

Hikma completes its FDA response for generic Advair®

London, 27 November, 2019 – Hikma Pharmaceuticals PLC (Hikma) (LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY) (rated Ba1/stable Moody's and BB+/positive S&P), the multinational pharmaceutical company, today announces that it has submitted to the US Food and Drug Administration (FDA) its response to deficiencies in its abbreviated new drug application (ANDA) for a generic version of GlaxoSmithKline's Advair Diskus® (fluticasone propionate and salmeterol inhalation powder).

Following receipt of a complete response letter (CRL) from the FDA, Hikma initiated a clinical endpoint study in 2018. This study has been completed and it, along with other information requested by the FDA, has been submitted to the FDA for review. The submission addresses the outstanding questions raised by the FDA in its CRL.

Siggi Olafsson, Chief Executive Officer of Hikma, said "Our team has worked extremely hard with Vectura to complete a large and challenging clinical study, which we believe demonstrates the safety and effectiveness of our product, and I am very pleased to have responded to the FDA. As we continue to develop our pipeline of complex generics, respiratory products are a key strategic focus for Hikma and our generic Advair submission is an important milestone. We are confident in our ability to bring a generic version of Advair to the US market, which would enable us to improve patient access to this important medicine."

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About Hikma

Hikma helps put better health within reach every day for millions of people in more than 50 countries around the world. For more than 40 years, we've been creating high-quality medicines and making them accessible to the people who need them. We are a global company with a local presence across the United States (US), the Middle East and North Africa (MENA) and Europe, and we use our unique insight and expertise to transform cutting-edge science into innovative solutions that transform people's lives. We're committed to our customers, and the people they care for, and by thinking creatively and acting practically, we provide them with a broad range of branded and non-branded generic medicines. Together, our 8,400 colleagues are helping to shape a healthier world that enriches all our communities. We are a leading licensing partner, and through our venture capital arm, are helping bring innovative health technologies to people around the world. For more information, please visit: www.hikma.com.