

Hikma Launches New 503B Sterile Compounding Business

Builds on leading position in US sterile injectables market

Brings company's proven experience in quality and reliability to compounding

London, UK – 10 January 2022 – Hikma Pharmaceuticals PLC (“Hikma”), the multinational pharmaceutical company, announces the launch of Hikma 503B – a new outsourced sterile compounding business focused on providing high quality, ready-to-administer injectable medications that are customized to the specific needs of patients in the United States.

Sterile compounding – the process of combining, mixing, or altering ingredients to create medications in ready-to-administer formats tailored to the needs of health care providers – is an important specialized approach to drug manufacturing that serves a critical role in patient care. Hospital pharmacists, physicians and nurses increasingly need these medicines, resulting in a growing US market for outsourced compounded sterile injectable medications that is now estimated to exceed \$2 billion annually.

The launch of Hikma 503B builds on the company's expertise and position as a leading supplier of injectable medicines to US hospitals with a strong reputation for quality and reliability. Today, Hikma is the second-largest supplier by volume of generic injectables to US hospitals, and one out of every six generic injectable medicines used by US hospitals is a Hikma product. The company's extensive supplier relationships and access to raw materials also provide a unique point of differentiation to existing players in the outsourced sterile compounding space.

“Hikma 503B is a natural extension of our injectables business, building on our strong relationships with US hospitals and excellent quality manufacturing protocols to provide urgently needed product offerings to patients and health care providers in the US,” said Riad Mishlawi, President, Injectables, Hikma. “There is substantial demand for outsourced sterile compounded medicines among the thousands of hospitals we currently serve, representing a large opportunity to meet a growing and not fully met need within the US health care system. Hikma 503B is uniquely positioned to bring pharmaceutical manufacturing standards to the space, which we believe will establish us as a significant player in the market over time.”

Hikma 503B will operate principally out of a 65,000 sq. ft., purpose-built facility in Dayton, NJ, that was acquired by Hikma in 2020. Hikma has greatly enhanced the Dayton site to create a state-of-the-art sterile outsourced compounding and distribution facility in line with the company's high standards of quality, adding automation and segregation for enhanced productivity while minimizing risks.

“We are applying Hikma's expertise, talent, and engrained commitment to quality to ensure our 503B business meets CGMP standards, which is what the FDA requires of 503B outsourcing facilities,” said Joel Rosenstack, Chief Commercial Officer, US Injectables, Hikma. “Our 503B business is powered by the same team and philosophy that is behind Hikma's reputation for quality medicines.”

Hikma 503B is registering for state licenses across the US and expects to be operating nationwide by the end of 2022.

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About Hikma

(LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY) (rated BBB-/stable S&P and BBB-/stable Fitch)
Hikma helps put better health within reach every day for millions of people 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 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