Suven Life Sciences Presenting Study Design and Initiation of Phase-3 Global Clinical Trial of "Masupirdine (SUVN-502) for the Treatment of Agitation in Patients with Dementia of the Alzheimer's Type" at the 15th Annual Clinical Trials on Alzheimer's disease (CTAD-2022) Conference

HYDERABAD, INDIA (November 29, 2022): Suven Life Sciences announced today that it will be presenting a scientific poster on study design and initiation of Phase-3 global clinical trial of masupirdine (SUVN-502) for the treatment of agitation in patients with dementia of the Alzheimer's type at the 15thannual Clinical Trials on Alzheimer's Disease (CTAD-2022) hybrid conference, taking place during November 29 - December 2, 2022, in San Francisco, California and virtually. CTAD-2022 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 speeding the development of effective treatments to fight the Alzheimer's disease.

Poster Presentation Details:

Title: Phase-3 Study of Masupirdine (SUVN-502), a 5-HT6 Receptor Antagonist, For the Potential Treatment of Agitation in Participants with Dementia of Alzheimer's Type (**Poster: P170**).
Theme: Behavioral disorders and clinical trials.

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.

This study will enroll approximately 375 patients at approximately 50 centers worldwide. 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 by early 2025. Additional information on the trial can be found at ClinicalTrials.gov (NCT05397639).

About Masupirdine:

Masupirdine, a serotonin-6 (5-HT_6) receptor antagonist is being developed for the treatment of agitation in patients with dementia of the Alzheimer's type. In animal models, masupirdine showed significant reduction in agitation like behaviors and modulated the neurotransmitters implicated in 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 Limited ("Suven"):

Suven is a bio-pharmaceutical company, focused on discovering and developing novel pharmaceutical products, for central nervous system ("CNS") disorders using G ProteinCoupled Receptor targets. 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, gastro and pain. Suven has 7 clinical stage compounds, including this Phase 3 Masupirdine (SUVN-502) for treatment of agitation in patients with dementia of the Alzheimer's type, ongoing Phase-2 Samelisant (SUVN-G3031) for sleep disorders (Narcolepsy), Phase 2 ready Ropanicant (SUVN-911) for Major Depressive Disorder (MDD) and Phase 2 ready Usmarapride (SUVN-D4010) for cognitive disorders. 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.