Hikma receives FDA approval for Leucovorin Calcium Injection

London, 04 May 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 Leucovorin Calcium Injection, 350 mg Single-use vial has been approved by the U.S. Food and Drug Administration (FDA).

Leucovorin Calcium Injection is used for the prevention and treatment of certain blood cell disorders, and can be used in conjunction with other oncology drugs for the treatment of colorectal cancer. According to IMS Health, U.S. sales of Leucovorin Calcium Injection were approximately $35 million for the 12 months ending March 2016, of which the 350 mg presentation represented around $19 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 capabilities and remain committed to prioritising the re-introduction of Bedford products for patients in need."

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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.