



CSD/BSE&NSE/PR/2023-2024
June 1, 2023

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

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

Scrip Code: 530239

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 completed enrollment of patients to the phase-2, Proof of Concept
(PoC) clinical study of samelisant (SUVN-G3031) for the treatment of narcolepsy with or
without cataplexy in USA and Canada”**

This is for your information and record.

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

Shrenik Soni
Company Secretary

Suven Life Sciences Limited

Registered Office: 8-2-334 | SDE Serene Chambers | 6th Floor Road No.5 | Avenue 7
Banjara Hills | Hyderabad – 500 034 | Telangana | India | CIN: L24110TG1989PLC009713
Tel: 91 40 2354 1142/ 3311/ 3315 Fax: 91 40 2354 1152 Email: info@suven.com website: www.suven.com

News Release

Suven Life Sciences completed enrollment of patients to the phase-2, Proof of Concept (PoC) clinical study of samelisant (SUVN-G3031) for the treatment of narcolepsy with or without cataplexy in USA and Canada

HYDERABAD, INDIA (June 1, 2023) Suven Life Sciences, a clinical stage biopharmaceutical company discovering and developing novel medicines to treat Central Nervous System (CNS) disorders, today announced completion of enrollment for its phase-2 PoC clinical study evaluating the safety and efficacy of samelisant in adult narcolepsy patients with and without cataplexy. Data readout for the study is anticipated in second quarter of FY2024.

“We are pleased to have achieved this milestone with the development of samelisant in the narcolepsy space and look forward to the data readout in second quarter of FY2024”. “Narcolepsy is a chronic disease characterized by the symptoms such as excessive daytime sleepiness (EDS) and cataplexy that impairs quality of life, Samelisant’s mechanism of action increases histamine transmission in the brain which provides the scientific rationale for its potential clinical utility for the management of narcolepsy”, said Mr. Venkat Jasti, Chairman & CEO of Suven Life Sciences.

About Study Design: This phase-2 PoC clinical study is a double-blind, placebo-controlled, parallel-group, multicenter study to evaluate the safety, tolerability, pharmacokinetics, and efficacy of 2 mg and 4 mg samelisant compared with placebo in narcolepsy patients with and without cataplexy. Approximately 190 adult patients were randomized at a ratio of 1:1:1 to 2 mg samelisant, 4 mg samelisant, or placebo at 58 clinical study sites across the USA and Canada (ClinicalTrials.gov Identifier: NCT04072380). The primary efficacy endpoint is change from baseline in the mean Maintenance of Wakefulness Test (MWT) score at Day 14. Key secondary endpoint is change from baseline in the mean total Epworth Sleepiness Scale (ESS) score at Day 14.

Patient baseline characteristics and demographics from the phase-2 PoC study of samelisant will be presented at SLEEP 2023, the 37th annual meeting of the Associated Professional Sleep Societies, LLC (APSS) being held at Indianapolis, USA during June 3-7, 2023.

About Samelisant (SUVN-G3031): Samelisant is a novel, potent, selective, brain penetrant and orally active Histamine H3 receptor inverse agonist. H3 receptor blockade elevates histamine, norepinephrine and dopamine in brain, a potential for treatment EDS and cataplexy. Samelisant exhibited wake promoting activity in orexin knock-out mice (an animal model of narcolepsy) and also showed similar trend in healthy human subjects (phase-1 study

Suven Life Sciences Limited

Registered Office: 8-2-334 | SDE Serene Chambers | 6th Floor Road No.5 | Avenue 7
Banjara Hills | Hyderabad – 500 034 | Telangana | India | CIN: L24110TG1989PLC009713
Tel: 91 40 2354 1142/ 3311/ 3315 Fax: 91 40 2354 1152 Email: info@suven.com website: www.suven.com

observations). Pre-clinical *in vitro* and *in vivo* efficacy studies, supporting neurochemical studies, pharmacokinetic studies, safety studies and phase-1 clinical studies in healthy humans under US IND has been successfully completed for samelisant.

About Narcolepsy: Narcolepsy is a chronic, debilitating neurological disorder characterized by excessive daytime sleepiness (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 discovery and development of innovative molecules targeting diseases and areas, which has undiscovered medical treatment opportunities. Our Company singularly focuses on 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 ongoing), Ropanicant (SUVN-911) for Major Depressive Disorder (phase-2 ready) 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 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.*

Suven Life Sciences Limited

Registered Office: 8-2-334 | SDE Serene Chambers | 6th Floor Road No.5 | Avenue 7
Banjara Hills | Hyderabad – 500 034 | Telangana | India | CIN: L24110TG1989PLC009713
Tel: 91 40 2354 1142/ 3311/ 3315 Fax: 91 40 2354 1152 Email: info@suven.com website: www.suven.com