



February 16, 2024

**BSE Limited**

Department of Corporate Services,  
P. J. Towers,  
Dalai 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 regarding receipt of approval from the U.S. FDA for the Company's Abbreviated New Drug Application for Minzoya™ (Levonorgestrel and Ethinyl Estradiol Tablets, USP and Ferrous Bisglycinate Tablets), 0.1 mg/0.02 mg and 36.5 mg, to market a generic equivalent of Balcoltra® (Levonorgestrel and Ethinyl Estradiol Tablets, USP and Ferrous Bisglycinate Tablets) 0.1mg/0.02 mg and 36.5 mg, of Avion Pharmaceuticals LLC.

The above may kindly be considered as 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**

## Lupin Receives Approval from U.S. FDA for Minzoya™ (Levonorgestrel and Ethinyl Estradiol Tablets, USP and Ferrous Bisglycinate Tablets)

**Mumbai, Baltimore, February 16, 2024:** 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 Minzoya™ (Levonorgestrel and Ethinyl Estradiol Tablets, USP and Ferrous Bisglycinate Tablets), 0.1 mg/0.02 mg and 36.5 mg, to market a generic equivalent of Balcoltra® (Levonorgestrel and Ethinyl Estradiol Tablets, USP and Ferrous Bisglycinate Tablets) 0.1 mg/0.02 mg and 36.5 mg, of Avion Pharmaceuticals LLC. The product will be manufactured at Lupin's Pithampur facility in India.

Minzoya™ Tablets are indicated for use by females of reproductive potential to prevent pregnancy.

Levonorgestrel and Ethinyl Estradiol Tablets, USP and Ferrous Bisglycinate Tablets (RLD Balcoltra®) had estimated annual sales of USD 42 million in the U.S. (IQVIA MAT December 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.

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**For further information or queries please contact –  
Heena Dhedhi**

Deputy General Manager - Corporate Communications

Email: [heenadhedhi@lupin.com](mailto:heenadhedhi@lupin.com)

### \*Safe Harbor Statement

Balcoltra® is a registered trademark of Avion Pharmaceuticals, LLC.