



## **Hikma announces launch of Generic Xeloda® Tablets 150 mg and 500 mg in the US**

**London, 20 July 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, today announces that its wholly owned U.S. affiliate, West-Ward Pharmaceuticals Corp. (West-Ward), has launched Capecitabine Tablets 150 mg and 500 mg, the generic equivalents to Xeloda®<sup>1</sup> Tablets. West-Ward's Capecitabine Tablets are indicated for adjuvant treatment in patients with Dukes' C colon cancer, as monotherapy in metastatic colorectal cancer, and in combination with docetaxel or as monotherapy in patients with metastatic breast cancer.

According to IMS Health, US sales of Capecitabine Tablets 150 mg and 500 mg were approximately \$493 million for the 12 months ending May 2016.

Said Darwazah, Chairman and CEO of Hikma said, "We are very pleased to have this product approval from the Columbus portfolio. We have an excellent pipeline of differentiated products and proven R&D, supply chain and operational capabilities that we expect will drive accelerated and sustainable future growth."

### **Important safety information**

Patients receiving concomitant capecitabine and oral coumarin-derivative anticoagulant therapy should have their anticoagulant response (INR or prothrombin time) monitored frequently in order to adjust the anticoagulant dose accordingly. A clinically important capecitabine-warfarin drug interaction was demonstrated in a clinical pharmacology trial. Altered coagulation parameters and/or bleeding, including death, have been reported in patients taking capecitabine concomitantly with coumarin-derivative anticoagulants such as warfarin and phenprocoumon. Post-marketing reports have shown clinically significant increases in prothrombin time and INR in patients who were stabilised on anticoagulants at the time capecitabine was introduced. These events occurred within several days and up to several months after initiating capecitabine therapy and, in a few cases, within 1 month after stopping capecitabine. These events occurred in patients with and without liver metastases. Age greater than 60 and a diagnosis of cancer independently predispose patients to an increased risk of coagulopathy.

Capecitabine is contraindicated in patients with severe renal impairment, with known dihydropyrimidine dehydrogenase deficiency, or with a known hypersensitivity to capecitabine or any of its components, or 5-fluorouracil. Patients receiving therapy with capecitabine should be monitored by a physician experienced in the use of cancer chemotherapeutic agents. For additional information, please refer to the Package Insert for full prescribing information, available on <https://dailymed.nlm.nih.gov>.

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### **Enquiries**

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<sup>1</sup> Xeloda® is a registered trademark of Hoffmann-LaRoche Inc.

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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 the United States, Hikma operates through its wholly owned subsidiary, West-Ward Pharmaceuticals (West-Ward), with operations based in New Jersey, Ohio and Tennessee.