

Press Release

For Immediate Release

Glenmark Pharmaceuticals' partner Elite Pharmaceuticals receives US FDA approval for generic methadone hydrochloride tablets

- Glenmark will sell and distribute the product in the US

Mumbai, India, August 7, 2018: Glenmark Pharmaceuticals Ltd, a research-based global integrated pharmaceutical company, announced today that its partner Elite Pharmaceuticals, Inc., a US specialty pharmaceutical company, has received approval from the U.S. Food and Drug Administration (FDA) for the abbreviated new drug application (ANDA) for methadone hydrochloride 5 mg and 10 mg tablets.

Methadone is indicated for the management of pain severe enough to require daily, around-the-clock long-term opioid treatment and for which alternative treatment options are inadequate. Methadone can also be used for maintenance treatment of opioid addiction (heroin or other morphine-like drugs) in conjunction with appropriate social and medical services.

Glenmark Pharmaceuticals, Inc., Elite's marketing alliance partner, will sell and distribute methadone for Elite for which Elite will receive manufacturing and license fees. Based on QuintilesIMS Health data, the annual retail sales for the brand and generic products were approximately \$30 million.

About Glenmark Pharmaceuticals Ltd:

Glenmark Pharmaceuticals Ltd. (GPL) is a research-driven, global, integrated pharmaceutical organization. It is ranked among the top 75 Pharma & Biotech companies of the world in terms of revenue (SCRIP 100 Rankings published in the year 2017). Glenmark is a leading player in the discovery of new molecules both NCEs (new chemical entity) and NBEs (new biological entity). Glenmark has several molecules in various stages of clinical development and is focused in the areas of oncology, dermatology and respiratory.

The company has a significant presence in the branded generics markets across emerging economies including India. Glenmark has 16 manufacturing facilities across five countries and has six R&D centers. The Generics business of Glenmark services the requirements of the US and Western European markets. The API business sells its products in over 80 countries, including the US, various countries in the EU, South America and India.

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