open both to treatment-naïve participants and to the substantial proportion of OSA patients who are unwilling or unable to tolerate treatment with positive airway pressure devices (e.g., CPAP), the current standard of care therapy for OSA.

MARIPOSA also incorporated other standard clinical endpoints designed to characterize improvement of oxygenation, sleep, and daytime function in OSA.

It is one of the largest clinical trials ever conducted of potential drug treatments designed to target the underlying cause of OSA.

About AD109

AD109 has the potential to be the first oral pharmacologic that both treats the underlying cause of OSA, airway obstruction at night, and improves daytime consequences of OSA, such as fatigue. It is a potential first-in-class, novel, investigational combination dosed once daily at bedtime, 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/or invasive (e.g., surgery or implanted devices).

AD109 has been granted Fast Track designation by the FDA.

About Obstructive Sleep Apnea

Obstructive Sleep Apnea is one of the most common and serious sleep disorders. It is estimated to affect more than 35 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 obstruction that occurs during sleep, which 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 [Twitter](#) and [LinkedIn](#).

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