



GLAND PHARMA LIMITED

May 07, 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 Plerixafor Injection, 24 mg/1.2 mL (20 mg/mL), 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 Plerixafor Injection, 24 mg/1.2 mL (20 mg/mL), 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 Plerixafor for Injection

Hyderabad, May 07, 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 **Plerixafor Injection, 24 mg/1.2 mL (20 mg/mL)**, Single-Dose Vial (Product).

The Product is bioequivalent and therapeutically equivalent to the reference listed drug (RLD), MOZOBIL® (plerixafor) injection of Genzyme Corporation, a Sanofi Company.

The Product is a hematopoietic stem cell mobilizer indicated in combination with filgrastim to mobilize hematopoietic stem cells (HSCs) to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin's lymphoma or multiple myeloma.

The Company expects to launch this Product through its marketing partner within FY25. According to IQVIA, the product had US sales of approximately USD 152 million for the twelve months ending January 2024.

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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This press release may include statements of future expectations and other forward-looking statements based on management's current expectations and beliefs. Actual results may vary materially from those expressed or implied by the statements herein due to changes in economic, business, competitive, technological, and/or regulatory factors. Gland Pharma Limited, its directors and any of the affiliates or employee is under no obligation to, and expressly assume any obligation to update any particular forward-looking statement contained in this release.