CSD/BSE&NSE/PR/2023-2024
October 30, 2023

To
The Manager
Department of Corporate Services
BSE Limited
25th Floor, P. J. Towers,
Dalal Street, Mumbai – 400 001

Scrip Code: 530239

To
The Manager
Listing Department
National Stock Exchange of India Limited
Exchange Plaza, Bandra Kurla Complex
Bandra (E), Mumbai – 400 051

Scrip Symbol: SUVEN

Dear Sir/Madam,

Sub: News Release

With reference to above subject, please find enclosed News Release of our company titled **"Suven Life Sciences announces Positive Topline Results from a Phase-2 study evaluating Samelisant (SUVN-G3031) for Excessive Daytime Sleepiness (EDS) in adult Narcolepsy patients with and without cataplexy"**

This is for your information and record.

Thanking You,
Yours faithfully,
For **Suven Life Sciences Limited**

SHRENIK SONI
Digitally signed by SHRENIK SONI
Date: 2023.10.30 14:30:38 +05'30'

Shrenik Soni
Company Secretary

Encl: as above

News Release

Suven Life Sciences announces Positive Topline Results from a Phase-2 study evaluating Samelisant (SUVN-G3031) for Excessive Daytime Sleepiness (EDS) in adult Narcolepsy patients with and without cataplexy

- *Samelisant as a monotherapy achieves primary efficacy endpoint demonstrating statistically significant and clinically meaningful reduction in Epworth Sleepiness Scale (ESS) total score compared to placebo at Day 14 ($p<0.05$).*
- *This primary efficacy result was supported by a statistically significant improvement on the other efficacy endpoints like CGI-S ($p<0.01$), PGI-C ($p<0.001$), and CGI-C ($p<0.0001$).*
- *Samelisant was generally safe and well tolerated. There were no serious adverse events or death reported in the study.*
- *Suven plans to approach U.S. Food & Drug Administration (FDA) in Q1 2024 for an End-of-Phase-2 (EOP2) meeting to discuss the study results and seek the Agency's guidance for pivotal Phase-3 study.*

HYDERABAD, INDIA (October 30, 2023) Suven Life Sciences, a clinical stage biopharmaceutical company discovering and developing novel medicines to treat Central Nervous System (CNS) disorders, today announced positive topline 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 statistically significant and clinically meaningful reduction in EDS measured by the ESS total score compared to placebo at Day 14 ($p<0.05$). Highly statistically significant effects were observed against placebo for the other efficacy endpoints like Clinical Global Impression of Severity (CGI-S) score related to EDS, Patient Global Impression-Change (PGI-C), and Clinical Global Impression of Change (CGI-C). Exposures of samelisant in narcolepsy patients were observed to be in agreement with the exposures from Phase-1 studies in healthy subjects. These plasma concentrations of samelisant were projected to be sufficient for achieving receptor occupancy required to demonstrate efficacy in narcolepsy patients. Samelisant was generally safe and well tolerated. There were no serious adverse events or death reported in the study.

"*We are thrilled by these compelling topline results and the magnitude of improvement observed for Narcolepsy patients in this study with Samelisant as a monotherapy. We are deeply grateful to the patients and investigators who participated in the study*", said Mr. Venkat Jasti, Chairman & CEO of Suven Life Sciences.

"*These results demonstrate rapid onset of action of Samelisant and its ability to significantly address the symptoms of EDS that impair quality of life in Narcolepsy patients, we look forward to working closely with the FDA as we focus on our goal to advance Samelisant to the Phase-3 clinical development program*", said Ramakrishna Nirogi, Vice President, Drug Discovery & Development, Suven Life Sciences.

Topline data from this clinical trial are scheduled to be presented at the Neuroscience-2023 (Society for Neuroscience annual meeting) to be held at Washington, D.C., USA during 12-15th November. The full study results are planned to be submitted for scientific publication at a later date.

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 excessive daytime sleepiness 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. 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.

About Narcolepsy: Narcolepsy is a chronic, debilitating neurological disorder characterized by EDS and intermittent, uncontrollable episodes of falling asleep during the daytime. These sudden sleep attacks may occur during any type of activity at any time of the day. Narcolepsy is segmented into 2 categories: narcolepsy type 1 (with cataplexy, a sudden loss of muscle tone) and narcolepsy type 2 (without cataplexy). About one in 2,000 people have some form of narcolepsy. Symptoms present in the teens or early twenties but occasionally occur as early as 5 years of age or after 40 years old.

About Suven Life Sciences ("Suven"): Suven is a clinical-stage biopharmaceutical company, focused on discovering and developing novel pharmaceutical products, for CNS disorders. Our focus has been on the discovery and development of innovative molecules targeting diseases and areas, which has undiscovered medical treatment opportunities. Suven singularly focuses on the development of "New Chemical Entities" ("NCEs") molecules for CNS diseases such as Alzheimer's, various forms of Dementia, Narcolepsy, Major Depressive Disorder ("MDD"), Attention Deficient Hyperactivity Disorder ("ADHD"), Huntington's disease, Parkinson, Bipolar disorder and different forms of neuropsychiatry disorders, gastrointestinal disorders, and pain disorders. Suven has 7 clinical-stage compounds, Masupirdine (SUVN-502) for treatment of agitation in patients with dementia of the Alzheimer's type (Phase-3 ongoing), Samelisant (SUVN-G3031) for sleep disorders (Phase-2 completed), Ropanicant (SUVN-911) for Major Depressive Disorder (Phase-2 ongoing) and Usmarapride (SUVN-D4010) for cognitive disorders (Phase-2 ready) and 3 other compounds in early stages of clinical development. In addition to clinical candidates, Suven has 8 molecules in the development pipeline.

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.*