

In search of new CNS therapies for better living

Suven Life Sciences Discovery and Development of NCE for unmet medical needs



June 2021

Safe Harbor Statement



Except for historical information, all of the statements, expectations and assumptions, including expectations and assumptions, contained in this presentation 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 these statements 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



Vision and Mission

World-class R&D solutions for

future needs

- Become a leading company
 focused on treatments for unmet
 medical needs in Mental Health
- Health for patients and value for partners





Our Evolution – through demerger



2020

SUVN-I6107: Ready for Phase 1

Life Scien



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Company Overview

- IPO and listing in 1995 on BSE and in 2003 on NSE
- Established Contract Research And Manufacturing Services (CRAMS) - Innovator for NCE based intermediates
- Demerged the business in 2020 by hiving off CRAMS business into Suven Pharmaceuticals (resultant entity) and continue to focus on discovery and development of molecules under CNS for unmet medical needs
- Created Suven Neurosciences, Inc., USA, a Delaware Company in 2015 for clinical development and commercialization of Suven's NCE molecules



Suven's chosen therapeutic area: CNS

- Why CNS?
- Central Nervous System (CNS) market is the Second Largest
 Therapeutic Category (15%) and it is one of the Fastest Growing segment
- Highly unmet medical need
- More than 200 compounds under development
- Challenges High attrition during discovery and clinical development
- Highly rewarding Based on the recent licensing deals in this segment



Potential First-in-Class medicines in selected therapeutic areas in United States



Source: PhRMA 2015 report and article from Analysis Group. Innovation in the biopharmaceutical pipeline: a multidimensional view, January 2013



In Search of New CNS Therapies

Suven's core focus - Neuroscience

Focused on Neuroscience, the most challenging area in drug discovery



To discover & develop Differentiated Therapeutics

for the treatment of neurodegenerative disorders



In Search of New CNS Therapies

Chosen Therapeutic Targets

Alzheimer's Disease

- Potential to be a symptomatic treatment
 - 5-HT₆ receptor antagonist
 - Histamine H₃ receptor inverse agonist
- Potential to be both symptomatic and disease modifying treatment
 - 5-HT₄ receptor partial agonist
 - M1 receptor positive allosteric modulator

Schizophrenia

• Dopamine D₂, 5-HT_{2A}, SSRI

Depression

Cholinergic α4β2 antagonist

Pain

Cannabinoid 2 receptor agonist



SUVEN NCE Clinical Pipeline



Potential to address unmet medical needs



SUVN 502 (Masupirdine): Phase 2 Study in USA



SUVN-502 (Masupirdine), a lead clinical candidate having undergone phase 2 study for moderate Alzheimer's disease without meeting primary end point, a new phase 2 clinical trial is planned for the treatment of Agitation and aggression in Alzheimer's type dementias and the Phase 2 clinical study is likely to commence by August 2021. This study expected to be completed in about 42 months (completed by end of 2024).

SUVN-502 is a pure 5-HT6 receptor antagonist with >1200-fold selectivity over 5-HT2A receptor with a superior profile that differentiates from competitor 5-HT6 antagonists. SUVN-502 has an excellent human pharmacokinetics for once-a-day treatment.

Prior to the initiation of first Phase 2A study, SUVN-502 has successfully undergone two phase 1 studies in Switzerland and USA on 122 healthy young and elderly male populations with no major adverse events and no serious adverse events.





Completed and data announced in November 2019.

The first Phase 2A trial designed to evaluate the safety, tolerability, pharmacokinetics and efficacy of SUVN-502 for the treatment of moderate Alzheimer's Disease (AD) commenced in August 2015. This trial enrolled 564 patients in USA and the primary objective of the study was to evaluate the efficacy of a serotonin receptor subtype 6 (5-HT6) antagonist, SUVN-502, at daily doses of 50 mg or 100 mg compared to placebo, as adjunct treatment in subjects with moderate Alzheimer's disease (Mini-Mental State Examination [MMSE] score of 12 to 20) currently treated with the acetylcholinesterase inhibitor, Donepezil Hydrochloride (HCI) and the N-methyl-D-aspartic acid (NMDA) antagonist, MemantineHCI. Efficacy will be assessed by the 11-item Alzheimer's Disease Assessment Scale for Cognitive Behaviour (ADAScog-11) after 26 weeks of treatment.

Secondary objectives of this POC study were to further evaluate the efficacy of these treatments using Clinical Dementia Rating (CDR) Scale, Sum of Boxes (CDR-SB), MMSE, Alzheimer's Disease Co-operative Study Activity of Daily Living (ADCS-ADL), Neuropsychiatric Inventory (NPI) 12 item and Cornell Scale for Depression and Dementia (C-SDD).







