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OSA Patients Need Treatment Options: ASAP on Potential New Oral Treatment

Apnimed's positive Phase 3 clinical trial results could mark a potentially transformative moment for sleep apnea patients

The Alliance of Sleep Apnea Partners welcomed Apnimed's May 19 announcement that its investigational once-daily oral medication, AD109, performed well in a Phase 3 clinical trial and noted that patients suffering from obstructive sleep apnea (OSA) need such innovation to lead to a range of effective treatment options.

Today's announcement represents a potentially transformative moment for the millions of Americans living with sleep apnea. For decades, patients have faced limited treatment options that many find difficult to tolerate or incorporate into their daily lives.

The possibility of an effective oral medication that targets the root cause of OSA could dramatically improve how this serious condition is managed.

Monica Mallampalli, PhD
President & CEO
Alliance of Sleep Apnea Partners

The Phase 3 SynAIRgy clinical trial results showed that AD109 achieved a mean reduction in patients' apnea-hypopnea index (AHI) of 55.6% from baseline. AHI is the average number of times a patient stops breathing (apnea) or has abnormally shallow breathing (hypopnea) in an hour. Slightly more than half of trial participants experienced a reduction in OSA disease severity category. Notably, 22.3% of participants reached complete disease control, defined as fewer than five breathing events per hour, Apnimed reported.

While we are encouraged by these results, we also recognize the importance of continued research and development of multiple treatment options. Sleep apnea is a complex condition that affects people differently. Our community needs a range of effective treatments to address the full spectrum of patient needs and preferences.

Monica Mallampalli, PhD
President & CEO
Alliance of Sleep Apnea Partners

ASAP will work closely with healthcare providers, insurers, and policymakers to ensure that, if approved by the Food and Drug Administration (FDA), this new treatment option will be accessible to all patients who could benefit from it.

Explore OSA Treatment Options

Read Apnimed's Release

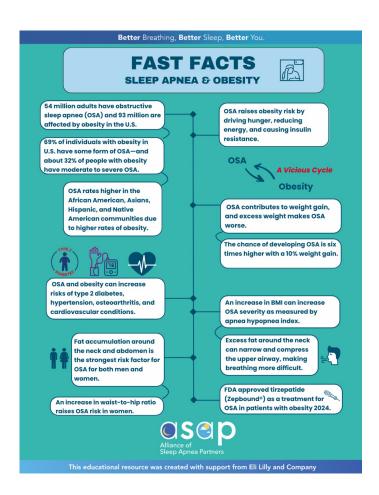
The Obesity-Sleep Apnea Connection

Obesity and obstructive sleep apnea often are intertwined: OSA can contribute to obesity, and excess weight makes OSA symptoms worse—creating a vicious cycle for the patient that can raise the risk for serious health complications like type 2 diabetes, cardiovascular conditions, and more.

It's important for patients to be aware of the link between OSA and obesity and understand its implications for their health. ASAP has created a group of resources to highlight this connection for at-risk patients—and make it easier to talk to your healthcare providers about steps to take to optimize your health and quality of life.

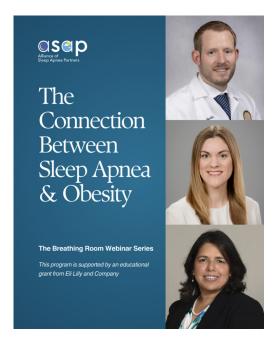
These educational resources were created with support from Eli Lilly and Company.

Download ASAP's Fast Facts on Sleep Apnea and Obesity



Learn more about how obstructive sleep apnea and obesity intersect—and the health implications—with our free, educational Fast Facts download at <u>apneapartners.org</u>.

What to Know About Sleep Apnea, Obesity, and Zepbound®



The Food and Drug Administration's approval of Zepbound (tirzepatide) for sleep apnea patients who also have obesity has provided patients with another treatment tool. That doesn't necessarily mean patients should stop using their CPAP devices.

As patients and healthcare providers navigate obesity, sleep apnea, and new therapy options, the landscape is still complex. In this videotaped discussion and accompanying blog post, UC San Diego sleep researcher and ASAP medical advisory team member Dr. Chris Schmickl and Obesity Action Coalition director Dr. Tracy Zvenyach joined ASAP's Dr. Monica Mallampalli to talk about what patients need to know.

Read the Blog Post

Watch the Video

Sleep Apnea and Obesity: It's Important to Treat Both

The link between OSA and obesity is clear and impactful, with each condition making the other worse. The good news? Taking steps to address your weight can not only ease the symptoms of OSA but also lead to better overall health and well-being.

Guest blogger Dr. Maria Guzman—a triple board-certified internal medicine, sleep medicine, and obesity medicine physician—discusses how obesity increases the risk of obstructive sleep apnea and can make it more severe.

She also discusses treatment approaches for OSA and obesity—and why addressing both conditions ins essential.

