

News Release

Suven Life Sciences announces Top-Line Results of SUVN-502 (Masupirdine) Phase 2A Study in Patients with Moderate Alzheimer's Disease (AD).

SUVN-502 did not meet the pre-specified primary endpoint

Meaningful improvements and potential beneficial effects on cognitive function, behavioral and neuropsychiatric end points were emerged based on subgroup analyses.

SUVN-502 was safe and well tolerated with no significant adverse events

HYDERABAD, INDIA (November 30, 2019) - **Suven Life Sciences** announces top-line results from its Phase 2A proof of concept study evaluating the efficacy, safety and tolerability of Masupirdine (SUVN-502). The first of its kind trial which focused on advanced stage AD patients (moderate AD) who are currently treated with standard of care Donepezil and Memantine. The unique triple-therapy (Masupirdine+ Donepezil+ Memantine) design was based on efficacy results in pre-clinical cognition models in which masupirdine enhances the effects of combined treatment with Donepezil and Memantine.

The primary efficacy endpoint of the trial is change from baseline to Week 26 in ADAS-Cog 11 score. The secondary outcome measures are MMSE, CDR-SB, ADCS-ADL, NPI, C-SDD, safety and tolerability assessment.

Findings of this Phase 2A study:

- Masupirdine (SUVN-502) is safe and well tolerated without significant adverse events.
- **Triple therapy of Masupirdine (SUVN-502) with Donepezil and Memantine proof of concept phase 2 study missed its pre-specified primary endpoint.**
- Subgroup analyses on cognition, function, behavioral, neuropsychiatric inventory and secondary endpoints revealed interesting, statistically significant and potentially beneficial data sets.
- Potential beneficial effects and statistically significant results with Masupirdine treated groups on cognition emerged upon considering combinations of Patients Age, Memantine regimen, Memantine plasma concentration, Memantine treatment duration and Alzheimer's disease duration.
- Sub-population of Masupirdine treated patients showed significant improvement and statistically significant reduction in the behavioral symptoms in the domains of agitation/ aggression and delusions /hallucination as assessed by the NPI subscale scores.
- Detailed study outcomes of the above findings will be presented through one oral and six poster presentations at **Clinical Trials on Alzheimer's Disease (CTAD)** being held at San Diego from 4th - 7th December 2019.

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We are very disappointed with the outcome of this trial but the findings present an important step forward in further exploration of the potential therapeutic effects of Masupirdine (SUVN-502) in Alzheimer's Disease (AD) and Behavioral & Psychological Symptoms in Dementia (BPSD). We will work with regulators and potential partnering companies in the design and conduct of future studies for further exploration of the potential of Masupirdine (SUVN-502) says Venkat Jasti, CEO of Suven.

About the study:

The Phase 2A randomized, double-blind, placebo-controlled, multi-center, parallel group study compared the efficacy and safety of two doses of Masupirdine (50 mg and 100 mg per day) to placebo in moderate AD patients (ClinicalTrials.gov Identifier: NCT02580305). In this phase-2 study, a total of 564 subjects with a diagnosis of AD for at least one year, Mini-Mental State Examination (MMSE) scores between 12 and 20, and currently treated with stable doses of both Donepezil 10 mg/day and Memantine 10 mg twice a day or Namenda XR (Memantine) 28 mg/day or Namzaric™ (28 mg Memantine HCl extended-release / 10 mg Donepezil HCl) once a day for at least 3 months were randomized (1:1:1) to treatment. This 30-week study included a 26-week double-blind treatment period followed by a 4-week single-blind placebo washout period.

The safety of Masupirdine was evaluated through physical and neurological examinations, monitoring blood pressure, ECGs, laboratory tests and review of adverse events. In addition, an independent Data Safety Monitoring Board (DSMB) met three times during the study to review safety data; each time recommending that the study to be continued as planned. Masupirdine appeared to be well tolerated in AD population with most reported adverse events similar to placebo. No significant changes were observed in physical, neurological, cardiology and laboratory tests.

Subjects who completed the entire study as planned were allowed to participate in compassionate Expanded Access Program (EAP). The EAP provided treatment with Masupirdine (50 mg daily) for an additional 6-12 months if the subject, caregiver and investigator felt the subject could be benefited from the treatment.

The masupirdine Phase 2A study was conducted at centers across the United States. A total of 77 investigators from 27 states contributed subjects. Dr. Jeffrey Cummings, who was instrumental in the development of the protocol design, was the coordinating investigator. We would like to thank all the investigators, their dedicated staff, and the commitment of the subjects and their caregivers without whom this study would not have been possible.

About Masupirdine:

Masupirdine is a promising potent and selective serotonin 6 (5-HT₆) receptor antagonist (>1200 fold selectivity over 5-HT_{2A}) in development as a novel approach in the symptomatic treatment of AD dementia. In preclinical studies, masupirdine has demonstrated excellent ADME properties; promising pro-cognitive effects; robust psychophysiological and biochemical signals; and a good safety profile. In animal models assessing behavior,

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neurochemistry and electrophysiology, Masupirdine + Donepezil + Memantine triple combination demonstrated superior pro-cognitive effects (object recognition task), acetylcholine modulation (microdialysis) and theta modulation (electrophysiology) compared to Donepezil + Memantine dual combination. Long-term animal toxicity studies with Masupirdine, Donepezil, and Memantine did not identify any significant toxicity risk signal; suggesting a broad exposure safety margin. Finally, in healthy younger and older adult human subjects, Masupirdine was well-tolerated following single or multiple oral administrations.

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 SUVN-502, Phase 2 (proof of concept) undergoing SUVN-G3031 for the treatment of Narcolepsy of both type I and type 2 , Phase1 completed SUVN-D4010 and SUVN-911.

In addition to these clinical compounds the Company has nine (9) 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 Web site at <http://www.suven.com>

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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.

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