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

London, 12 March 2018 – Hikma Pharmaceuticals PLC (Hikma, Group) (LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY) (rated Ba1 Moody's / BB+ S&P, both stable) announces that it is has received a response from the United States 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).

On 11 May 2017, Hikma announced it had received a complete response letter (CRL) from the FDA. In the following months, Hikma worked collaboratively with the FDA and was able to address and clarify the majority of the questions raised. However, there remained an outstanding issue regarding the clinical endpoint study and, in response, the company decided to engage in the FDA's dispute resolution process.

The FDA has now concluded this process, upholding its original determination and requesting the completion of an additional clinical endpoint study. In anticipation of this as one of the potential outcomes, Hikma has already finalised the planning of a new clinical study and expects to start patient enrolment in the coming weeks. Hikma anticipates being able to submit a response to the FDA with new clinical data as early as possible in 2019.

Hikma remains committed to bringing this important product to the US market. 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.

About Hikma Hikma

Pharmaceuticals PLC is a pharmaceutical group focused on developing, manufacturing and marketing a broad range of both branded and non-branded generic and in-licensed products. Hikma's operations are conducted through three businesses: 'Branded', 'Injectables' and 'Generics' based primarily in the Middle East and North Africa (MENA), the United States and Europe.