

CS/BSE/NSE/PR/2020-2021 April 06, 2020

To The General Manager Department of Corporate Services BSE Limited 25th Floor, P. J. Towers, Dalal Street, Mumbai - 400 001 To The Manager Listing Department National Stock Exchange of India Limited Exchange Plaza, Bandra Kurla Complex Bandra (E), Mumbai – 400 051

Scrip Code: 530239

Scrip Symbol: SUVEN

Dear Sir/Madam,

Sub: News Release

With reference to above subject, please find enclosed News Release of our company titled "Suven Life Sciences presented exploratory sub-group analyses data from Masupirdine (SUVN-502) Phase 2A Study at the Advances in Alzheimer's and Parkinson's Therapies (AAT-AD/PD) focus meeting 2020"

This is for your information and record.

Thanking You, Yours faithfully, For **Suven Life Sciences Limited** 

**Shrenik Soni** Company Secretary

Suven Life Sciences Limited

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### **News Release**

# Suven Life Sciences presented exploratory sub-group analyses data from Masupirdine (SUVN-502) Phase 2A Study at the Advances in Alzheimer's and Parkinson's Therapies (AAT-AD/PD) focus meeting 2020

**HYDERABAD, INDIA (April 04, 2020)** Suven Life Sciences presented exploratory sub-group analyses data from Masupirdine (SUVN-502) Phase 2A proof of concept Study in Patients with Moderate Alzheimer's Disease (AD) at the Advances in Alzheimer's and Parkinson's Therapies (AAT-AD/PD<sup>™</sup>) focus meeting 2020. This meeting, originally scheduled to take place in Vienna, Austria, was converted to a virtual meeting due to the COVID-19 pandemic.

The outcome of the analyses was discussed through a virtual symposium chaired by Dr. Jeffrey Cummings, MD, ScD., USA; Dr. Alireza Atri, MD, PhD, USA highlighted the potential signals of benefit for masupirdine on cognition, function, and global progression in Alzheimer's disease; Professor Clive Ballard, MD, M.R.C. Psych. UK discussed the potential benefits of masupirdine on neuropsychiatric symptoms in patients with Alzheimer's disease. The symposium panel concluded that if the exploratory analyses hold in the confirmatory trial, masupirdine could be a first line treatment option for the management of agitation/aggression in patients with Alzheimer's disease. In addition, the panel also opined that masupirdine may have potential benefit on cognition, function, and global progression in Alzheimer's disease.

#### *Key findings from exploratory analyses:*

- In participants whose memantine plasma concentrations were ≤100 ng/mL at Week 26, there was lesser cognitive decline (ADAS-Cog 11) in participants taking masupirdine than in those on placebo (p<0.05) at Week 26. There were congruent signals for beneficial effects on MMSE, ADCS-ADL, NPI and CDR-SB as well.</li>
- Masupirdine significantly reduced agitation/aggression in patients having baseline symptoms (p<0.001; Cohen's d = 0.45 at Week 13).
- Masupirdine also attenuated delusions and/or hallucinations in patients with dementia of the Alzheimer's type (p=0.016; Cohen's d = 0.58 at Week 13).
- In patients with psychotic symptoms, masupirdine treatment had beneficial effects on cognition (p=0.067; Cohen's d = 0.57 at Week 26).
- Masupirdine showed sustained and durable efficacy on neuropsychiatric symptoms for the entire study duration of 26 weeks.
- Masupirdine is safe and well tolerated without significant adverse events.

These exploratory and thought-provoking observations merit better understanding and further possible investigations of masupirdine effects and its role as a potential future drug in the AD pharmaceutical armamentarium.

Page 1

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# This sub-group analysis demonstrates potential utility of Masupirdine in cognition and neuropsychiatric symptoms in patients with Alzheimer's disease as follows:

- 1. Potential benefit on cognition, function, and global progression in Alzheimer's disease.
- 2. Potential beneficial effects on several domains of neuropsychiatric inventory related to agitation/aggression and delusions/hallucinations.
- 3. Potential beneficial effects on cognition in patients with psychotic symptoms.

To view the presentations and panel discussion, please visit www.suven.com or use the link: https://kenes365my.sharepoint.com/:v:/g/personal/zizackov kenes com/Eekj5tpK5clPvh E D7NuiM4BQIaDSV1xBVgpF2dsuybRRA?e=8BuyTa

#### 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 NamzaricTM (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 primary efficacy endpoint of the trial was change from baseline to Week 26 in ADAS-Cog 11 score. The secondary outcome measures were MMSE, CDR-SB, ADCS-ADL, NPI-12, C-SDD, safety and tolerability assessment. The safety and tolerability of masupirdine was evaluated through physical and neurological examinations, monitoring blood pressure, ECGs, laboratory tests, review of adverse events and C-SSRS.

#### About Masupirdine:

Masupirdine is a promising potent and selective serotonin 6 (5-HT6) receptor antagonist (>1200 fold selectivity over 5-HT2A) 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, neurochemistry and electrophysiology, masupirdine + donepezil + memantine triple combination demonstrated superior pro-cognitive effects (object recognition task), acetylcholine modulation (micro dialysis) and theta modulation (electrophysiology) compared to Donepezil + Memantine dual combination. Long-term animal toxicity studies with masupirdine 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. Page 2

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#### 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 four (4) clinical stage compounds; Masupirdine (Phase 2 completed), SUVN-G3031(Phase 2 proof of concept study for the treatment of Narcolepsy is in progress), and SUVN-D4010 and SUVN-911 (Phase 2 ready).

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

#### Disclaimer and 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.

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Page 3