



March 23, 2023

BSE Limited

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

✓ **National Stock Exchange of India Limited**

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

Dear Sir/Madam,

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

We are pleased to enclose a Press Release as regards, receipt of tentative U.S. FDA approval for Company's Abbreviated new Drug Application, Obeticholic Acid Tablets, 5 mg and 10 mg, to market a generic equivalent of Ocaliva® Tablets, 5 mg and 10 mg, of Intercept Pharmaceuticals, Inc.

This may kindly be considered as a disclosure pursuant to Regulation 30 of the Listing Regulations.

The above is for your information and dissemination.

Thanking you,

For LUPIN LIMITED

R. V. SATAM
COMPANY SECRETARY
(ACS - 11973)

Encl: a/a



BSE: 500257

NSE: LUPIN

REUTERS: LUPIN.BO

BLOOMBERG: LPCIN

Lupin Receives Tentative Approval from U.S. FDA for Obeticholic Acid Tablets

Mumbai, Baltimore, March 23, 2023: Global pharma major Lupin Limited (Lupin) today announced that it has received tentative approval from the United States Food and Drug Administration (U.S. FDA) for its Abbreviated New Drug Application (ANDA), Obeticholic Acid Tablets, 5 mg and 10 mg, to market a generic equivalent of Ocaliva® Tablets, 5 mg and 10 mg, of Intercept Pharmaceuticals, Inc.

Obeticholic Acid Tablets (RLD Ocaliva®) had estimated annual sales of USD 255 million in the U.S. (IQVIA MAT December 2022).

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 the Asia Pacific (APAC), Latin America (LATAM), Europe, and Middle East regions.

The Company enjoys a leadership position in the cardiovascular, anti-diabetic, and respiratory segments and has a 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 8.7% of its revenue in research and development in FY22.

Lupin has 15 manufacturing sites, 7 research centers, 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.

Follow us on Twitter: <https://twitter.com/LupinGlobal> | LinkedIn: <https://www.linkedin.com/company/lupin>

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

For further information or queries please contact –

Shweta Munjal

Vice President & Global Head – Corporate Communications

Email: shwetamunjal@lupin.com

***Safe Harbor Statement**

Ocaliva® is a registered trademark of Intercept Pharmaceuticals, Inc.