CSD/BSE&NSE/PR/2024-2025
September 18, 2024

To
Department of Corporate Services
BSE Limited
25th Floor, P. J. Towers,
Dalal Street, Mumbai – 400001

Scrip Code: 530239

To
Listing Department
National Stock Exchange of India Limited
Exchange Plaza, Bandra Kurla Complex
Bandra (E), Mumbai – 400051

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 Phase-2a Proof-of-Concept Signal Detection Open Label Study of Ropanicant (SUVN-911) for the Treatment of Moderate to Severe Major Depressive Disorder (MDD)"**

This is for your information and record.

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

Shrenik Soni
Digitally signed by Shrenik Soni
Date: 2024.09.18 11:26:39 +05'30'

Shrenik Soni
Company Secretary

Encl: as above

News Release

Suven Life Sciences Announces Positive Topline Results from Phase-2a Proof-of-Concept Signal Detection Open Label Study of Ropanicant (SUVN-911) for the Treatment of Moderate to Severe Major Depressive Disorder (MDD)

Ropanicant was generally well-tolerated with no study drug-related serious adverse events. No notable differences in the safety profile across different doses and regimens.

Change from baseline in MADRS scores at week 2 are highly statistically significant ($p < 0.0001$) across all treatment groups and aligns with the efficacy seen in agents used to treat MDD patients.

The onset of action appears faster demonstrating rapid improvement in depressive symptoms within the first week.

Suven plans to advance Ropanicant into double-blind, placebo-controlled Phase-2b clinical study in MDD patients, which is expected to begin in early 2025.

HYDERABAD, INDIA (18-Sept-2024): 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-2a proof-of-concept signal detection open label fixed-dose study assessing the safety and efficacy of Ropanicant (SUVN-911) for the treatment of moderate to severe Major Depressive Disorder (MDD). The primary objective was to evaluate safety and tolerability of Ropanicant in patients with MDD. There are no significant differences in the safety profile across different doses and regimens. The secondary objective (efficacy objective) was to assess the change from baseline in the Montgomery-Asberg Depression Rating Scale (MADRS) total score at Week 2. The changes from the baseline in MADRS score at Week 2 are highly statistically significant ($p < 0.0001$) for all treatment groups and are consistent with the approved agents used to treat MDD patients. Treatment with Ropanicant resulted in mean improvement from the baseline in MADRS total score of 5.9 to 13.4 points at Day 7, and 10.4 to 12.7 points at Day 14 across different doses. The baseline MADRS score of patients entering the study was 32.1, representing moderate to severe depression.

"These findings from the Phase-2 study mark a significant milestone in our efforts to address the unmet medical need in treating moderate to severe Major Depressive Disorder patients. We are deeply grateful to the patients and investigators for their contributions." said Mr. Venkat Jasti, Chairman & MD of Suven Life Sciences.

"We are greatly encouraged by the strong signal and rapid onset of action observed in this study. The study met the criteria for a positive outcome, supporting our decision to advance Ropanicant to the double-blind, placebo-controlled Phase-2b study which we expect to initiate in early 2025." said Ramakrishna Nirogi, Vice President, Drug Discovery & Development, Suven Life Sciences.

Topline data from this clinical study will be presented at the Neuroscience-2024 (Society for Neuroscience annual meeting) to be held at Chicago, USA during 5-9th October, 2024.

About Ropanicant (SUVN-911) Phase-2 Study: The study was a multicenter, randomized, open-label, parallel-group fixed dose study conducted across 10 sites in the USA (ClinicalTrials.gov Identifier: NCT06126497). The study recruited 41 patients who met the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, (DSM-5) criteria for MDD without psychotic features and a diagnosis confirmed by the Mini-International Neuropsychiatric Interview (MINI). Patients were randomized in a 1:1:1 ratio (13 to 14 patients in each treatment group) to receive Ropanicant either 45 mg once a day, 30 mg twice a day, or 45 mg twice a day. Following a screening period of up to 4 weeks, the patients were treated for 2 weeks.

The primary objective was to evaluate the safety and tolerability of Ropanicant in patients with MDD. The secondary objective was to assess efficacy by measuring the change from baseline in the MADRS total score at Week 2.

About Ropanicant (SUVN-911): Ropanicant is a novel, potent and selective α4β2 nAChR antagonist, and is being developed for the treatment of MDD. Ropanicant has shown robust efficacy in various animal models of depression. Ropanicant may have potential to overcome significant limitations of existing treatments for depressive disorders by providing a rapid onset of action, avoiding sexual dysfunction, and enhancing cognitive functions. Ropanicant non-clinical safety has been established in various safety pharmacology and toxicity studies (up to 9-month duration). Ropanicant was evaluated in healthy subjects in two phase-1 studies (NCT03155503 and NCT03551288). It was well tolerated up to the highest tested dose in both single and multiple ascending dose studies. No significant effect of food and age was noted on Ropanicant pharmacokinetics. Ropanicant intellectual property rights are well protected in all major markets.

About Suven Life Sciences ("Suven"): Suven Life Sciences Limited (Suven) is focused on the 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 (Open-label Phase-2 study completed; Placebo-controlled Phase-2 study in planning); Usmarapride (SUVN-D4010) for cognitive disorders (Phase-2 study in planning), SUVN-I6107 for cognitive disorders (Phase-1 study initiated) 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 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.*