

Hikma launches Dexrazoxane for Injection

London, 20 April 2018 – Hikma Pharmaceuticals PLC (Hikma, Group) (LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY) (rated Ba1 Moody's / BB+ S&P, both stable) announces that its wholly-owned US subsidiary West-Ward Pharmaceuticals Corp. (West-Ward), has launched Dexrazoxane for Injection, 250mg and 500mg vials, the generic equivalent to Zinecard®.¹

West-Ward's Dexrazoxane for Injection is indicated for reducing the incidence and severity of cardiomyopathy associated with doxorubicin administration in certain women with metastatic breast cancer who have received a cumulative doxorubicin dose of 300 mg/m² and who will continue to receive doxorubicin therapy to maintain tumor control. It should not be used with the initiation of doxorubicin therapy.

According to IQVIA, US sales of Dexrazoxane for Injection, 250mg and 500mg, were approximately \$15 million in the 12 months ending February 2018.

Riad Mechlaoui, Chief Executive Officer of Injectables said, "We are very pleased to be adding Dexrazoxane for Injection to our oncology portfolio. By launching Dexrazoxane, we hope to reduce the shortage of this product in the US market."

Important Safety Information

WARNINGS AND PRECAUTIONS

The following warnings and precautions should be taken when administering Dexrazoxane for Injection:

- **Myelosuppression:** Can add to the myelosuppression caused by chemotherapeutic agents. Monitor blood counts prior to and during each treatment.
- **Concomitant Chemotherapy:** Only use Dexrazoxane for injection in patients who have received a cumulative dose of 300 mg/m² and are on continuing doxorubicin therapy. Do not use with chemotherapy initiation.
- **Cardiac Toxicity:** Dexrazoxane does not eliminate the risk of anthracycline-induced cardiac toxicity. Monitor cardiac function before and periodically during therapy.
- **Secondary malignancies** have been reported, such as acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS). Dexrazoxane for injection is not indicated for use in pediatric patients.
- **Embryo-Fetal Toxicity:** Can cause fetal harm. If used during pregnancy, the patient should be apprised of the potential hazard to a fetus. Advise patients of reproductive potential to use highly effective contraception during treatment.

Do not use Dexrazoxane for injection with non-anthracycline chemotherapy regimens.

DO NOT ADMINISTER VIA AN INTRAVENOUS PUSH.

Reduce dosage in patients with renal impairment.

In clinical trials of Dexrazoxane for injection with Fluorouracil, Doxorubicin, and Cyclophosphamide (FAC), patients experienced more severe leukopenia, granulocytopenia, and thrombocytopenia than patients receiving FAC without Dexrazoxane for injection.

¹ Zinecard® is a registered trademark of Pharmacia and Upjohn Company LLC



Patient Counseling Information should be shared with the patient prior to administration.

Please refer to the Package Insert for full prescribing information, available [here](#). Additional information on West-Ward Pharmaceuticals Corp. products is available at www.west-ward.com.

Enquiries

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About Hikma

Hikma helps put better health within reach every day for millions of people in more than 50 countries around the world. For 40 years, we've been creating high-quality medicines and making them accessible to the people who need them. We're a global company with a local presence across the United States (US), 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 8,500 colleagues are helping to shape a healthier world that enriches all our communities. We are a leading licensing partner in the MENA region, 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.