News Release

Suven Life Sciences Announces Scientific Presentation at CTAD-2023: Study Design of Global Phase-3 Program of Masupirdine (SUVN-502) for the Treatment of Agitation in Patients with Dementia of the Alzheimer's Type

HYDERABAD, INDIA (October 23, 2023), Suven Life Sciences, a clinical-stage biopharmaceutical company discovering and developing novel medicines to treat Central Nervous System (CNS) disorders, announced today scientific presentation at the 16th Clinical Trials on Alzheimer's Disease conference (CTAD), being held October 24 -27, 2023 in Boston, USA and virtually. The CTAD is a meeting focused entirely on Alzheimer's Disease Therapeutic Trials with key leaders in Alzheimer Disease research from Industry and Academia getting together and forming partnerships with the objective of speed-up the development of effective treatments to fight the disease.

Suven's scientific presentation at CTAD will highlight details of the study design of the global Phase-3 program of masupirdine (SUVN-502) for the treatment of agitation in patients with dementia of the Alzheimer's type. This study (ClinicalTrials.gov ID: NCT05397639 or EudraCT Number: 2021-003405-22) is currently recruiting patients in USA and Europe. Team of scientists from Suven will meet several Key Opinion Leaders (KOL) and Principle Investigators (PI) at CTAD-2023 to discuss various approaches and action plans to accelerate the study.

Presentation details:

- **Title:** Masupirdine (A Pure 5-HT6 Receptor Antagonist) for the Treatment of Agitation in Patients with Dementia of Alzheimer's Type - Rationale and Phase-3 Study Design
- **Theme:** New therapies and clinical trials

About Masupirdine Phase-3 Study Design:

Study Objectives:

- Primary Objective: To evaluate the efficacy of masupirdine (50 mg and 100 mg) compared to placebo for agitation as measured by the CMAI items score aligning to the International Psychogeriatric Association (IPA) agitation criteria domains after 12 weeks of treatment.
- Key Secondary Objective: To measure whether the effects of masupirdine (50 mg and 100 mg) are substantial enough to be detected by a skilled and experienced clinician based on a direct examination of the participant and an interview of the participant's caregiver.

Study Endpoints:

- Primary Outcome Measure: Change in CMAI items score aligning to the IPA agitation criteria domains (physical aggression, excessive motor activity, and verbal aggression) from Baseline to Week 12 visit. CMAI is a validated 29-item questionnaire to assess agitation.
- Key Secondary Outcome Measure: Change in Modified Alzheimer's Disease Cooperative Study-Clinical Global Impression of Change (mADCS-CGI-C) From Baseline to Week 12 visit. The mADCS-CGI-C is a modification of the ADCS-CGI-C instrument that focuses specifically on agitation.

Approximately 375 patients are planned to be enrolled in the study at about 70 clinical centers in USA and Europe. Patients will be randomly assigned to receive masupirdine either 50 mg QD or 100 mg QD or placebo QD, in a 1:1:1 ratio (125 participants/treatment group). The maximum duration of study participation for an individual participant is approximately 20 weeks, including an up to 4-week screening period, 12-week double blind treatment period, and a follow-up at Week 16. Topline data from the trial is expected to be available in 2026. Additional information on the trial can be found at ClinicalTrials.gov ID: NCT05397639 or EudraCT Number: 2021-003405-22.

About Masupirdine (SUVN-502): Masupirdine, a serotonin-6 (5-HT6) receptor antagonist is being developed for the treatment of agitation in patients with dementia of the Alzheimer's type. In animal models, masupirdine showed a significant reduction in agitation-like behaviors and modulated the neurotransmitters implicated in the modulation of mood and behavior. Post-hoc analyses of the Phase-2 study (NCT02580305) evaluating masupirdine for the treatment of cognitive deficits in patients with moderate Alzheimer's disease (AD) suggested potential beneficial effects on agitation/aggression.

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 the 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.*