

## **Suven Life Sciences to Present New Data Analyses from Samelisant Positive Phase-2 Study Results at the SLEEP 2024 Annual Meeting, Houston, USA.**

*Results highlight the clinical effectiveness of Samelisant for Excessive Daytime Sleepiness (EDS) in adults with narcolepsy Na-1 and Na-2.*

*Highly statistically significant effects were observed against placebo for the Clinical Global Impression of Severity (CGI-S), Patient Global Impression-Change (PGI-C), and Clinical Global Impression of Change (CGI-C).*

*Discussions with Key Opinion Leaders (KOL) at SLEEP 2024 to finalize the study design for the global Phase-3 study for the treatment of EDS in adult Narcolepsy patients with and without cataplexy.*

*Global Phase-3 study initiation is expected in the second half of 2024.*

*Exhibit booth # 440 at SLEEP 2024 is showcasing the Innovations pipeline of Suven Life Sciences.*

HYDERABAD, INDIA (3-June-2024), Suven Life Sciences, a clinical-stage biopharmaceutical company discovering and developing novel medicines to treat Central Nervous System (CNS) disorders, announced its participation and scientific presentations at SLEEP 2024, the 38<sup>th</sup> annual meeting of the American Academy of Sleep Medicine and the Sleep Research Society being held in Houston, June 1-5, 2024.

The SLEEP 2024 meeting is one of the largest gatherings of sleep professionals and offers top-tier education and the latest scientific discoveries, clinical updates, and many more from around the globe.

### **Suven Presentations at SLEEP 2024:**

- Samelisant (SUVN-G3031) Improves the Symptoms of Excessive Daytime Sleepiness in Patients with Narcolepsy: Results from a Phase-2 study (**Session: P-13/269, 3-June-2024**).
- Samelisant (SUVN-G3031): Clinician and Patient Global Impression from a Double-Blind, Randomized Placebo-Controlled, Phase-2 study in Patients with Narcolepsy (**Session: P-29/322, 4-June-2024**).

## **Suven Life Sciences Limited**

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Suven's P-13/269 scientific presentation will highlight details of the positive study results from its Phase-2 proof-of-concept study assessing the safety and efficacy of samelisant for the treatment of excessive daytime sleepiness (EDS) in adult narcolepsy patients with and without cataplexy. The study met primary endpoint, with samelisant demonstrating a statistically significant and clinically meaningful reduction in EDS measured by the Epworth Sleepiness Scale (ESS) total score compared to placebo at Day 14 ( $p < 0.05$ ). The second scientific presentation P-29/322 will elaborate on analysis of important efficacy endpoints: Clinician and Patient Global Impression. Highly statistically significant effects were observed against placebo for the important efficacy endpoints related to EDS, Clinical Global Impression of Severity (CGI-S) score, Patient Global Impression-Change (PGI-C), and Clinical Global Impression of Change (CGI-C). These patient and clinician reported outcomes support the efficacy of samelisant observed in the primary endpoint, ESS in patients with narcolepsy.

Team of Chief Scientists from Suven will meet several Key Opinion Leaders (KOL), Medical and Regulatory advisors at SLEEP-2024 to discuss the global Phase-3 study design to evaluate samelisant for the treatment of EDS in adult Narcolepsy patients with and without cataplexy. Global Phase-3 study initiation is expected in the second half of 2024.

Suven is showcasing its innovations pipeline and comprehensive summaries at SLEEP 2024 with exhibit booth # 440.

**About Samelisant (SUVN-G3031) Phase-2 Study:** The Phase-2 clinical study was a randomized, double-blind, placebo-controlled study designed to assess the safety and efficacy of samelisant as a monotherapy in adult narcolepsy patients with and without cataplexy (ClinicalTrials.gov Identifier: NCT04072380). The study was conducted in USA and Canada and approximately 60 sites participated in this study. The study recruited 190 patients aged 18 to 65 years and were randomized 1:1:1 to 2 mg samelisant, 4 mg samelisant, or placebo treatment groups. The primary efficacy endpoint of this study was change in ESS total score from baseline to Day 14. Secondary and exploratory endpoints were change in CGI-S score, CGI-C score and PGI-C score with regard to EDS and change in Maintenance of Wakefulness Test score from baseline to Day 14.

**About Samelisant (SUVN-G3031):** Samelisant is a novel, potent, selective, brain penetrant, and orally active Histamine-3 (H3) receptor inverse agonist. H3 receptor blockade elevates histamine, norepinephrine, and dopamine in the brain, a potential for the treatment of EDS and cataplexy in narcolepsy. Samelisant exhibited wake-promoting activity in orexin knock-out mice (an animal model of narcolepsy). Pre-clinical in-vitro and in-vivo efficacy studies, supporting neurochemical studies, pharmacokinetic studies, safety studies and Phase-1 studies in healthy subjects under US IND have been successfully completed for samelisant.

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**About Suven Life Sciences (“Suven”):** Suven Life Sciences Limited (Suven) is focused on discovery and clinical development of innovative medicines that address unmet medical needs in central nervous system (CNS) disorders. We have portfolio of advanced stage clinical candidates and research programs that are designed for CNS disorders such as Alzheimer’s disease (AD), sleep disorders, major depressive disorders (MDD), Parkinson’s disease (PD), Schizophrenia, Pain disorders, and Gastrointestinal disorders. Suven has 7 clinical stage assets across focus areas: Masupirdine (SUVN-502) for the treatment of agitation in patients with dementia of the Alzheimer's type (phase-3 study ongoing); Samelisant (SUVN-G3031) for excessive daytime sleepiness (EDS) in narcolepsy (phase-2 study completed; pivotal phase-3 study in planning); Ropanicant (SUVN-911) for MDD (phase-2 study ongoing); Usmarapride (SUVN-D4010) for cognitive disorders (phase-2 study in planning), SUVN-I6107 for dementia in PD (phase-1 study in planning) and 2 other compounds in early stages of clinical development. In addition to these clinical assets, we have 6 projects in research pipeline across multiple potential indications. Suven owns all intellectual property rights for its assets in all major markets.

For more information please visit our website at <http://www.suven.com>

**Risk Statement:** *Except for historical information, all the statements, expectations, and assumptions, including expectations and assumptions, contained in this news release may be forward-looking statements that involve several risks and uncertainties. Although Suven attempts to be accurate in making these forward-looking statements, it is possible that future circumstances might differ from the assumptions on which such statements are based. Other important factors which could cause results to differ materially including outsourcing trends, economic conditions, dependence on collaborative partnership programs, retention of key personnel, technological advances, and continued success in growth of sales that may make our products/services offerings less competitive; Suven may not undertake to update any forward-looking statements that may be made from time to time.*

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