

# **News Release**

### SUVEN receives EIR from US FDA for its Pashamylaram facility

**HYDERABAD, INDIA (Dec 19, 2019)** – Suven Life Sciences Limited an ISO 9001, ISO 14001 and OHSAS 18001 company has undergone **US FDA renewal** inspection at their facility in **Pashamylaram** near Hyderabad for the manufacture and supply of active pharmaceutical ingredients (bulk drugs), intermediates and formulations under cGMP during **Oct 21**<sup>st</sup> **through Nov 1**<sup>st</sup>, **2019**.

Based on this FDA inspection and the review thereafter, FDA has determined that the inspection classification of this facility is "voluntary action indicated" ("VAI").

Also FDA has concluded that this inspection is "closed" under 21CFR20.64 (d) (3) and the agency has issued an Establishment Inspection Report (EIR) for Suven facility at Pashamylaram.

So far Suven Life Sciences has filed 22 DMF's , 6 ANDA's and 2 ANADA's from this facility which is FDA complaint under cGMP and continued after renewal inspection.

**Suven Life Sciences is a Hyderabad based biopharmaceutical company, a pioneer** in Contract Research and Manufacturing Services **(CRAMS) since 1995 and Drug Discovery and Development** since 2005.

**Suven's Drug Discovery** program is focused on discovering, developing and commercializing novel pharmaceutical products, which are **first in class or best in class CNS therapies** through the use of GPCR targets. **Suven has 4 clinical stage compounds**, a Phase 2 completed SUVN-502, Phase 2 undergoing SUVN-G3031, Phase 1 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 Alzheimer's disease, ADHD, dementia, depression, Huntington's disease, Parkinson's disease, pain and sleep disorders.

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

#### 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.

## Suven Life Sciences Limited

Registered Office: 8-2-334 I SDE Serene Chambers I 6th Floor Road No.5 I Avenue 7 Banjara Hills I Hyderabad – 500 034 I Telangana I India I CIN: L24110TG1989PLC009713 Tel: 91 40 2354 1142/ 3311/ 3315 Fax: 91 40 2354 1152 Email: info@suven.com website: www.suven.com