



GLAND PHARMA LIMITED

October 8, 2021

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: Product Tentative Approval

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 Sugammadex Injection, 200 mg/2 mL (100 mg/mL) and 500 mg/5 mL (100 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



Gland Pharma receives Tentative Approval for Sugammadex Injection

Hyderabad, October 08, 2021: Gland Pharma Limited, a generic injectable focused pharmaceutical company, received tentative approval from the United States Food and Drug Administration (US FDA) for Sugammadex Injection, 200 mg/2 mL (100 mg/mL) and 500 mg/5 mL (100 mg/mL) Single-Dose Vial, bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Bridion[®] Injection, 100 mg/mL, of Merck Sharp & Dohme Corp. (Merck Sharp & Dohme).

Sugammadex Injection is used to reverse the effects of the muscle relaxants Rocuronium Bromide and Vecuronium Bromide given to patients during surgery.

Gland Pharma will launch the product through its marketing partner on receipt of final approval.

The Sugammadex Injection, 200 mg/2 mL and 500 mg/5 mL Single-Dose Vial (RLD: Bridion[®]) has US sales of approximately USD 615 million for twelve months ending in April 2021, according to IQVIA.

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

Gland Pharma was established in 1978 in Hyderabad, has grown over the years from a contract manufacturer of small volume liquid parenteral products, to become one of the largest and fastest growing 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 have an excellent track record in the development, manufacturing and marketing of sterile injectables. It has a wide range of injectables, including vials, ampoules, pre-filled syringes, lyophilized vials, dry powders, infusions, oncology and ophthalmic solutions and also enjoys the distinction of having pioneered Heparin technology in India. For more information, log on to: www.glandpharma.com

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