

June 21, 2023

**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.**

*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 revised Press release regarding receipt of approval from the U.S. FDA for the Company's Abbreviated New Drug Application for Tiotropium Bromide Inhalation Powder, 18 mcg/capsule, a generic equivalent of Spiriva® HandiHaler® (Tiotropium Bromide Inhalation Powder), 18 mcg/capsule of Boehringer Ingelheim Pharmaceuticals, Inc.

This may kindly considered as a disclosure pursuant to Regulation 30 of SEBI 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**



**LUPIN**

## Lupin Receives Approval from U.S. FDA for Tiotropium Dry Powder Inhaler

**Mumbai, Baltimore, June 21, 2023:** Global pharma major Lupin Limited (Lupin) today announced that it has received approval from the United States Food and Drug Administration (U.S. FDA) for its Abbreviated New Drug Application for Tiotropium Bromide Inhalation Powder, 18 mcg/capsule, a generic equivalent of Spiriva® HandiHaler® (Tiotropium Bromide Inhalation Powder), 18 mcg/capsule of Boehringer Ingelheim Pharmaceuticals, Inc. This product will be manufactured at Lupin’s Pithampur facility in India.

“We are delighted to receive the final approval for generic Spiriva® HandiHaler from the U.S. FDA. This builds on our commitment to serving unmet needs for our patients across the world. This is the first generic approval for Spiriva® HandiHaler in the U.S., and is also the first DPI approval from India for the U.S. This is an important milestone in our journey of building our respiratory franchise globally,” **said Vinita Gupta, CEO, Lupin.**

Tiotropium Bromide Inhalation Powder (Spiriva® HandiHaler®) had estimated annual sales of USD 1,264 million in the U.S. (IQVIA MAT Mar 2023).

### 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 7.9% of its revenue in research and development in FY23.

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](http://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 –**



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REUTERS: LUPIN.BO

BLOOMBERG: LPCIN

**Shweta Munjal**

Vice President & Global Head – Corporate Communications

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***\*Safe Harbor Statement***

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