

## News Release

### First patient randomized in a Phase 2A, Proof of Concept (PoC) clinical trial of SUVN-G3031 for the treatment of Narcolepsy associated with or without Cataplexy in USA

**HYDERABAD, INDIA (September 24, 2019)** – Seven Life Sciences, a clinical stage biopharmaceutical company developing novel medicines to treat life threatening Central Nervous System (CNS) disorders, announced dose administration of the first patient in a Phase 2A clinical trial of SUVN G-3031, a Histamine H3 receptor inverse agonist in a Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Efficacy of 2 mg and 4 mg SUVN-G3031 Compared to Placebo in Patients with Narcolepsy with or without Cataplexy.

The clinical development program being executed through **Seven Neurosciences, Inc.**, a Delaware Company in USA, wholly owned subsidiary of Seven Life Sciences.

**Primary objective:** To evaluate the effectiveness of SUVN-G3031 compared with placebo as measured by an improvement in the Maintenance of Wakefulness Test (MWT) score.

**Secondary objective:** To evaluate the effectiveness of SUVN-G3031 compared with placebo as measured by subjective measures including an improvement in the Clinical Global Impression of Severity (CGI-S) score related to excessive daytime sleepiness (EDS) and the change in total Epworth Sleepiness Scale (ESS) score.

**Primary endpoint:** Change from baseline in the mean MWT score at Day 14

#### Study Design

This is a Phase 2, double-blind, placebo-controlled, parallel-group, multicenter study to evaluate the safety, tolerability, pharmacokinetics (PK), and efficacy of 2 mg and 4 mg SUVN-G3031 compared with placebo in patients with narcolepsy with and without cataplexy. Patients will be randomized at a ratio of 1:1:1 to 2 mg SUVN-G3031, 4 mg SUVN-G3031, or placebo, a total of 114 patients (38 per treatment group). This may be increased following a sample size re-estimation up to a maximum of 171 patients.

Investigational Therapy : •2 mg SUVN-G3031 and •4 mg SUVN-G3031  
Reference Therapy : Placebo  
Treatment Duration : Each patient will be dosed for 14 days. The study is expected to last a total of 12-15 months.

### Seven Life Sciences Limited



### **About SUVN -G3031**

SUVN-G3031: A novel, potent, selective, brain penetrant and orally active Histamine H3 receptor inverse agonist. H3 receptor blockade elevates acetylcholine, histamine, norepinephrine and Dopamine in brain, a potential for treatment of cognitive and sleep related disorders.

SUVN-G3031 exhibited wake promoting activity in wild-type rats, mice and also showed similar indications in healthy human subjects (Phase 1 study observations). The wake promoting effect is considered as a marker for Narcolepsy.

Pre-clinical in vitro and in vivo efficacy studies, supporting neurochemical studies, ADMET studies, drug product and Phase-1 clinical trial under US IND has been successfully completed for SUVN-G3031.

### **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 Life Science is a biopharmaceutical company focused on discovering, developing and commercializing novel pharmaceutical products, which are first in class or best in class CNS therapies using GPCR targets. Suven has 4 clinical stage compounds, a Phase 2 finished masupirdine (SUVN-502), Phase 2 entered samelisant (SUVN-G3031), Phase1 completed SUVN-D4010 and SUVN-911 and Phase 1 ready SUVN-I6107.

In addition to these clinical compounds the Company has eight (8) internally-discovered therapeutic drug candidates currently in various stages of pre-clinical development targeting conditions such as ADHD, dementia, depression, Huntington's disease, Parkinson's disease and pain.

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

#### ***Risk Statement:***

*Except for historical information, all of the statements, expectations and assumptions, including expectations and assumptions, contained in this news release may be forward-looking statements that involve a number of 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**

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