

## Hikma provides update on status of ANDA for generic Advair Diskus®

**London, 22 September 2020** – Hikma Pharmaceuticals PLC (Hikma or the Group), the multinational pharmaceutical company, announces that it has received a minor 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®<sup>1</sup> (fluticasone propionate and salmeterol inhalation powder).

Hikma is working closely with the FDA to quickly address the small number of questions raised in the CRL. Once answered, Hikma can expect to receive a response from the FDA within 90 days. Hikma now expects to receive approval for its generic Advair Diskus® in early 2021. As a result, Generics revenue is now anticipated to be in the range of \$710 million to \$730 million and core operating margin to be in the range of 18% to 19% for 2020 full year.

Hikma and its partner Vectura Group, are committed to bringing this important product to the US market and remain confident in the submission.

- ENDS -

### Enquiries

#### Hikma Pharmaceuticals PLC

Susan Ringdal  
EVP, Strategic Planning and Global Affairs

+44 (0)20 7399 2760/ +44 7776 477050  
[uk-investors@hikma.uk.com](mailto:uk-investors@hikma.uk.com)

Steve Weiss  
David Belian  
US Communications and Public Affairs

+1 732 720 2830/ +1 732 788 8279  
+1 732 720 2814/+1 848 254 4875  
[uscommunications@hikma.com](mailto:uscommunications@hikma.com)

#### Teneo (Press):

Charles Armitstead / Camilla Cunningham

+44 (0)7703 330 269/ +44 (0)7464 982 426

### About Hikma

(LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY) (rated Ba1/stable Moody's and BBB-/stable S&P)

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. Headquartered in the UK, 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

<sup>1</sup> Advair® and Advair Diskus® are registered trademarks of Glaxo Group Limited.



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 8,600 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](http://www.hikma.com)