



GLAND PHARMA LIMITED

April 03, 2025

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 Acetaminophen Injection, 10 mg/mL (500mg/50mL and 1000mg/100mL) Bags

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 **Acetaminophen Injection, 10 mg/mL (500mg/50mL and 1000mg/100mL) Bags**.

This is for your information and records.

Yours truly,

For Gland Pharma Limited

**Sampath Kumar Pallerlamudi
Company Secretary & Compliance Officer**

Encl: As above



Gland Pharma receives approval for Acetaminophen Injection

Hyderabad, April 03, 2025: 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 **Acetaminophen Injection, 10 mg/mL (500mg/50mL and 1000mg/100mL) Bags.**

The Product is bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Acetaminophen Injection, 500 mg/50 mL (10 mg/mL) and 1000 mg/100 mL (10 mg/mL), of B. Braun Medical, Inc.

This Product is indicated for the management of mild to moderate pain in adult and pediatric patients 2 years and older, as well as moderate to severe pain with adjunctive opioid analgesics in adult and pediatric patients 2 years and older.

The Company expects to launch this Product through its marketing partner in the near future. According to IQVIA, the product had US sales of approximately USD 55 million for the twelve months ending February 2025.

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

For investor queries, please mail us at investors@glandpharma.com

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.