CSD/BSE&NSE/PR/2024-2025
August 27, 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: Press Release

With reference to above subject, please find enclosed Press Release of our company titled **"Suven Life Sciences Announces FDA acceptance of Investigational New Drug (IND) and grant of "Study may proceed Letter" to initiate Phase-1 Clinical Trial of SUVN-I6107, a True Muscarinic M1 Receptor Positive Allosteric Modulator (M1-PAM)"**

This is for your information and record.

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

Shrenik Soni
Digitally signed by Shrenik Soni
Date: 2024.08.27 14:48:25 +05'30'

Shrenik Soni
Company Secretary

Encl: as above

Press Release

Suven Life Sciences Announces FDA acceptance of Investigational New Drug (IND) and grant of "Study may proceed Letter" to initiate Phase-1 Clinical Trial of SUVN-I6107, a True Muscarinic M1 Receptor Positive Allosteric Modulator (M1-PAM)

SUVN-I6107 is a potent, selective and true muscarinic M1 PAM with minimal agonist like activity

First-in-human Phase-1 study will evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of SUVN-I6107 in healthy subjects

HYDERABAD, INDIA (27-Aug-2024), Suven Life Sciences, a clinical stage biopharmaceutical company discovering and developing novel medicines to treat Central Nervous System (CNS) disorders, today announced the acceptance of its Investigational New Drug (IND) application by the United States Food and Drug Administration (FDA) and grant of "Study may proceed Letter" to evaluate SUVN-I6107 in a first-in-human phase-1 clinical trial.

"The FDA acceptance of the IND for SUVN-I6107 allows to proceed with the Phase 1 study for this novel true muscarinic M1 receptor positive allosteric modulator, a potential new treatment to address the significant dementia market. Preclinical evidence has shown that treatment with SUVN-I6107 results in precognitive properties in diverse animal models. Additionally, SUVN-I6107 was devoid of cholinergic side effects at doses effective in animal models. Based on these results, SUVN-I6107 may have a better efficacy and safety profile than the currently available cholinesterase inhibitors due to its allosteric modulation of muscarinic M1 receptor. We look forward to dosing the first subject with SUVN-I6107 during the H2-2024 with an expected data readout in the H1-2025."

The Phase-1 trial is a randomized, double-blind, placebo-controlled, single and multiple ascending oral dose study to assess the safety, tolerability, pharmacokinetics, and pharmacodynamics of SUVN-I6107 in healthy subjects. Part-1 will be a single ascending dose (SAD) study, expected to enroll approximately 40 participants, randomized into one of 5 planned cohorts. Part-2 will be a multiple ascending dose (MAD) study, expected to enroll approximately 24 participants, who will be randomized into 3 planned cohorts, each to receive 14 consecutive days of SUVN-I6107 or placebo.

The primary endpoint will assess the safety and tolerability of SUVN-I6107 by monitoring adverse events (AEs), clinical laboratory, vital signs and electrocardiographs. Secondary endpoints include the pharmacokinetic evaluation of SUVN-I6107, assessed via plasma concentrations. Exploratory endpoints will examine the effects of SUVN-I6107 on quantitative electroencephalogram and event-related potential, among other measures.

About SUVN-I6107

SUVN-I6107 is a novel, potent, and selective muscarinic M1 positive allosteric modulator with minimal agonist-like activity. It exhibits no affinity for muscarinic subtypes M2 to M5. SUVN-I6107 demonstrates excellent ADME properties and good brain penetration, achieving high cerebrospinal fluid concentrations in rats. It has shown robust efficacy in non-clinical models of cognition and has not caused cholinergic effects such as salivation, or diarrhea in nonclinical species. Additionally, it has a wide margin of safety based on 28-day toxicity studies. Suven Life Sciences owns the intellectual property rights for SUVN-I6107 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 (phase-2 study ongoing); Usmarapride (SUVN-D4010) for cognitive disorders (phase-2 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.*