

Greetings!

FDA Approves Drug Treatment for Rare Cancer

Cutaneous T-cell lymphoma affects about 1,500 Americans annually

The U.S. Food and Drug Administration has approved Istodax (romidepsin), an injectable medication, for treatment of patients with a rare form of cancer known as Cutaneous T-cell Lymphoma (CTCL).

Cutaneous T-cell lymphoma is a slow-growing cancer of infection-fighting white blood cells called T-lymphocytes. Most cases start with dry skin, red rash, and itching that can become severe. The skin may develop tumors that can become ulcerated, causing infection. In some cases, CTCL spreads to the blood, lymph nodes, or internal organs. There are about 1,500 new cases of CTCL every year in the United States.

Patients with localized CTCL on the skin are treated with topical agents or phototherapy, but chemotherapy may be used if the cancer advances.

Istodax interferes with processes required for cell replication. It is intended to be used in patients when CTCL gets worse or comes back after at least one other type of chemotherapy has been used.

"This approval demonstrates FDA's commitment to the development and approval of drugs for rare and uncommon diseases," said Richard Pazdur, M.D., director of the Office of Oncology Drug Products in the FDA's Center for Drug Evaluation and Research. The FDA approved Istodax on Nov. 6, 2009.

Previous approvals for CTCL included Zolinza (vorinostat), Ontak (denileukin difitox), and Targretin (bexarotene).

Istodax was evaluated based on two clinical studies involving a total of 167 patients. About 35 percent of patients in both of the trials experienced tumor responses, indicating a reduction of the size of tumors. Responses lasted a median of 15 months in one study and 11 months in the other study. Six percent of those studied had complete responses, indicating no apparent evidence of the tumor on physical, laboratory, and X-ray examinations.

Common side effects include nausea, fatigue, infections, vomiting, decreased appetite, decreased red blood cell count, decreased platelet count, and decreases in the components of white blood cells.

Istodax may cause changes in an electrocardiogram (ECG). Periodic blood tests should be done to monitor electrolytes, and periodic ECG monitoring should be considered in patients at risk for certain heart rhythm abnormalities. Istodax may harm a fetus and women should not become pregnant while taking the drug.

Istodax is marketed by Gloucester Pharmaceuticals Inc. of Cambridge, Mass.