

# Hikma provides update on generic Advair Diskus® launch

This announcement contains inside information.

London, 15 January 2021 – Hikma Pharmaceuticals PLC (Hikma), the multinational pharmaceutical company, announces that it has temporarily paused the launch of its generic version of GlaxoSmithKline's Advair Diskus®1.

Following the US FDA's approval of Hikma's Abbreviated New Drug Application (ANDA) for generic Advair Diskus® in December 2020, Hikma has submitted to the US FDA an amendment to its application. The amendment reflects enhanced packaging controls to meet new industry standards adopted since the initial submission of its ANDA application. This amendment will be classified as a Prior Approval Supplement and will not affect the approved status of Hikma's ANDA for generic Advair Diskus®.

Hikma will work closely with the FDA in its review and will commence distribution of the product once the review has been completed.

#### - ENDS -

The person responsible for the release of this announcement on behalf of Hikma is Peter Speirs (Company Secretary).

## **Enquiries**

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# **About Hikma**

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

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

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<sup>&</sup>lt;sup>1</sup> Advair<sup>®</sup> and Advair Diskus<sup>®</sup> are registered trademarks of GSK group of companies.



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 8,600 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: <a href="https://www.hikma.com">www.hikma.com</a>

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