



GLAND PHARMA LIMITED

April 29, 2024

BSE Limited
Corporate Relationship Department
Phiroze Jeejeebhoy Towers
25th floor, Dalal Street
Mumbai - 400 001
Scrip Code: 543245

National Stock Exchange of India Limited
Listing Department
Exchange Plaza, 5th floor
Plot no. C-1, Block G, Bandra Kurla Complex
Bandra (East), Mumbai - 400 051
Symbol: GLAND (ISIN: INE068V01023)

Dear Sir/Madam,

Sub: Press Release - Gland Pharma receives approval from the United States Food and Drug Administration (US FDA) for Cetorelix Acetate for Injection, 0.25 mg/vial, Single-Dose Vial

Pursuant to Regulation 30 read with Part A of Schedule III of the Securities and Exchange Board of India (Listing Obligations and Disclosure Requirements) Regulations, 2015; please find attached announcement regarding the receipt of US FDA approval for Cetorelix Acetate for Injection, 0.25 mg/vial, Single-Dose Vial.

This is for your information and records.

Yours truly,

For Gland Pharma Limited

Sampath Kumar Pallerlamudi
Company Secretary and Compliance Officer

Encl: As above



Gland Pharma receives approval for Cetrorelix Acetate for Injection

Hyderabad, April 29, 2024: Gland Pharma Limited (Gland or Company), a generic injectable-focused pharmaceutical company, has received approval from the United States Food and Drug Administration (USFDA) for Cetrorelix Acetate for Injection, 0.25 mg/vial, Single-Dose Vial (Product).

The Product is bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Cetrotide for Injection, 0.25 mg/vial, of EMD Serono, Inc.

The Company expects to launch this Product in the near-term through its marketing partner. According to IQVIA, the product had US sales of approximately USD 129 million for the twelve months ending February 2024.

Cetrorelix Acetate for Injection is used to prevent premature LH surges in women undergoing controlled ovarian stimulation. It blocks the effects of a natural hormone called gonadotropin-releasing hormone (GnRH), which controls the secretion of another hormone called luteinizing hormone (LH), which induces ovulation during the menstrual cycle.

Cetrorelix further expands the company's fertility product line, underscoring its commitment to developing and manufacturing complex injectables to meet patients' unmet needs.

About Gland Pharma Limited (BSE: 543245, NSE: GLAND)

Gland Pharma was established in 1978 in Hyderabad and has grown over the years from a contract manufacturer of small-volume liquid parenteral products to become one of the largest injectable-focused companies, with a global footprint across 60 countries, including the United States, Europe, Canada, Australia, India, and other markets. It operates primarily under a business-to-business (B2B) model and has an excellent track record in developing, manufacturing, and marketing sterile injectables. It has a wide range of injectables, including vials, ampoules, pre-filled syringes, lyophilized vials, dry powders, infusions, oncology, and ophthalmic solutions. It also enjoys the distinction of having pioneered Heparin technology in India. For more information, log on to: www.glandpharma.com

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