



GLAND PHARMA LIMITED

April 22, 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 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 regards to the receipt of US FDA approval for Foscarnet Sodium Injection, 6000 mg/250 mL (24 mg/mL) Single-Dose Bag for Infusion.

This is for your information and records.

Yours truly,

For Gland Pharma Limited



Sampath Kumar Pallerlamudi
Company Secretary



Gland Pharma received approval for generic Foscarnet Sodium Injection, Single- Dose Bag for Infusion

Hyderabad, April 22, 2021: Gland Pharma Limited (BSE: 543245 | NSE: GLAND), a generic injectable focused pharmaceutical company, received approval from the United States Food and Drug Administration (US FDA) for generic Foscarnet Sodium Injection, 6000 mg/250 mL (24 mg/mL) Single-Dose Bag for Infusion. Generic Foscarnet Sodium Injection is the bioequivalent and therapeutically equivalent to the Reference Listed Drug (RLD), Foscavir® Injection, 24 mg/mL, of Clinigen Healthcare Limited. With this approval, Gland Pharma secured the first generic offering status in Single-Dose Bag for Infusion.

Gland Pharma Limited (Gland Pharma) was granted a Competitive Generic Therapy (CGT) designation for Foscarnet Sodium Injection as it is the “first approved applicant” for such competitive generic therapy, as per US FDA norms and therefore, is eligible for 180 days of CGT exclusivity. This exclusivity will begin only after commercial launch date and as per criteria set out by US FDA.

Gland Pharma is backward integrated with in-house API source for this product.

Foscarnet Sodium Injection is indicated for the treatment of cytomegalovirus (CMV) retinitis in patients with acquired immunodeficiency syndrome (AIDS). It is also used for the treatment of acyclovir-resistant mucocutaneous herpes simplex virus (HSV) infections in immunocompromised patients.

The Foscarnet Sodium Injection, 6000 mg/250 mL (24 mg/mL) and its generic equivalents had US sales of approximately USD 28 million for twelve months ending in January 2021, according to IQVIA.

Gland Pharma intends to supply this product globally and recently launched the product in the Canadian market. Global markets size is estimated to be USD 50 million.

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 complex 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.

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