



## Shionogi Announces Further Agreement with Apnimed for Sleep Disorder Treatments

- Introduction of New Assets to Joint Venture Shionogi-Apnimed Sleep Science – (SASS)

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**OSAKA, Japan, April 25, 2025** - Shionogi & Co., Ltd. (Head Office: Osaka, Japan; Chief Executive Officer: Isao Teshirogi, Ph.D.; hereafter "Shionogi") announced that it has entered into an agreement with Apnimed, Inc. (Head Office: Massachusetts, USA; Chief Executive Officer: Lawrence G. Miller, MD; hereafter "Apnimed") for the introduction of sulthiame\* and a new drug development program.

\* Sulthiame: A carbonic anhydrase inhibitor approved as an antiepileptic drug in certain regions. Sulthiame has successfully completed two Phase 2 trials in over 300 obstructive sleep apnea (OSA) patients studied for up to 3 months in Europe.<sup>1</sup>

With the conclusion of this agreement, Shionogi acquired a joint ownership interest in the intellectual property rights related to the use of sulthiame in the field of sleep apnea and also in other intellectual property rights related to a different drug development program of Apnimed by paying a one-time fee to Apnimed.\* Furthermore, Shionogi and Apnimed have already equally contributed this intellectual property to SASS, which will now conduct the future research and development of sulthiame and the other drug development program.

\* Note: Shionogi retains exclusive negotiation rights for the development and sales rights in Japan, Korea, Taiwan, and China.

"We are pleased to add new assets to the SASS OSA pipeline," said John Keller, Ph.D., Senior Executive Officer, Senior Vice President, R&D Supervisory Unit at Shionogi. "Our joint venture, combining the scientific and medical resources of Apnimed and Shionogi, represents the most robust global effort to bring new pharmacologic treatments for people with sleep apnea and related disorders."

"We are delighted to announce that this transaction further strengthened our SASS pipeline," commented Larry Miller, MD, Chief Executive Officer of Apnimed. "The 80 million people with OSA in the US, and hundreds of millions more around the globe, need more convenient options that directly treat the root causes of OSA."

Shionogi has identified Contributing to a Healthy and Prosperous Life as one of our material focus areas. We are committed to creating a society where everyone can lead a longer, more vibrant life, realizing their goals. Through the partnership with Apnimed, Shionogi continues to strive to deliver innovative treatments for diseases with high unmet medical needs, including sleep apnea and related disorders, to patients as quickly as possible.

### About Apnimed

Apnimed, based in Cambridge, Massachusetts, is a pharmaceutical company with exceptional expertise in sleep disorders. The company is building a portfolio of novel drug treatments for sleep-related breathing disorders, including Sleep Apnea Syndrome (SAS). Apnimed's lead development candidate, AD109, aims to maintain upper airway patency during sleep with a once-daily oral medication for the treatment of OSA, which, if approved, could bring a dramatic change to conventional therapies for OSA. For more details, please visit [apnimed.com](https://apnimed.com), X, or LinkedIn.

### **About Shionogi-Apnimed Sleep Science, LLC**

In November 2023, Shionogi and Apnimed established a joint venture, Shionogi-Apnimed Sleep Science, LLC, with each company holding a 50% stake.<sup>2</sup> The aim of SASS is to provide promising solutions to meet the unmet needs in the field of sleep disorders. SASS combines Shionogi's capabilities in small molecule drug discovery, first-in-class and best-in-class compound creation with Apnimed's advanced expertise in the field of sleep disorders, including a highly experienced clinical-stage drug development team and a strong network with clinical facilities. This collaboration leverages superior translational research to create promising solutions in the field of sleep disorders more rapidly than either company could achieve alone.

### **References:**

1. Hedner et al. Efficacy, Safety, and Tolerability of Three Doses of Sulthiame in Patients With Obstructive Sleep Apnea. A Randomized, Double-blind, Placebo Controlled, Dose-ranging Study (STM-042/K). B14. American Thoracic Society Annual Meeting 2024.
2. Press Release: November 1, 2023 - Establishment of a Joint Venture Company with Apnimed for Solving Challenges in Sleep Disorders

### **Forward-Looking Statements**

*This announcement contains forward-looking statements. These statements are based on expectations in light of the information currently available, assumptions that are subject to risks and uncertainties which could cause actual results to differ materially from these statements. Risks and uncertainties include general domestic and international economic conditions such as general industry and market conditions, and changes of interest rate and currency exchange rate. These risks and uncertainties particularly apply with respect to product-related forward-looking statements. Product risks and uncertainties include, but are not limited to, completion and discontinuation of clinical trials; obtaining regulatory approvals; claims and concerns about product safety and efficacy; technological advances; adverse outcome of important litigation; domestic and foreign healthcare reforms and changes of laws and regulations. Also for existing products, there are manufacturing and marketing risks, which include, but are not limited to, inability to build production capacity to meet demand, lack of availability of raw materials and entry of competitive products. The company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise.*

### **For Further Information, Contact:**

SHIONOGI Website Inquiry Form: <https://www.shionogi.com/global/en/contact.html>