



## **Hikma receives FDA approval for Ketamine Hydrochloride Injection**

**London, 03 June 2016** – Hikma Pharmaceuticals PLC (Hikma) (LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY), (rated Ba1 Moody's / BB+ S&P, both stable), the fast growing multinational pharmaceutical group, announces that its supplemental Abbreviated New Drug Application (sANDA) for Ketamine Hydrochloride Injection USP, 500 mg (base)/10 mL (50 mg (base)/mL) and 500 mg (base)/5 mL (100 mg (base)/mL) multi-dose vials have been approved by the U.S. Food and Drug Administration (FDA).

Ketamine Hydrochloride is indicated as an anaesthetic agent for diagnostic and surgical procedures that do not require skeletal muscle relaxation. According to IMS Health, total U.S. sales of Ketamine Injection were approximately \$11 million for the 12 months ending April 2016, of which the Hikma approved presentations represented around \$5 million.

Said Darwazah, Chairman and CEO of Hikma, said, "We are very pleased this product has been approved for the US market. We continue to leverage our strong R&D, regulatory and high-quality manufacturing facilities and remain committed to prioritising the re-introduction of Bedford products for patients in need."

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### **Enquiries**

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### **About Hikma**

Hikma Pharmaceuticals PLC is a fast growing multinational group focused on developing, manufacturing and marketing a broad range of both branded and non-branded generic and in-licensed products. Hikma operates through three businesses: "Injectables", "Branded" and "Generics", based principally in the United States, the Middle East and North Africa (MENA) and Europe. In 2015, Hikma achieved revenues of \$1,440 million and profit attributable to shareholders of \$252 million.