

Suven Life Sciences Reached 50% Patient Enrollment Milestone in Global Phase-3 Clinical Trial of Masupirdine (SUVN-502) for the Treatment of Agitation in Patients with Dementia of the Alzheimer's Disease.

Hyderabad, India (28-Nov-2025) - Suven Life Sciences, a clinical-stage biopharmaceutical company focused on discovering and developing innovative treatments for Central Nervous System (CNS) disorders, today announced strong momentum in its development pipeline, with its global Phase-3 clinical trial of Masupirdine for the Treatment of Agitation in Patients with Dementia of the Alzheimer's Type successfully achieving the 50% patient enrollment milestone. This multicenter, randomized, double-blind, placebo-controlled Phase 3 study (NCT05397639, EudraCT Number 2021-003405-22) is being conducted across North America and Europe.

“This milestone reflects the meaningful progress we are making in advancing Masupirdine, a pure 5-HT₆ receptor antagonist, being developed for the treatment of agitation in patients with dementia of the Alzheimer’s Disease. Over the past one year, we have strategically expanded our global clinical footprint by activating additional study sites to strengthen the geographic reach and demographic representation. Added additional medical experts and AI enabled patient identification and referral to the sites. With patient enrollment steadily gaining momentum across our growing network of experienced investigators, we remain well positioned to complete recruitment in year 2026.” said Mr. Venkat Jasti, Chairman and Managing Director of Suven Life Sciences.

“Agitation represents one of the most challenging neuropsychiatric manifestations of Alzheimer’s disease and imposes substantial burden on patients and caregivers. Current treatment options, primarily atypical antipsychotics, and many late-stage investigational therapies act through dopaminergic or sedative pathways and do not confer mechanism-based cognitive benefits. Masupirdine, through selective modulation of the serotonergic system, is engineered to overcome these limitations while providing therapeutic improvement. The exploratory analyses from an earlier Phase-2 clinical study (NCT02580305) of Masupirdine demonstrated reductions in agitation and aggression alongside improvements in cognitive performance. These data further substantiate the mechanistic rationale and clinical promise of Masupirdine.” said Dr. Ramakrishna Nirogi, President and CSO of Suven Life Sciences.

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About Masupirdine study: The trial is a multicenter, randomized, double-blind, placebo-controlled Phase-3 study conducted across North America and Europe. Approximately 375 patients will be randomized 1:1:1 to receive Masupirdine 50 mg QD, 100 mg QD, or placebo for 12 weeks. The primary endpoint is the change from baseline to Week 12 in the Cohen-Mansfield Agitation Inventory (CMAI) items aligned with the International Psychogeriatric Association (IPA) agitation criteria. Key secondary endpoint is the modified Alzheimer's Disease Cooperative Study–Clinical Global Impression of Change (mADCS-CGI-C) related to agitation.

Additional details are available <https://agitation-study.com>, at ClinicalTrials.gov NCT05397639 and at EudraCT Number 2021-003405-22.

About Suven Life Sciences: Suven Life Sciences Limited (Suven) is focused on the discovery and clinical development of innovative medicines that address unmet medical needs in 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 5 clinical stage assets across focus areas: Masupirdine (SUVN-502) for the treatment of agitation in patients with dementia of the Alzheimer's type (Global Phase-3 study ongoing); Samelisant (SUVN-G3031) for excessive daytime sleepiness (EDS) in narcolepsy (Phase-2 study for EDS completed for EDS; Phase-2 study for Cataplexy and pivotal Phase-3 study for EDS are in planning); Ropanicant (SUVN-911) for MDD (Open-label Phase2a study completed; Double blind randomized Placebo controlled Phase-2b study ongoing); Usmarapride (SUVN-D4010) for cognitive disorders (Phase-2 study in planning), SUVN-I6107 for cognitive disorders (Phase-1 study in progress). In addition to these clinical assets, we have 7 projects in research pipeline across multiple 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.

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