Glenmark Pharmaceuticals Ltd.



Press Release

For Immediate Release

Glenmark announces grant of substitution and successful launch of generic Seretide® Accuhaler® in Denmark

- This is Glenmark's first inhaled respiratory product launch in Europe
- Glenmark has secured National Marketing Authorizations for the product in Sweden,
 Finland, Norway and Iceland
- The product was developed by Celon Pharma, and Glenmark has marketing & distribution rights for the product across 15 European countries

Mumbai, India; May 16, 2018: Glenmark Pharmaceuticals Europe Ltd. (Glenmark) today announced that it has launched a generic version of Seretide® Accuhaler® in Denmark. This is Glenmark's first inhaled respiratory product launch in Europe.

Glenmark is the first generic company to receive regulatory approval for substitution in Denmark for its generic of Seretide® Accuhaler®

Glenmark had entered into a strategic development & licensing agreement with Celon Pharma S.A. (Celon) to develop and market a generic version of GlaxoSmithKline's Seretide Accuhaler® product - Fluticasone/Salmeterol dry powder inhaler in 15 European countries. Fluticasone/Salmeterol dry powder inhaler is a combination product for the treatment of asthma and chronic obstructive pulmonary disease (COPD).

Glenmark has already received National Marketing Authorizations for the product in Sweden, Finland, Norway and Iceland.

"Denmark is the first country in Europe where Glenmark has launched its generic Fluticasone/Salmeterol Dry powder Inhaler (DPI) and we plan to commercialize this product across the Nordics in the near future. The grant of substitution in Denmark for this complex product affirms Glenmark's capabilities in the respiratory segment," said Achin Gupta, Executive Vice President & Business Head of Europe and Latin America, Glenmark Pharmaceuticals Ltd.

According to IQVIA data, Fluticasone/Salmeterol Dry powder Inhaler (DPI) had sales of USD 864 million in Europe in the 12 month period ending September 2017.

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About Glenmark Pharmaceuticals

Glenmark Pharmaceuticals Ltd. (GPL) is a global innovative pharmaceutical company with operations in more than 50 countries. Glenmark has a diverse pipeline with several compounds in various stages of clinical development primarily focused in the areas of oncology, respiratory disease, and dermatology. Glenmark's current respiratory pipeline is aimed at addressing the global public health burden of allergic rhinitis, asthma, and COPD, and includes four investigational treatments across the disease spectrum and devices. Glenmark has improved the lives of millions of patients by offering safe, affordable medications for nearly 40 years. For more information visit www.glenmarkpharma.com.

About Celon Pharma S.A

Celon Pharma S.A. is an integrated pharmaceutical company which conducts advanced research and manufactures modern drugs. It was founded in 2002 by Maciej Wieczorek, PhD. The primary objective of the company is the manufacturing of specialist prescription drugs which improve quality of life of patients and constitute an answer to their unmet clinical needs. Celon Pharma S.A. has two fully equipped laboratories, dedicated to research and development (R&D) of medicinal products, both generic and innovative. Two of Celon Pharma S.A's production plants have appropriate GMP (Good Manufacturing Practice) authorisations. The main office and the laboratories are located within 30 km from the centre of Warsaw. The company currently has approx. 200 employees. It employs 50 scientists responsible for research and development.

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