Glenmark announces successful closure of the decentralised registration procedure (DCP) for generic Seretide® Accuhaler® in the Nordic region

- National Marketing Authorizations in Sweden, Finland, Denmark, Norway and Iceland are expected shortly
- This will be Glenmark’s first Inhaled respiratory product approval in Europe
- Awaiting Substitution and pricing approvals
- Product was developed by Celon, and Glenmark has Semi-exclusive Marketing & Distribution rights for the product across 15 European countries

MUMBAI, December 1, 2017 – : Glenmark Pharmaceuticals Europe Ltd. (Glenmark) today announced that it has successfully closed the decentralised registration procedure for generic Seretide® Accuhaler® in the Nordic region, including Sweden, Denmark, Norway, Finland and Iceland. This will be Glenmark’s first inhaled Respiratory product approval in Europe, and re-enforces Glenmark’s commitment in the respiratory area. The commercialization of the product would depend on national approval as well as substitution and pricing approvals.

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 Europe. This is the first approval from the deal, and marks the entry of Glenmark in the Respiratory Generic segment.

“Our successful registration closure of a complex respiratory product like Fluticasone/ Salmeterol Dry powder Inhaler (DPI) in a developed market re-enforces Glenmark’s capability and determination towards the respiratory segment. This continues to emphasize Glenmark’s focus in this complex product segment and in Europe.” said Glenn Saldanha, Chairman & MD, Glenmark Pharmaceuticals Limited. He further added ‘we will continue to work in the area of respiratory especially devices in Europe and we will continue to launch products in this area in future’
The Fluticasone / Salmeterol dry powder Inhaler is a combination product for the treatment of asthma and chronic obstructive pulmonary disease (COPD). Seretide® marketed by GlaxoSmithKline is among the top 3 pharmaceutical brands in Europe with sales of USD 1.1 billion as per IMS.

**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](http://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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