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Press Release

Hikma launches Dacarbazine for Injection, USP

London, July 24, 2020 – Hikma Pharmaceuticals PLC (Hikma), the multinational pharmaceutical company, has launched Dacarbazine for Injection, USP, 200mg, in the United States through its US affiliate, Hikma Pharmaceuticals USA Inc.

Dacarbazine for Injection, USP is indicated in the treatment of metastatic malignant melanoma. In addition, dacarbazine is also indicated for Hodgkin's disease as a second-line therapy when used in combination with other effective agents.

According to IQVIA, US sales of Dacarbazine for Injection, USP, 200mg were approximately $2 million in the 12 months ending May 2020.

Hikma is the third largest US supplier of generic injectable medicines by volume, with a growing portfolio of over 100 products. Today one in every six injectable generic medicines used in US hospitals is a Hikma product.

- ENDS -

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About Hikma
(LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY) (rated Ba1/stable Moody's and BBB-/stable S&P)

Hikma helps put better health within reach every day for millions of people in more than 50 countries around the world. For more than 40 years, we've been creating high-quality medicines and making them accessible to the people who need them. Headquartered in the UK, we are 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 8,600 colleagues are helping to shape a healthier world that enriches all our communities. We are a leading licensing partner, 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

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Important Safety Information for Dacarbazine for Injection, USP, 200mg:

BOXED WARNING

It is recommended that dacarbazine be administered under the supervision of a qualified physician experienced in the use of cancer chemotherapeutic agents.

1. Hemopoietic depression is the most common toxicity with dacarbazine (see **WARNINGS**).
2. Hepatic necrosis has been reported (see **WARNINGS**).
3. Studies have demonstrated this agent to have a carcinogenic and teratogenic effect when used in animals.
4. In treatment of each patient, the physician must weigh carefully the possibility of achieving therapeutic benefit against the risk of toxicity.

CONTRAINDICATIONS

Dacarbazine is contraindicated in patients who have demonstrated a hypersensitivity to it in the past.

WARNINGS & PRECAUTIONS

- Hemopoietic depression is the most common toxicity with dacarbazine and involves primarily the leukocytes and platelets, although, anemia may sometimes occur. Leukopenia and thrombocytopenia may be severe enough to cause death. The possible bone marrow depression requires careful monitoring of white blood cells, red blood cells, and platelet levels. Hemopoietic toxicity may warrant temporary suspension or cessation of therapy with dacarbazine.
- Hepatic toxicity accompanied by hepatic vein thrombosis and hepatocellular necrosis resulting in death, has been reported. The incidence of such reactions has been low; approximately 0.01% of patients treated. This toxicity has been observed mostly when dacarbazine has been administered concomitantly with other anti-neoplastic drugs; however, it has also been reported in some patients treated with dacarbazine alone.
- Anaphylaxis can occur following the administration of dacarbazine.
- Hospitalization is not always necessary but adequate laboratory study capability must be available. Extravasation of the drug subcutaneously during intravenous administration may result in tissue damage and severe pain. Local pain, burning sensation, and irritation at the site of injection may be relieved by locally applied hot packs.
- Carcinogenicity of dacarbazine was studied in rats and mice. Proliferative endocardial lesions, including fibrosarcomas and sarcomas were induced by dacarbazine in rats. In mice, administration of dacarbazine resulted in the induction of angiosarcomas of the spleen.

ADVERSE REACTIONS

Symptoms of anorexia, nausea, and vomiting are the most frequently noted of all toxic reactions. Over 90% of patients are affected with the initial few doses. The vomiting lasts 1 to 12 hours and is incompletely and unpredictably palliated with phenobarbital and/or prochlorperazine. Rarely, intractable nausea and vomiting have necessitated discontinuance of therapy with dacarbazine. Rarely, dacarbazine has caused diarrhea. Some helpful suggestions include restricting the patient's oral intake of food for 4 to 6 hours prior to treatment. The rapid toleration of these symptoms suggests that a central nervous system mechanism may be involved, and usually these symptoms subside after the first 1 or 2 days.

There are a number of minor toxicities that are infrequently noted. Patients have experienced an influenza-like syndrome of fever to 39°C, myalgias and malaise. These symptoms occur usually after large single doses, may last for several days, and they may occur with successive treatments.

Alopecia has been noted as has facial flushing and facial paresthesia. There have been few reports of significant liver or renal function test abnormalities in man. However, these abnormalities have been observed more frequently in animal studies.

Erythematous and urticarial rashes have been observed infrequently after administration of dacarbazine. Rarely, photosensitivity reactions may occur.

DRUG INTERACTIONS

Hepatic toxicity accompanied by hepatic vein thrombosis and hepatocellular necrosis resulting in death, has been observed when dacarbazine has been administered concomitantly with other anti-neoplastic drugs.

USE IN SPECIFIC POPULATIONS

Pregnancy
There are no adequate and well-controlled studies in pregnant women. Dacarbazine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Lactation
It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for tumorigenicity shown for dacarbazine in animal studies, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

DOSAGE AND ADMINISTRATION

Refer to package insert for dosage and administration instructions specific for Malignant Melanoma and Hodgkin's Disease.

Dacarbazine 200 mg/vial is reconstituted with 19.7 mL of Sterile Water for Injection. The resulting solution contains 10 mg/mL of dacarbazine having a pH of 3.0 to 4.0. The calculated dose of the resulting solution is drawn into a syringe and administered *only* intravenously.

The reconstituted solution may be further diluted with 5% dextrose injection, or sodium chloride injection, and administered as an intravenous infusion.

After reconstitution and prior to use, the solution in the vial may be stored at 4°C for up to 72 hours or at normal room conditions (temperature and light) for up to 8 hours. If the reconstituted solution is further diluted in 5% dextrose injection or sodium chloride injection, the resulting solution may be stored at 4°C for up to 24 hours or at normal room conditions for up to 8 hours.

Procedures for proper handling and disposal of anticancer drugs should be considered. Several guidelines on this subject have been published. There is no general agreement that all of the procedures recommended in the guidelines are necessary or appropriate.

Parenteral drug products should be inspected visually for particulate matter or discoloration prior to administration whenever solution and container permit.

OVERDOSAGE

Give supportive treatment and monitor blood cell counts.

ENDING INFORMATION

For additional information, please refer to the Package Insert for full prescribing information, available on www.hikma.com.

To report SUSPECTED ADVERSE REACTIONS, contact West-Ward Pharmaceuticals Corp. (now Hikma Pharmaceuticals USA Inc.) at 1-877-845-0689, or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. For Product Inquiry call 1-877-845-0689.

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