Hikma's ANDA for Generic Advair Diskus® accepted for filing by FDA

London, 8 April 2016 – Hikma Pharmaceuticals PLC (Hikma) (LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY), (rated Ba1 Moody's / BB+ S&P, both stable), the fast growing multinational pharmaceutical group, today confirms that its abbreviated new drug application (ANDA) for fluticasone propionate and salmeterol inhalation powder has been accepted for filing by the U.S. Food and Drug Administration (FDA).

The FDA provided Hikma, through its wholly-owned subsidiary, West-Ward Pharmaceuticals, a GDUFA goal date of May 10, 2017. This product is the generic version of GlaxoSmithKline's Advair Diskus®, which is indicated for the treatment of asthma and the maintenance treatment of airflow obstruction and reducing exacerbations in patients with chronic obstructive pulmonary disease (COPD) and is delivered using Vectura's proprietary dry powder inhaler and formulation technology.

Said Darwazah, Chairman and CEO of Hikma said, "We are very pleased to have achieved this important milestone in the development of generic Advair Diskus®. With our partner, Vectura, our team has worked closely with the FDA to ensure the quality of the ANDA submission. Our interactions with the FDA have helped clarify the requirements for the development of a robust, patient friendly, (AB-rated) substitutable generic product for Advair Diskus®. We look forward to bringing to market this very important product for patients."

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About Hikma
Hikma Pharmaceuticals PLC is a fast growing multinational group focused on developing, manufacturing and marketing a broad range of both branded and non-branded generic and in-licensed products. Hikma operates through three businesses: "Injectables", "Branded" and "Generics", based principally in the United States, the Middle East and North Africa (MENA) and Europe. In 2015, Hikma achieved revenues of $1,440 million and profit attributable to shareholders of $252 million.