



GLAND PHARMA LIMITED

July 23, 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 tentative approval from the United States Food and Drug Administration (US FDA) for Latanoprostene Bunod Ophthalmic Solution, 0.024%

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 tentative approval for Latanoprostene Bunod Ophthalmic Solution, 0.024%.

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 Tentative Approval from the USFDA for Latanoprostene Bunod Ophthalmic Solution

Hyderabad, July 23, 2024: Gland Pharma Limited (Gland or Company), a generic injectable-focused pharmaceutical company, has received tentative approval from the United States Food and Drug Administration (USFDA) for **Latanoprostene Bunod Ophthalmic Solution, 0.024%**.

The Product is bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Vyzulta® Ophthalmic Solution, 0.024%, registered by Bausch & Lomb Inc. (Bausch & Lomb).

Based on the available updates, the Company believes that it is the first applicant to have filed its ANDA with Paragraph IV certification. Upon final approval, the Company may be eligible for 180 days of generic drug exclusivity.

Latanoprostene Bunod Ophthalmic Solution, 0.024%, is indicated for reducing elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. According to IQVIA, the product had US sales of approximately USD 153 million for the twelve months ended December 2023.

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 economic, business, competitive, technological, and/or regulatory factors changes. Gland Pharma Limited, its directors, and any of the affiliates or employees are under no obligation to, and expressly assume, any obligation to update any particular forward-looking statement contained in this release.