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Press Release

Hikma advances its epinephrine nasal spray with multi-market regulatory filings

London, 09 September 2026 – Hikma Pharmaceuticals PLC (Hikma, Group) today announces that regulatory submissions for its epinephrine nasal spray, being developed for the emergency treatment of allergic reactions (anaphylaxis), have been accepted for review by regulators in the United States, Europe, and the UK. Hikma has also filed a submission for its epinephrine nasal spray in Canada, with plans to expand filings beyond these markets in due course.

Hikma's epinephrine nasal spray is an investigational, non-injectable product designed for the emergency treatment of allergic reactions (anaphylaxis).

In the United States, the US Food and Drug Administration (FDA) has accepted for review the New Drug Application for Hikma's epinephrine nasal spray. This 505 (b) (2) submission is comprised of the required non-clinical and clinical data package for the approval of the nasal spray for the emergency treatment of anaphylaxis in patients. In Europe and the UK, Hikma's hybrid marketing authorisation dossier for the nasal spray has been validated and accepted for review through the Decentralised Procedure (DCP) and National Procedure respectively, with a view to authorisation across multiple European and UK markets.

"The acceptance of our regulatory submissions for Hikma's epinephrine nasal spray in the US, Europe, and the UK represents an important growth milestone for Hikma's complex product line and, most importantly, will provide patients and caregivers with alternate access to life-saving treatment for anaphylaxis," said Hafrun Fridriksdottir, President Hikma US and Chief R&D Officer. "This reflects our continued focus on developing differentiated and innovative medicines, leveraging our manufacturing expertise and broadening affordable access for patients around the world."

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Hikma's epinephrine nasal spray is an investigational product and has not been approved by the FDA. The safety and efficacy of Hikma's product have not been established by the FDA.

Hikma has submitted its epinephrine nasal spray for regulatory review by the FDA. Submission of an application does not mean that the FDA has approved the application or determined that Hikma's epinephrine nasal spray is safe or effective. There can be no assurance that Hikma's epinephrine nasal spray product or any particular indication for that product will receive regulatory approval.

About Hikma Pharmaceuticals PLC

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 9,400 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

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