Glenmark Pharmaceuticals Ltd.

Press Release



For Immediate Dissemination

Glenmark receives approval for generic Seretide® in Russia

~ Enters the inhaler market in Russia with approval of Salmecort (Salmeterol + Fluticasone) MDI inhaler~

Mumbai, March 12, 2015: Glenmark Pharmaceuticals Limited, the research-led global integrated pharmaceutical company announced today that it has received approval for Salmecort (Salmeterol+Fluticasone) MDI inhaler, from the Ministry of Health (MoH), Russia. The combination preparation contains salmeterol xinafoate and fluticasone propionate, used in the management of asthma and chronic obstructive pulmonary disease (COPD). The approval is for 25mcg+50mcg/dose, 25 mcg + 125 mcg/dose and 25 mcg + 250 mcg/dose formulation strengths.

The approval marks Glenmark's entry into the respiratory inhaler market in Russia. According to IMS, the total inhaler market in Russia is estimated to be around USD 283 million, out of which the total MDI market is valued at around USD 107 million. Salmecort is expected to be available in the Russian market in Q2 FY 2015-16.

"We want to be a significant player in the respiratory space in emerging markets and hence the generic Seretide[®] approval (Salmecort) in Russia, one of the key countries for the company, is an important development for the organisation." **said Glenn Saldanha, Chairman & MD – Glenmark**. "The R&D in vitro equivalence for generic Seretide[®]; as well as the chemistry manufacturing and control (CMC) development were extremely challenging and hence it's a great testimony of our cutting edge R&D capabilities"; **he added**.

In addition to generic Seretide[®], Glenmark has also received a couple of other key product approvals such as Oflomil nail lacquer, which is the first generic of Loceryl in the Russian market and Sertamycol (sertaconazole) cream in FY 2014-15. The company also launched Kerawort (topical imiquimod, generic of Aldara) in the Russian market in FY 2014-15.

"We are delighted to make an entry into the respiratory inhaler space in the country with the launch of the generic version of this innovative block buster drug. Respiratory along with dermatology are focus therapeutic segments for Glenmark Russia and the launch of Salmecort will further strengthen our equity in this niche category,"- **stated Elena Astakhova, General Director & Country Manager – Glenmark Russia.**

Glenmark has already launched generic Seretide[®] in a host of emerging markets like Mexico and Philippines.



About Glenmark

Glenmark Pharmaceuticals Ltd. (GPL) is a research-driven, global, integrated pharmaceutical company headquartered at Mumbai, India. It is ranked among the top 80 Pharma& Biotech companies of the world in terms of revenues. (SCRIP 100 Rankings published in the year 2014). 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 primarily focused in the areas of Inflammation [asthma/COPD, rheumatoid arthritis etc.] and Pain [neuropathic pain and inflammatory pain].

The company has a significant presence in branded generics markets across emerging economies including India. GPL along with its subsidiary has 14 manufacturing facilities in four countries and has six R&D centers. Its subsidiary, Glenmark Generics Limited services the requirements of the US and Western Europe generics 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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