Generic Name:
Moxetumomab pasudotox-tdfk
Trade Name:
Lumoxiti
Company:
AstraZeneca
Notes:

FDA approved moxetumomab pasudotox-tdfk injection for I.V. use for the treatment of adult patients with relapsed or refractory hairy cell leukemia (HCL) who have received at least two prior systemic therapies, including treatment with a purine nucleoside analog. The agent is a CD22-directed cytotoxin and is the first of this type of treatment for patients with HCL.

HCL is a rare, slow-growing cancer of the blood in which the bone marrow makes too many lymphocytes. HCL is named after these extra B cells, which look ?hairy? when viewed under a microscope. As the number of leukemia cells increases, fewer healthy white blood cells, red blood cells, and platelets are produced.

Efficacy of the agent was studied in a single-arm, open-label clinical trial of 80 patients who had received prior treatment for HCL with at least two systemic therapies, including a purine nucleoside analog. The trial measured durable complete response (CR), defined as maintenance of hematologic remission for more than 180 days after achievement of CR. Thirty percent of patients in the trial achieved durable CR, and the overall response rate (number of patients with partial or complete response to therapy) was 75%.

Common adverse effects include infusion-related reactions, edema, nausea, fatigue, headache, fever, constipation, anemia, and diarrhea.

The prescribing information includes a boxed warning to advise health professionals and patients about the risk of developing capillary leak syndrome, a condition in which fluid and proteins leak out of tiny blood vessels into surrounding tissues. Symptoms of capillary leak syndrome include difficulty breathing, weight gain, hypotension, or swelling of arms, legs, and/or face.

The boxed warning also notes the risk of hemolytic uremic syndrome, a condition caused by the abnormal destruction of red blood cells. Patients should be made aware of the importance of maintaining adequate fluid intake, and blood chemistry values should be monitored frequently.

Other serious warnings include decreased renal function, infusion-related reactions, and electrolyte abnormalities. Women who are breastfeeding should not take the drug.

Medication Monitor Categories:
New Drug Approvals