

### **News Release**

# Suven Initiates Phase 2A trial of SUVN-502 in USA in Alzheimer's Disease

**HYDERABAD, INDIA (Dec 7, 2015)** – Suven Life Sciences, a clinical stage biopharmaceutical company developing novel medicines to treat life-threatening Central Nervous System (CNS) disorders, announced dose administration of the first patient in a Phase 2A clinical trial of SUVN-502, a 5HT6 antagonist in patients with moderate Alzheimer's Disease (AD). The clinical development program being executed through Suven, Inc., a Delaware Company in USA, wholly owned subsidiary of Suven Life Sciences.

This trial is designed to evaluate the safety, tolerability, pharmacokinetics and efficacy of SUVN-502 for the treatment of moderate Alzheimer's Disease (AD). disease treatments is among the most important health needs worldwide, but presents huge challenges.

This trial is expected to enroll 537 patients and the primary objective of the study is 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 (HCl) and the N-methyl-D-aspartic acid (NMDA) antagonist, MemantineHCl. Efficacy will be assessed by the 11-item Alzheimer's Disease Assessment Scale for Cognitive Behavior (ADAScog-11) after 26 weeks of treatment. The trial is likely to complete by end of second quarter 2017, subject to the achievement of estimated 12 months' enrollment goal in USA.

Secondary objectives are to further evaluate the efficacy of these treatments using the following scales:

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).

This study is being coordinated by Dr. Jeffrey Cummings, MD, Director, Cleveland Clinic Lou Ruvo Center for Brain Health, Las Vegas, NV, USA.

#### About SUVN-502

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 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.

## **About Alzheimer's Disease**

Alzheimer's disease occupies the highest unmet medical needs with an estimated global population of 26 million. Around 5.3 million affected people in US alone in 2015, with women aged 65 and above, occupying almost 2/3 of the total affected population. Alzheimer's disease accounts for 60 to 80 percent of dementia and is the sixth leading cause of death in the United States.

Alzheimer's is a type of dementia that causes problems with memory, thinking and behavior. Alzheimer's is not a normal part of aging and worsens over time. Alzheimer's has no current cure.

The current \$10 Billion market size of Alzheimer's is likely to triple in 8 to 10 years in USA and with a major impact on indirect cost estimated to be more than triple from the current level of \$225 Billion in United States alone.

#### About Suven Life Sciences Ltd:

Suven Life Sciences Ltd, Hyderabad, an Indian biopharmaceutical company is a public listed, traded on Bombay Stock Exchange and National stock exchange in India. Suven, a successful and dividend paying company is in existence for over 26 years, involved in path breaking business model "CRAMS" (Contract Research and Manufacturing Services) offering services to global pharma companies. Revenues earned out of this business model are used for funding CNS based drug discovery and development programs for the past 10 years.

Suven discovery research programs are focused on discovering and developing novel pharmaceutical products, which are first in class or best in class CNS therapies through the use of GPCR targets. At this point of time, Suven has a pipeline of 13 compounds for 27 inventions with 750+ granted product patents, all of them focused on diseases under Central Nervous System disorders.

Suven has 3 clinical stage compounds, a Phase 2 initiated candidate SUVN-502, Phase 1 completed candidate SUVN-G3031 and Phase 1 initiated candidate SUVN-D-4010 for Alzheimer's disease and Schizophrenia. In addition, the Company has ten (10) internally-discovered therapeutic drug candidates currently in pre-clinical stage of development targeting conditions such as ADHD, dementia, depression, Huntington's disease, Parkinson's disease and pain.

"We are very pleased with our first molecule entering Phase 2A clinical trial in USA and we are exited to announce this major milestone in the history of Suven Discovery. Suven has a pipeline of molecules in CNS arena that are being developed for cognitive disorders with high unmet medical need with huge market potential globally" says Venkat Jasti, CEO of Suven.

For more information please visit our Web site at <a href="http://www.suven.com">http://www.suven.com</a>

## 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;