Gland Pharma Secures USFDA Approval for Methylprednisolone Injection with USD 214 Million US Market Potential

New Delhi: Gland Pharma Limited (Gland or Company), a generic injectable & ophthalmic focused pharmaceutical company, has received approval from the United States Food and Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) filed for Methylprednisolone Acetate Injectable Suspension USP, 40 mg/mL and 80 mg/mL Single-Dose Vials and 200 mg/5 mL (40 mg/mL), 400 mg/10 mL (40 mg/mL), and 400 mg/5 mL (80 mg/mL) Multiple-Dose Vials.

The Product is bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Depo-Medrol Injectable Suspension, 40 mg/mL and 80 mg/mL, of Pfizer Inc.

The Product is indicated for the treatment of Allergic States, Dermatologic Diseases, Endocrine Disorders,Gastrointestinal Diseases, Hematologic Disorders, Neoplastic Diseases, Nervous System, Ophthalmic Diseases, Renal Diseases, Respiratory Diseases, Rheumatic Disorders and Miscellaneous.

According to IQVIA, the Methylprednisolone injection had US sales of approximately USD 214 million for the twelve months ending August 2026.

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.

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