

# Hikma announces global agreement with Vectura to develop generic versions of GSK's Ellipta® portfolio

**London, 8 November 2018** – Hikma Pharmaceuticals PLC (Hikma, Group) (LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY) (rated Ba1 Moody's / BB+ S&P, both stable) today announces that it has signed an agreement with Vectura Group plc (Vectura) for the global development and commercialisation of generic versions of GSK's Ellipta® portfolio, utilising Vectura's proprietary Open-Inhale-Close dry powder inhaler device.

Siggi Olafsson, Chief Executive Officer of Hikma, said: "The generic respiratory market is a key area of pipeline focus for Hikma. This agreement leverages the investment we have made and the experience we have gained through our generic Advair Diskus® programme. By strengthening and expanding our partnership with Vectura, we will develop a pipeline of complex respiratory products that will enable us to deliver sustainable long-term growth."

### A significant opportunity to bring complex respiratory products to market

Following interactions with the US FDA, Vectura and Hikma believe the Open-Inhale-Close dry powder inhaler device has the potential to be developed as an AB-rated substitutable drug-device combination for generic versions of the GSK Ellipta® portfolio. This presents a significant opportunity, with net sales for Ellipta® products in the US projected to be \$4 billion by 2024 and approximately \$5.5 billion globally.¹

The Open-Inhale-Close dry powder inhaler programme includes the development of AB-rated substitutable generics of up to five GSK respiratory medicines. Hikma and Vectura have agreed to develop and commercialise at least three of the portfolio products. A substitutable generic version of Breo® Ellipta® (fluticasone furoate and vilanterol trifenatate) will be prioritised for the first wave of development. Pharmaceutical and device development work has progressed in parallel with partnering discussions. The new device is an evolution of Vectura's lever-operated multidose (LOMI) device and builds on Vectura and Hikma's shared experience with the generic Advair Diskus® programme, enabling accelerated development under this new agreement.

## **Financial considerations**

Upon signing, Hikma will make an upfront payment of \$15 million to Vectura. Vectura will be responsible for, and fund, initial device and formulation development. Hikma will be responsible for clinical development, regulatory submission and commercialisation. Upon transfer of the first product to Hikma's manufacturing facility to enable clinical manufacturing, Hikma will make a \$5 million milestone payment to Vectura. Thereafter, Hikma will make milestone payments of up to \$75 million at various stages of development, including the delivery of pharmacokinetic clinical trials, pivotal clinical trials, ANDA submissions and FDA approvals. On approval, Hikma will pay a share of distributable net profit of up to a mid-teen percentage for each portfolio product. Hikma will also pay sales milestones on the achievement of certain cumulative net sales targets. Vectura will contribute up to \$70 million towards Hikma's development activities for the portfolio. Vectura's contribution to the development costs will be deferred and made through a reduced profit share mechanism following commercial launch of the first product.

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#### **Enquiries**

## **Hikma Pharmaceuticals PLC**

Susan Ringdal EVP, Strategic Planning and Global Affairs

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

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<sup>&</sup>lt;sup>1</sup> Global Data, October 2018



## **FTI Consulting**

Ben Atwell/Brett Pollard

+44 (0)20 3727 1000

## **About Hikma**

Hikma helps put better health within reach every day for millions of people in more than 50 countries around the world. For 40 years, we've been creating high-quality medicines and making them accessible to the people who need them. We're 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 8,500 colleagues are helping to shape a healthier world that enriches all our communities. We are a leading licensing partner in the MENA region, 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>.

The information contained within this announcement is deemed by the Company to constitute inside information stipulated under the Market Abuse Regulation (EU) No. 596/2014. Upon the publication of this announcement via the Regulatory Information Service, this inside information is now considered to be in the public domain.