Would you like to share your own sleep apnea experience with other patients in the sleep apnea community? Submit your story to info@apneapartners.org.



POLICY NOTES

FDA Cautions Against Using Unapproved Compounded Tirzepatide (Zepbound®)



The Food and Drug Administration has raised concerns about patients taking unapproved versions of popular GLP-1 weight-loss drugs, such as tirzepatide, noting that these "copycat" versions known as compounded drugs "do not undergo FDA's review for

safety, effectiveness, and quality before they are marketed."

The statement on FDA's website also revealed that the federal agency has received

- 480 reports of adverse events associated with compounded versions of tirzepatide
- 520 associated with compounded semaglutide.

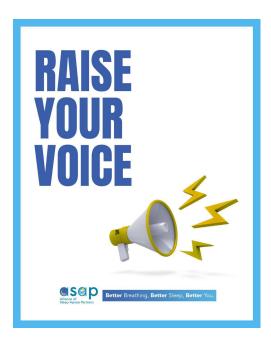
Last year the FDA has approved tirzepatide, manufactured by Eli Lilly and Company and sold under the name Zepbound, for the treatment of sleep apnea in patients who also have obesity. Last year, the FDA temporarily allowed the sale of compounded versions to combat a shortage, but it has since declared an end to the shortage, requiring compounding these medications to end.

"A compounded drug might be appropriate if a patient's medical need cannot be met by an FDA-approved drug or the FDA-approved drug is not commercially available," the FDA said. "However, compounded drugs are not FDA-approved."

Earlier this year, ASAP expressed similar concerns around patient use of compounded tirzepatide in an <u>article</u> published in Sleep Review magazine.

Read the Full FDA Notice

ASAP NEWS



Tell Us: Your Experience With the Philips Recall

As part of our ongoing advocacy and policy efforts, the Alliance of Sleep Apnea Partners is collecting patients' personal experiences with the recall of Philips Respironics positive airway pressure devices.

Personal stories are compelling to highlight the real-world effects of policy on patients. They also help ensure that the patient voice remains at the center of policymaking.

How and when did you first become aware of the recall? Were you able to replace your recalled PAP machine—and, if so, how long did that take? Did you have to pay to replace your machine? How were your sleep apnea treatment and health affected by the recall? Let us know.

Raise your voice as part of ASAP's work to shape policy for better patient outcomes.

Share Your Story

Meet ASAP's Corporate Council

The Alliance of Sleep Apnea Partners Corporate Council serves as a platform for discussing policy issues related to patients' access to care and also offers industry partners the opportunity to develop a long-term relationship with ASAP through advocacy alliances and program sponsorship.

Current ASAP Corporate Council members include Apnimed, Eli Lilly and Company, Somnics Health, and Resmed.

If your company is interested in becoming a member of our Corporate Council, please reach out to us at info@apneapartners.org.

See Our Corporate Council Members

Visit Us This Month at the SLEEP Meeting

Alliance of Sleep Apnea Partners President and CEO Dr. Monica Mallampalli, PhD., will be among presenters at the <u>SLEEP 2025</u> conference in Seattle, Washington, June 8-11.

Her presentation, "A Breath of Fresh Care: Advocating for Sleep Apnea Patients" will take place on Sunday, June 8, from 3:15-4:15 p.m. PST as session A-03 for the American Association of Sleep Technologists. She also will join the "Closing the Gender Gap in Sleep Diagnostics" panel discussion presented by Nox Medical on Tuesday, June 10, at 11:45 a.m. PST.

Dr. Mallampalli also will present a poster on Tuesday, June 10, at 10 a.m. PST. The poster title is "The SHINE Survey: Uncovering Gender Differences in Psychosocial Burden of Obstructive Sleep Apnea" (abstract ID 671, poster number P-31, board number 287).

ASAP also will have a booth in the exhibit hall—come visit us at **Booth 106** in the Advocacy Pavilion to the right of the exhibit hall entrance.

See the Map

ASAP Tabling at Obesity Action Coalition's Your Weight Matters National Convention

As part of its partnership with Obesity Action Coalition, Alliance of Sleep Apnea Partners will have a presence at the OAC's Your Weight Matters National Convention in Washington, D.C., July 24-26.



Obesity Action Coalition, a national nonprofit representing the many people affected by the disease of obesity, is one of ASAP's Alliance Partners.

Learn more about ASAP's Alliance Partners here.

ASAP Co-Founder Dr. Susan Redline Receives 2025 Edward Livingston Trudeau Medal

Dr. Susan Redline, MD, MPH—a co-founder of the Alliance of Sleep Apnea Partners and a pioneer in sleep apnea research—was honored with the American Thoracic Society's 2025 Edward Livingston Trudeau Medal in May. The award is one of the ATS's most prestigious prizes and honors Dr. Redline's many contributions toward the understanding of sleep apnea and breathing and sleep disorders throughout individual patients' lives.

