Press Release

Hikma launches Adriamycin™ (DOXOrubicin HCl) for Injection, USP

London, 17 September 2018 – Hikma Pharmaceuticals PLC (Hikma, Group) (LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY) (rated Ba1 Moody's / BB+ S&P, both stable) announces that Hikma Pharmaceuticals USA Inc., formerly known as West-Ward Pharmaceuticals Corp., has launched Adriamycin™ (DOXOrubicin HCl) for Injection, USP 10mg and 50mg.

Hikma's Adriamycin™ (DOXOrubicin HCl) for Injection, USP is an anthracycline topoisomerase II inhibitor indicated as a component of multi-agent adjuvant chemotherapy for treatment of women with axillary lymph node involvement following resection of primary breast cancer. Additionally, Doxorubicin is indicated for the treatment of certain other cancers: acute lymphoblastic leukemia, acute myeloblastic leukemia, Hodgkin lymphoma, non-Hodgkin lymphoma (NHL), metastatic breast cancer, metastatic Wilms' tumor, metastatic neuroblastoma, metastatic soft tissue sarcoma, metastatic bone sarcomas, metastatic ovarian carcinoma, metastatic transitional cell bladder carcinoma, metastatic thyroid carcinoma, metastatic gastric carcinoma, metastatic bronchogenic carcinoma.

According to IQVIA, US sales of doxorubicin HCl were approximately $13 million in the 12 months ending July 2018. Sales of doxorubicin HCl 10mg and 50mg currently comprise approximately 15 per cent of the market.

This new product introduction expands Hikma's broad offering of more than 90 products and further solidifies our position as one of the top three suppliers of generic injectable products to US hospitals.

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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.

Important Safety Information for Adriamycin™ (DOXOrubicin HCl) for Injection, USP:

BOXED WARNING regarding CARDIOMYOPATHY, SECONDARY MALIGNANCIES, EXTRAVASATION AND TISSUE NECROSIS, and SEVERE MYELOSUPPRESSION

- **Cardiomyopathy: Myocardial damage can occur with doxorubicin with incidences from 1% to 20% for cumulative doses from 300 mg/m^2 to 500 mg/m^2 when doxorubicin is administered every 3 weeks. The risk of cardiomyopathy is further increased with concomitant cardiotoxic therapy. Assess left ventricular ejection fraction (LVEF) before and regularly during and after treatment with doxorubicin HCl.**

- **Secondary Malignancies: Secondary acute myelogenous leukemia (AML) and myelodysplastic syndrome (MDS) occur at a higher incidence in patients treated with anthracyclines, including doxorubicin.**

- **Extravasation and Tissue Necrosis: Extravasation of doxorubicin can result in severe local tissue injury and necrosis requiring wide excision and skin grafting. Immediately terminate the drug, and apply ice to the affected area.**

- **Severe myelosuppression resulting in serious infection, septic shock, requirement for transfusions, hospitalization, and death may occur.**

Warnings and Precautions

The following warnings and precautions should be taken when administering Adriamycin™ (DOXOrubicin HCl) for Injection, USP:

- Doxorubicin can result in arrhythmias, including life-threatening arrhythmias, during or within a few hours after doxorubicin administration and at any time point during treatment.

- Contraindicated in patients with severe hepatic impairment. The clearance of doxorubicin is reduced in patients with elevated serum bilirubin levels. Reduce the dose of doxorubicin in patients with serum bilirubin levels greater than 1.2 mg/dL.

- Doxorubicin may induce tumor lysis syndrome in patients with rapidly growing tumors.

- Use of doxorubicin can increase radiation-induced toxicity to the myocardium, mucosa, skin, and liver. Radiation recall, including but not limited to cutaneous and pulmonary toxicity, can occur in patients who receive

doxorubicin after prior radiation therapy.

- Administration of doxorubicin can cause fetal harm in a pregnant woman. If used during pregnancy, or if the patient becomes pregnant while taking this drug, apprise the patient of the potential hazard to a fetus. Female patients of reproductive potential should be advised to use highly effective contraception during treatment with doxorubicin and for 6 months after treatment.

- Doxorubicin is contraindicated in patients with severe myocardial insufficiency, recent (occurring within the past 4 to 6 weeks) myocardial infarction, severe persistent drug-induced myelosuppression, severe hepatic impairment (defined as Child Pugh Class C or serum bilirubin level greater than 5 mg/dL) and severe hypersensitivity reaction to doxorubicin including anaphylaxis.

- Drug Interactions with Doxorubicin have been reported with inhibitors of CYP3A4, CYP2D6, and/or P-gp (e.g., verapamil), Trastuzumab, Paclitaxel, Dexrazoxane, and 6-Mercaptopurine.

The following adverse reactions have been identified during post-approval use of doxorubicin: Cardiac (cardiogenic shock); Cutaneous (skin and nail hyperpigmentation, oncolysis, rash, itching, photosensitivity, urticaria, acral erythema, palmar plantar erythrodysesthesia); Gastrointestinal (nausea, mucositis, stomatitis, necrotizing colitis, typhlitis, gastric erosions, gastrointestinal tract bleeding, hematochezia, esophagitis, anorexia, abdominal pain, dehydration, diarrhea, hyperpigmentation of the oral mucosa); Hypersensitivity (anaphylaxis); Laboratory Abnormalities (increased alanine aminotransferase, increased aspartate aminotransferase); Neurological (Peripheral sensory and motor neuropathy, seizures, coma); Ocular (conjunctivitis, keratitis, lacrimation); Vascular (phlebosclerosis, phlebitis/thrombophlebitis, hot flashes, thromboembolism); Other (malaise/asthenia, fever, chills, weight gain).

Please refer to the Package Insert for full prescribing information. Additional information on Hikma US products is available on www.hikma.com/us.

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