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Pfizer Injectables Adds Doxorubicin Hydrochloride Injection, USP to Its Portfolio of Off-Patent Oncology Products

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Pfizer Injectables is delivering quality off-patent medicines to help address oncology drug shortages in the U.S.

"Pfizer is committed to improving the lives of patients with cancer,"

(BUSINESS WIRE)--Pfizer Injectables, part of Pfizer Inc.'s (NYSE: PFE) Established Products Business Unit, announced today the addition of doxorubicin hydrochloride injection, USP, to Pfizer Injectables' growing portfolio of off-patent oncology products.

In March 2011, the US Food and Drug Administration (FDA) approved the reintroduction of doxorubicin hydrochloride injection, USP, in medical grade Cytosafe® polypropylene vials in the following vial sizes: 5 mL (10 mg), 10 mL (20 mg), 25 mL (50 mg), 75 mL (150 mg) and 100 mL (200 mg).

"Pfizer is committed to improving the lives of patients with cancer," said James Hageman, vice president of Pfizer Injectables. "This approval is good news for the physicians, patients and caregivers who need access to oncology medicines but encountered issues with limited supply. We seek to provide our customers with quality established products – medicines that have lost patent protection or are close to losing protection – so that patients do not have to be turned away as a result of drug shortages."

About Doxorubicin HCl for Injection, USP

Doxorubicin has been used successfully to produce regression in disseminated neoplastic conditions such as acute lymphoblastic leukemia, acute myeloblastic leukemia, Wilms' tumor, neuroblastoma, soft tissue and bone sarcomas, breast carcinoma, ovarian carcinoma, transitional cell bladder carcinoma, thyroid carcinoma, gastric carcinoma, Hodgkin's disease, malignant lymphoma and bronchogenic carcinoma in which the small cell histologic type is the most responsive compared to other cell types.

Doxorubicin is also indicated for use as a component of adjuvant therapy in women with evidence of axillary lymph node involvement following resection of primary breast cancer.

Important Safety Information

WARNING

1. Severe local tissue necrosis will occur if there is extravasation during administration. Doxorubicin must not be given by the intramuscular or subcutaneous route.

2. Myocardial toxicity manifested in its most severe form by potentially fatal congestive heart failure (CHF) may occur either during therapy or months to years after termination of therapy. The probability of developing impaired myocardial function based on a combined index of signs, symptoms and decline in left ventricular ejection fraction (LVEF) is estimated to be 1 to 2% at a total cumulative dose of 300 mg/m2 of doxorubicin, 3 to 5% at a dose of 400 mg/m2, 5 to 8% at 450 mg/m2 and 6 to 20% at 500 mg/m2. The risk of developing CHF increases rapidly with increasing total cumulative doses of doxorubicin in excess of 400 mg/m2. Risk factors (active or dormant cardiovascular disease, prior or concomitant radiotherapy to the mediastinal/pericardial area, previous therapy with other anthracyclines or anthracenediones, concomitant use of other cardiotoxic drugs) may increase the risk of cardiac toxicity. Cardiac toxicity with doxorubicin may occur at lower cumulative doses whether or not cardiac risk factors are present. Pediatric patients are at increased risk for developing delayed cardiotoxicity.

