



# GLAND PHARMA LIMITED

May 07, 2024

BSE Limited  
Corporate Relationship Department  
Phiroze Jeejeebhoy Towers  
25<sup>th</sup> 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 Edaravone Injection, 30 mg/100 mL (0.3 mg/mL) and 60 mg/100 mL (0.6 mg/mL), Single-Dose 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 Edaravone Injection, 30 mg/100 mL (0.3 mg/mL) and 60 mg/100 mL (0.6 mg/mL), Single-Dose Bags.

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 Edaravone 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 **Edaravone Injection, 30 mg/100 mL (0.3 mg/mL) and 60 mg/100 mL (0.6 mg/mL), Single-Dose Bags.**

The Product is bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Radicava Injection, 30 mg/100 mL (0.3 mg/mL) and 60 mg/100 mL (0.6 mg/mL) of Mitsubishi Tanabe Pharma Corporation.

The Product is used to treat amyotrophic lateral sclerosis (ALS), a condition in which the nerves that control muscle movement slowly die, causing the muscles to shrink and weaken.

The Company expects to launch this Product through its marketing partner within FY25. According to IQVIA, the product had US sales of approximately USD 19 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](http://www.glandpharma.com)

### **Contacts:**

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