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Press Release

Hikma acquires Novugen's FDA-approved ANDA for trametinib

London, 17 April 2025 – Hikma Pharmaceuticals PLC (Hikma), the multinational pharmaceutical company, today announces it has acquired the FDA-approved Abbreviated New Drug Application (ANDA) for trametinib tablets from Novugen. Hikma also announces it has entered into a commercial agreement with Novugen where Hikma will be responsible for all US sales and marketing of this product, which Novugen will manufacture and supply to Hikma.

Trametinib is an orally administered kinase inhibitor medication used to treat certain cancers. When launched, Hikma will have 180 days of US generic market sales exclusivity for this product.

"Hikma's Generics business is accelerating its efforts to expand its pipeline by developing and acquiring important medicines in growing therapeutic areas most needed by US patients and healthcare providers," said Dr. Hafrun Fridriksdottir, president of Hikma Generics. "Our acquisition of this cancer treatment strengthens our broad US pipeline of essential medicines and will further our ability to put better health within reach every day for millions of Americans."

"As cancer treatment remains a critical healthcare challenge, our partnership with Hikma reflects a shared commitment to ensuring the availability of effective, cost-efficient, and high-quality oncology treatments in the US," said Rahil Mahmood, Chief Executive Officer of Novugen. "This exclusive first-to-file molecule is a testament to Novugen's innovation, regulatory excellence, and dedication to expanding access to high-barrier, niche products with limited alternatives—ensuring life-changing treatments reach more US patients. With Hikma's strong market presence and commercial capabilities, this collaboration represents an excellent strategic synergy."

According to IQVIA, US sales of trametinib, sold under the brand name Mekinist® (trametinib) Tablets, were approximately $436 million in the 12 months ending December 2024.

Hikma's Generics business supplies a range of oral, inhalation and other generic and specialty products in the North American market, and has expertise in complex technologies, such as nasal sprays, where we are the largest supplier by volume in the US[1].

[1]IQVIA MAT December 2024, volumes by eaches

Mekinist® is a registered trademark of Novartis Pharma AG

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This product has been approved for marketing in the United States by the US FDA. This product approval does not confer the right on Hikma, or any other party, to market this product outside the United States.

Enquiries

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About Hikma

(LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY) (rated BBB-/stable S&P and BBB-/positive Fitch)

Hikma helps put better health within reach every day for millions of people around the world. For more than 45 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 North America, 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 9,500 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

About Novugen

Novugen is a wholly owned subsidiary of SciTech International, a UAE-based group with over 30 years of expertise in the healthcare industry. The company has successfully ventured into strategic healthcare businesses and developed world-class healthcare facilities worldwide. Driven by a passion for science and a bold global strategy, Novugen specializes in niche, difficult-to-formulate generics across various therapeutic areas, including general and oncology pharmaceuticals, while adhering to stringent global quality standards. With vertical integration from research and development to manufacturing in Malaysia, Novugen maintains full control over its supply chain. Its state-of-the-art manufacturing facilities, comply with USFDA, EMA, PIC/S, and WHO regulatory requirements. Novugen is also the first in Malaysia and the only in Southeast Asia with USFDA-approved pharmaceutical manufacturing facilities dedicated to oral solid dosage forms for general medicines and highly potent oncology drugs. This accreditation positions Novugen as the first in Malaysia to manufacture and export high-quality medicines for the U.S. market. Novugen is committed to expanding early access to complex pharmaceutical products that often lack robust generic alternatives. Through continuous innovation, we strive to lead the way in delivering high-quality, technology-driven pharmaceuticals globally.