

## **Laurus Labs receives USFDA tentative approval for Tenofovir/Lamivudine/Dolutegravir (TLD) 300/300/50mg Tablets.**

***And also received an EIR from USFDA for its Unit 6***

**Hyderabad, February 03, 2019, Laurus Labs Ltd. (BSE: 540222, NSE: LAURUSLABS, ISIN: INE947Q01010)**

Laurus Labs Ltd is pleased to announce that the Company has received tentative approval from United States Food and Drug Administration (US FDA) under PEPFAR for Tenofovir/Lamivudine/Dolutegravir (TLD) 300/300/50mg fixed dose combination (FDC).

The TLD product will be available in the Generic form in low and middle income countries (LMIC). TLD is the preferred treatment recommended by US department of Health and Human Services Panel and also WHO has recommended TLD as one of the preferred first line regimen for the treatment of people living with HIV.

Laurus Labs expects to commercialise this important medicine in the access markets and the product will be manufactured from the company's Unit 2 located at APSEZ, Atchutapuram, Visakhapatnam, Andhra Pradesh.

Laurus Labs also received an Establishment Inspection Report (EIR) from USFDA for its Unit 6 on February 2, 2019. The manufacturing unit 6 was inspected by the regulatory agency in the month of November 2018 and is located at APSEZ, Atchutapuram, Visakhapatnam, Andhra Pradesh.

Commenting on the USFDA approval, Dr.Satyanarayana Chava, Founder and CEO, Laurus Labs said "it is a significant approval for Laurus Labs which has forayed into finished dosage forms recently. This product would demonstrate the company's capability to develop fixed dose combinations of ARVs. And we are also happy to announce that we have received an EIR from the USFDA for our unit 6 which was inspected by the agency in the month of November 2018."

#### **About Laurus Labs Limited:**

Laurus Labs is a leading research & development driven and fully integrated pharmaceutical company in India. The Company has grown consistently to become one of the leading manufacturers of Active Pharmaceutical Ingredients (APIs) for anti-retroviral (ARV) and Hepatitis C. Laurus also manufactures APIs in Oncology and other therapeutic areas. Its strategic and early investments in R&D and manufacturing infrastructure have enabled it to become one of the leading suppliers of APIs in the ARV therapeutic area. The company has also ventured into develop a Finished Dosages Forms on the back of existing strengths in APIs with a current capacity of 5 billion units per year, expandable up to 8 billion units per year. The Company is also driving growth opportunities in the Synthesis and Ingredients businesses. Corporate Identification No: L24239AP2005PLC047518.

For more information about us, please visit <http://www.lauruslabs.com> or Contact particulars:

**Pavan Kumar N**  
**Laurus Labs Ltd.**

**Tel: +91 40 3980 4380**

**Email: [mediarelations@lauruslabs.com](mailto:mediarelations@lauruslabs.com)**



#### **DISCLAIMER:**

Certain statements in this document may be forward-looking statements. Such forward-looking statements are subject to certain risks and uncertainties like regulatory changes, local political or economic developments and many other factors that could cause our actual results to differ materially from those contemplated by the relevant forward-looking statements. Laurus Labs Limited (Laurus) will not be in any way responsible for any action taken based on such statements and undertakes no obligation to publicly update these forward-looking statements to reflect subsequent events or circumstances.

**FEBRUARY 03, 2019**

**Press Release**