SUVN-G3031

Histamine H3 Inverse Agonist

Sleep Disorders (Narcolepsy)

Cognitive Disorders (Alzheimer's)

Phase 1 Completed in USA; Ongoing Phase-2 for Narcolepsy; Expected outcome in Q2-2021



About SUVN-G3031 (Samilisant)



- SUVN-G3031 is a potent, selective, brain penetrant and orally active Histamine H3 inverse agonist for the treatment of cognitive dysfunction associated with AD / Schizophrenia. SUVN-G3031 completed all the Pre-clinical, Safety, early Tox and GLP Tox studies. US IND has been approved in Sept-2014. Phase-1 SAD & MAD studies have been completed. SUVN-G3031 demonstrated excellent safety profile and PK.
- A Phase 2, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Efficacy of 2 mg and 4 mg SUVN-G3031 Compared to Placebo in Patients with Narcolepsy with and without Cataplexy commenced in Aug 2019 with a targeted enrollment of 114 subjects in USA.
- The ongoing phase 2 study in USA has been presented to the Data Safety Monitoring Board (DSMB) for interim analysis and the DSMB did not find any safety related issues. During the meeting DSMB suggested for better outcome of the trial, a key secondary endpoint ESS (Epworth Sleepiness Scale) in addition to the Primary end point of MWT (Maintenance of Wakefulness Test) which is being tested at present. This led to addition of 57 patients and with this the total number of patients increased from 114 to 171 and the study is expected to complete by end of the year 2022.
- Covid conditions in US affected this study in enrollment of patients and with the increase of 57 patients for the study it is going to be taking another 18 months to close this study



SUVN-G3031 significantly differentiated from other therapies approved and in development

- Strong preclinical data and early clinical package supporting efficacy and safety profile of SUVN-G3031
- Clear potential to serve unmet need in narcolepsy, where few safe and effective treatments exist
- Differentiated asset and mechanism opportunity to gain significant market share
- Additional upside potential in Alzheimer's and other indications



New CNS Therapies



SUVN-D4010

5-HT4 Partial Agonist

Dual Mechanism of Action (Disease Modifying and Symptomatic Treatment Potential for AD) Gastro-Intestinal Motility Disorders

Phase 1 Completed in USA; Ready for Phase 2 POC







SUVN-911

Selective $\alpha 4\beta 2$ nAChR Antagonist

Addressing the Limitations of Current SOC for Major Depressive Disorders

Phase 1 Completed in USA; Ready for Phase 2 POC







SUVN-I6107 M1 True PAM - No Cholinergic Side Effects

Muscarinic 1 True Positive Allosteric Modulator

For Treatment of Cognitive Deficits; Ready for Phase 1



New CNS Therapies – Early stages

1) SUVN-I6107

Muscarinic positive allosteric modulator (M1 PAM) for the potential treatment of cognitive deficits

SUVN-I6107 is a potent and selective muscarinic M1 PAM with no agonist-like activity. It has excellent ADME properties and robust efficacy in preclinical animal models of cognition. In preclinical studies, no cholinergic side-effects like salivation, emesis or diarrhea were observed.

Current status: GLP toxicity studies initiated.

2) SUVN-M8036

Multimodal compound for the potential treatment of psychiatric disorders

SUVN-M8036 is the lead compound from the multimodal project with excellent affinity for serotonin and dopamine receptors. It has robust antidepressant effects in non-clinical models. The efficacy doses were devoid of motor impairment i.e. a clear separation between the doses which produced efficacy and side effects. SUVN-M8036 has excellent safety margin in the short term non-clinical safety studies.

Current status: Long-term and GLP toxicity studies are in the planning stage.



New CNS Therapies – Early stages

3) SUVN-D1044

5-HT₄ receptor agonist for the potential treatment of gastrointestinal disorders

SUVN-D1044 is potent and selective 5-HT₄ receptor agonist. It has excellent ADME properties and does not have brain penetration, a favourable feature for gastrointestinal disorders. It has robust efficacy in animal models of gastrointestinal disorders. SUVN-D1044 showed excellent safety margin in short-term non-clinical safety studies.

Current status: Long-term and GLP toxicity studies are in the planning stage.

4) 5-HT1A

Receptor-Partial Agonist: Potential treatment for depressive disorders

We are working on two chemically diverse novel series which are showing promise as 5-HT1A receptor partial agonist. Further structure activity relationship is ongoing. Preliminary preclinical covering in vitro affinity, pharmacokinetic profiling in rats and efficacy in depression models have been completed.

Current status: Hit to Lead stage.

5) Muscarinic 4 positive Allosteric Modulator (M4 PAM)

Potential treatment for psychosis

We are working on 2-3 chemically diverse novel series which are showing promise as M4 PAM. Further structure activity relationship is ongoing.

Current status: Hit to Lead stage.



Contact



Suven Life Sciences Ltd.

Serene Chambers, Road No. 5, Ave 5 Banjara Hills, Hyderabad 500034, India Tel: +91 40 2354 1142/3314 <u>www.suven.com</u> <u>Info@suven.com</u>

Suven Neurosciences, Inc.

1100 Cornwall Road, Suite 110 Monmouth Junction, New Jersey 08852, USA Tel: +1 732 274 0037