3. Secondary acute myelogenous leukemia (AML) or myelodysplastic syndrome (MDS) has been reported in patients treated with anthracyclines, including doxorubicin. The occurrence of refractory secondary AML or MDS is more common when anthracyclines are given in combination with DNA-damaging anti-neoplastic agents or radiotherapy, when patients have been heavily pretreated with cytotoxic drugs, or when doses of anthracyclines have been escalated. The rate of developing secondary AML or MDS has been estimated in an analysis of 8563 patients with early breast cancer treated in 6 studies conducted by the National Surgical Adjuvant Breast and Bowel Project (NSABP), including NSABP B-15. Patients in these studies received standard doses of doxorubicin and standard or escalated doses of cyclophosphamide (AC) adjuvant chemotherapy and were followed for 61,810 patient years. Among 4483 such patients who received conventional doses of AC, 11 cases of AML or MDS were identified, for an incidence of 0.32 cases per 1000 patient years (95% CI 0.16–0.57) and a cumulative incidence at 5 years of 0.21% (95% CI 0.11–.41%). In another analysis of 1474 patients with breast cancer who received adjuvant treatment with doxorubicin-containing regimens in clinical trials conducted at University of Texas M.D. Anderson Cancer Center, the incidence was estimated at 1.5% at 10 years. In both experiences, patients who received regimens with higher cyclophosphamide dosages, who received radiotherapy, or who were aged 50 or older had an increased risk of secondary AML or MDS. Pediatric patients are also at risk of developing secondary AML.

4. Dosage should be reduced in patients with impaired hepatic function.

5. Severe myelosuppression may occur.

6. Doxorubicin should be administered only under the supervision of a physician who is experienced in the use of cancer chemotherapeutic agents.

Patients should not be treated with doxorubicin if they have any of the following conditions: baseline neutrophil count <1500 cells/mm3; severe hepatic impairment; recent myocardial infarction; severe myocardial insufficiency; severe arrhythmias; previous treatment with complete cumulative doses of doxorubicin, daunorubicin, idarubicin, and/or other anthracyclines and anthracenediones; or hypersensitivity to doxorubicin, any of its excipients, or other anthracyclines or anthracenediones.

Phlebosclerosis may result from an injection into a small vessel or from repeated injections into the same vein.

Doxorubicin can cause fetal harm when administered to a pregnant woman (category D). Women of childbearing age should be advised to avoid becoming pregnant.

Patients should be informed of the expected adverse effects of doxorubicin, including gastrointestinal symptoms (nausea, vomiting, diarrhea, and stomatitis) and potential neutropenic complications. Patients should consult their physician if vomiting, dehydration, fever, evidence of infection, symptoms of CHF, or injection-site pain occurs following therapy with doxorubicin. Patients should be informed that they will almost certainly develop alopecia. Patients should be advised that their urine may appear red for 1 to 2 days after administration of doxorubicin and that they should not be alarmed. Patients should understand that there is a risk of irreversible myocardial damage associated with treatment with doxorubicin, as well as a risk of treatment-related leukemia. Because doxorubicin may induce chromosomal damage in sperm, men undergoing treatment with doxorubicin should use effective contraceptive methods. Women treated with doxorubicin may develop irreversible amenorrhea, or premature menopause. Mothers should be advised to discontinue nursing during doxorubicin therapy.

Pediatric patients are at increased risk for developing delayed cardiotoxicity and are at risk for developing acute myelogenous leukemia and other neoplasms.

Adverse reactions to doxorubicin include reversible complete alopecia, acute nausea and vomiting, and less commonly mucosotis (stomatitis and esophagitis), systemic infections, toxic shock and cardiotoxicity (e.g. CHF).

For more information about Pfizer Injectables' doxorubicin HCl injection, USP, including full prescribing information, please visit www.pfizerinjectables.com. To report an adverse event or to speak to a member of Pfizer Medical Information, please call 1-800-438-1985.

About Pfizer Injectables

Pfizer Injectables is a trusted supplier of sterile injectables because of our heritage of quality, reliable manufacturing, and customer-focused flexibility. The professionals at Pfizer Injectables are dedicated to supplying and supporting medicines essential to the health and well-being of patients throughout the United States.

About Pfizer Inc: Working Together for a Healthier World®

At Pfizer, we apply science and our global resources to improve health and well-being at every stage of life. We strive to set the standard for quality, safety and value in the discovery, development and manufacturing of medicines for people and animals. Our diversified global health care portfolio includes human and animal biologic and small molecule medicines and vaccines, as well as nutritional products and many of the world's best-known consumer products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as the world's leading biopharmaceutical company, we also collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. To learn more please visit http://www.pfizer.com.

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