



June 30, 2021

BSE Limited

Department of Corporate Services,
P. J. Towers, Dalal Street,
Mumbai Samachar Marg,
MUMBAI - 400 001.

✓ **National Stock Exchange of India Limited**

Exchange Plaza,
Bandra Kurla Complex,
Bandra (East),
MUMBAI - 400 051.

Sub: Disclosure pursuant to Regulation 30 of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015.

Dear Sir/Madam,

Enclosed is a Press Release as regards receipt of tentative approval from the U.S. FDA under the U.S. President's Emergency Plan for AIDS Relief for the Company's New Drug Application for Dolutegravir, Lamivudine and Tenofovir Disoproxil Fumarate (TLD) Tablets, 50 mg/300 mg/300 mg, and antiretroviral Fixed Dose Combination.

This may kindly be considered as a disclosure pursuant to Regulation 30 of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015.

Thanking you,

FOR LUPIN LIMITED

**R. V. SATAM
COMPANY SECRETARY
(ACS -1 1973)**

Encl- : a/a.

Lupin Receives Tentative U.S. FDA Approval for Dolutegravir, Lamivudine and Tenofovir Disoproxil Fumarate (TLD) Tablets under PEPFAR

Mumbai, Baltimore, June 30, 2021: Global pharma major Lupin Limited (Lupin) today announced that it has received tentative approval from the United States Food and Drug Administration (FDA) under the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) for its New Drug Application for Dolutegravir, Lamivudine and Tenofovir Disoproxil Fumarate (TLD) Tablets, 50 mg/300 mg/300 mg, and antiretroviral Fixed Dose Combination (FDC). This product would be manufactured at Lupin's Nagpur facility in India.

TLD is recommended by World Health Organisation (WHO), the U.S. Agency for International Development (USAID), and PEPFAR as a preferred first-line treatment regimen for the treatment of HIV in adults and pediatric patients weighing at least 35 kg, and will be available for supplies to low-and-middle-income countries (LMIC).

Commenting on the USFDA tentative approval, **Mr. Naresh Gupta, President, API Plus, Lupin** said "I am delighted that we have received FDA's tentative approval for TLD. It is a significant approval for Lupin which has recently forayed into HIV business arena. We have a deep commitment to increasing access to quality and affordable treatment options for low-and-middle-income countries for decades. Being integrated with in-house manufacture of APIs and formulations gives us an opportunity to provide quality products and uninterrupted supplies for affordable access for patients in these countries."

About Lupin

Lupin is an innovation-led transnational pharmaceutical company headquartered in Mumbai, India. The Company develops and commercializes a wide range of branded and generic formulations, biotechnology products and APIs in over 100 markets in the U.S., India, South Africa and across Asia Pacific (APAC), Latin America (LATAM), Europe and Middle-East regions.

The Company enjoys leadership position in the cardiovascular, anti-diabetic, and respiratory segments and has significant presence in the anti-infective, gastro-intestinal (GI), central nervous system (CNS) and women's health areas. Lupin is the third largest pharmaceutical company in the U.S. by prescriptions. The company invested 9.6% of its revenue on research and development in FY21.

Lupin has 15 manufacturing sites, 7 research centres, more than 20,000 professionals working globally, and has been consistently recognized as a 'Great Place to Work' in the Biotechnology & Pharmaceuticals sector.

Please visit www.lupin.com for more information.

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Facebook: <http://www.facebook.com/LupinWorld/>



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For further information or queries please contact –

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[**Safe Harbor Statement*](#)