"Among other findings, Dr. Redline's research and collaboration have revealed phenomena such as racial differences in sleep apnea between Black and white children in sample populations in the United States, the significant impact of environmental tobacco on children with sickle cell anemia, and the effect of fine particulate matter on sleep apnea in children," the ATS noted in announcing the award.

Dr. Redline is the Peter C. Farrell Professor of Sleep Medicine at Harvard Medical School and Director of the Programs in Sleep and Cardiovascular Medicine and Sleep Medicine Epidemiology at Brigham and Women's Hospital and Beth Israel Deaconess Medical Center.

Read About Dr. Redline

ASAP President Discusses Sleep Apnea, Women's Health in D.C. and Beyond



Dr. Mallampalli (third from left) at AWHP's Power, Policy, and Prevention meeting. Photo: PhotoGK.com

Dr. Monica Mallampalli, President and CEO of the Alliance of Sleep Apnea Partners, has represented the organization and the patient voice at a number of important gatherings so far this year.

In April, she was attended the Alliance for Women's Health and Prevention's "Power, Policy, and Prevention: A Women's Health Conversation with Senators Angela Alsobrooks and Lisa Blunt Rochester." This intimate, closeddoor gathering brought together women CEOs, top leaders, and patient advocates for a candid discussion about healthcare access, cost, prevention, and equity. During the event, Senators Alsobrooks and Blunt Rochester shared their vision for improving healthcare for women, children, and underserved communities.

In March, Dr. Mallampalli participated in



the Philadelphia Sleep Conference's Sleep Disorders Patient Advocacy Roundtable alongside (left to right) Mary Schneider (Project Sleep), Alissa Mendoza (Apnimed), Michael DiDomenico (Publisher and President, SleepWorld), Dr. Mallampalli, Rebecca King (Idiopathic Hypersomnia Foundation), Cara Weaver and Tammy Anderson (Wake Up Narcolepsy).

Dr. Mallampalli (center) and fellow panelists at the Philadelphia Sleep Conference's Sleep Disorders Patient Advocacy Roundtable.

Dr. Mallampalli Addresses "Keeping Patients First," Women and Sleep in Magazine Articles

Alliance of Sleep Apnea Partners President and CEO Dr. Monica Mallampalli highlighted issues of concern to patients in two recent magazine articles read by sleep medicine practitioners.

Writing in the American Academy of Sleep Medicine's Montage magazine, Dr. Mallampalli noted that sleep differences between men and women can result in missed diagnoses and delayed care, especially for women, in whom obstructive sleep apnea might present differently.

In SleepWorld magazine, Dr. Mallampalli focused on recent innovations that offer potential new treatments for OSA and also on the vital importance of patient advocacy groups like ASAP, which can provide crucial education for patients who are newly diagnosed and help rebuild patient trust among those affected by the poorly communicated <u>recall</u> of Philips Respironics CPAP machines.

Read the Montage Article

Read the SleepWorld
Article

Missed Sleep Apnea Education Week? Catch Up on the ASAP Website

Our annual Sleep Apnea Education Week campaign, which took place this year April 18-26 across our social media platforms, raises awareness about sleep apnea, the people it affects, and its economic impact.

Thanks to patients, our supporters, and our SAEW partners, we're building momentum to make sleep apnea a national priority.

Learn more about the campaign and see this year's social media posts on our dedicated SAEW webpage

here.





Help ASAP's Patient Advocacy Mission

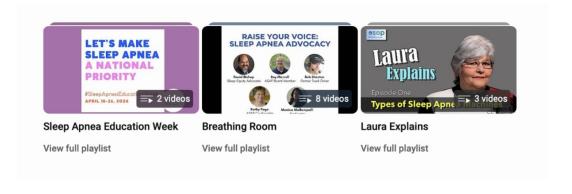
The Alliance of Sleep Apnea Partners is a patient-centered 501(c)(3) nonprofit working to ensure not only that patient voices are heard, but that health care policies benefit patients and improve their health outcomes.

We're dedicated to serving those living with sleep-disordered breathing or who have been diagnosed with obstructive sleep apnea. We strive to represent diverse patient voices at the local, regional, and national levels through education, advocacy, and support to eliminate gaps in patient care.

Your donation helps ASAP carry out this work to create a brighter future for everyone living with sleep apnea.

DONATE TO ASAP

Explore ASAP and Our Resources Online



Stay up to date with Alliance of Sleep Apnea Partners news, webinars, and social media on all of ASAP's online channels. Bookmark our website and follow us on social!

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YouTube: <u>youtube.com/@apneapartners</u>

• LinkedIn: @ApneaPartners • Twitter/X: @OfApnea

• Facebook: <a>@ApneaPartners • Instagram: @ApneaPartners

We Want to Hear From You!



Do you have questions or concerns about sleep apnea? Do you have a sleep apnea story to share? Email ASAP and let us know!

Email ASAP











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