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Press Release

Hikma launches Daunorubicin HCl Injection

London, 18 July 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, has launched Daunorubicin HCl Injection, 20mg/4mL and 50mg/10mL.

Hikma's Daunorubicin HCl Injection in combination with other approved anticancer drugs is indicated for remission induction in acute nonlymphocytic leukemia (myelogenous, monocytic, erythroid) of adults and for remission induction in acute lymphocytic leukemia of children and adults.

According to IQVIA, US sales of Daunorubicin HCl Injection, 20mg/4mL and 50mg/10mL, were approximately $9 million in the 12 months ending May 2018.

Important Safety Information about Daunorubicin HCl Injection

WARNINGS

- DAUNORUBICIN HYDROCHLORIDE INJECTION MUST BE GIVEN INTO A RAPIDLY FLOWING INTRAVENOUS INFUSION. IT MUST NEVER BE GIVEN BY THE INTRAMUSCULAR OR SUBCUTANEOUS ROUTE. SEVERE LOCAL TISSUE NECROSIS WILL OCCUR IF THERE IS EXTRAVASATION DURING ADMINISTRATION.
- MYOCARDIAL TOXICITY MANIFESTED IN ITS MOST SEVERE FORM BY POTENTIALLY FATAL CONGESTIVE HEART FAILURE MAY OCCUR EITHER DURING THERAPY OR MONTHS TO YEARS AFTER TERMINATION OF THERAPY. THE INCIDENCE OF MYOCARDIAL TOXICITY INCREASES AFTER A TOTAL CUMULATIVE DOSE EXCEEDING 400 TO 550 MG/M^2 IN ADULTS, 300 MG/M^2 IN CHILDREN MORE THAN 2 YEARS OF AGE, OR 10 MG/KG IN CHILDREN LESS THAN 2 YEARS OF AGE.
- SEVERE MYELOSUPPRESSION OCCURS WHEN USED IN THERAPEUTIC DOSES; THIS MAY LEAD TO INFECTION OR HEMORRHAGE.
- IT IS RECOMMENDED THAT DAUNORUBICIN HYDROCHLORIDE BE ADMINISTERED ONLY BY PHYSICIANS WHO ARE EXPERIENCED IN LEUKEMIA CHEMOTHERAPY AND IN FACILITIES WITH LABORATORY AND SUPPORTIVE RESOURCES ADEQUATE TO MONITOR DRUG TOLERANCE AND PROTECT AND MAINTAIN A PATIENT COMPROMISED BY DRUG TOXICITY. THE PHYSICIAN AND INSTITUTION MUST BE CAPABLE OF RESPONDING RAPIDLY AND COMPLETELY TO SEVERE HEMORRHAGIC CONDITIONS AND/OR OVERWHELMING INFECTION.
- DOSAGE SHOULD BE REDUCED IN PATIENTS WITH IMPAIRED HEPATIC OR RENAL FUNCTION.

WARNINGS AND PRECAUTIONS

The following warnings and precautions should be taken when administering Daunorubicin Hydrochloride Injection:

- Daunorubicin hydrochloride is a potent bone marrow suppressant. Therapy should not be started in patients with pre-existing drug-induced bone marrow suppression unless the benefit warrants the risk.
- Special attention must be given to the potential cardiac toxicity of daunorubicin hydrochloride, particularly in infants and children. An electrocardiogram and/or determination of systolic ejection fraction should be performed before each course of daunorubicin hydrochloride.

- Significant hepatic or renal impairment can enhance the toxicity of the recommended doses of daunorubicin hydrochloride; therefore, prior to administration, evaluation of hepatic and renal function is recommended.
- Daunorubicin hydrochloride may cause fetal harm when administered to a pregnant woman.
- Women of childbearing potential should be advised to avoid becoming pregnant.
- Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from daunorubicin, mothers should be advised to discontinue nursing during therapy.
- There have been reports of secondary leukemias in patients exposed to topoisomerase II inhibitors when used in combination with other antineoplastic agents or radiation therapy.
- Closely observe and monitor patient's complete blood-count.
- Advise patients to expect a red coloration to the urine after administration.
- Caution should be exercised when handling Daunorubicin Hydrochloride Injection. Procedures for proper handling and disposal of anticancer drugs should be utilized.

Daunorubicin hydrochloride is contraindicated in patients who have demonstrated a hypersensitive or an idiosyncratic reaction to it.

The following adverse reactions have been reported: dose-limiting toxicity including myelosuppression and cardiotoxicity, reversible alopecia, rash, contact dermatitis, urticaria, acute nausea and vomiting, severe local tissue necrosis, thrombophlebitis, anaphylactoid reaction, fever and chills, and hyperuricemia.

Drug Interactions

Use of daunorubicin in a patient who has previously received doxorubicin increases the risk of cardiotoxicity. Daunorubicin hydrochloride should not be used in patients who have previously received the recommended maximum cumulative doses of doxorubicin or daunorubicin hydrochloride. Cyclophosphamide used concurrently with daunorubicin hydrochloride may also result in increased cardiotoxicity. When used concurrently with other myelosuppressive agents, a dosage reduction of daunorubicin hydrochloride may be required. Hepatotoxic medications, such as high-dose methotrexate, may impair liver function and increase the risk of toxicity.

Indications

Daunorubicin hydrochloride in combination with other approved anticancer drugs is indicated for remission induction in acute nonlymphocytic leukemia (myelogenous, monocytic, erythroid) of adults and for remission induction in acute lymphocytic leukemia of children and adults.

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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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.