Hikma provides an update on the status of its ANDA for generic Advair Diskus®

London, 11 May 2017 – 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 announces that it has received a complete response letter (CRL) from the US Food and Drug Administration (FDA) in relation to its abbreviated new drug application (ANDA) for its generic version of GlaxoSmithKline's Advair Diskus® (fluticasone propionate and salmeterol inhalation powder).

The FDA has categorised the CRL as 'Major'. Hikma is in the process of reviewing the response and will provide an update on its application as soon as practicable once it has completed its review of the CRL and discussed this with the FDA. Based on the initial assessment, no material issues were raised regarding the substitutability of the proposed device.

Given the nature of the feedback, Hikma believes there is a low likelihood of approval this year. Hikma is committed to bringing this important product to the US market and will work collaboratively with the FDA to address their outstanding questions.

Hikma's fluticasone propionate and salmeterol inhalation powder is indicated for the treatment of asthma and the maintenance treatment of airflow obstruction and reducing exacerbations in patients with chronic obstructive pulmonary disease and is delivered using Vectura's proprietary dry powder inhaler and formulation technology.

-- ENDS --

Enquiries

Investor Relations

Susan Ringdal, VP Corporate Strategy and Investor Relations	+44 (0)20 7399 2760/ +44 7776 477050
Lucinda Baker, Deputy Director of Investor Relations	+44 (0)20 7399 2765/ +44 7818 060211

Media

Brooke Clarke, VP Corporate Affairs	+44 (0)20 7399 2795/ +44 7970 338 250
Ben Atwell/ Matthew Cole, FTI Consulting	+44 (0)20 3727 1000

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 2016, Hikma achieved revenue of $1,950 million and profit attributable to shareholders of $155 million. In the United States, Hikma operates through its wholly owned subsidiary, West-Ward Pharmaceuticals Corp., with operations based in New Jersey, Ohio and Tennessee.