Generic Name:
Tagraxofusp-erzs
Trade Name:
Elzonris
Company:
Stemline Therapeutics
Notes:

FDA approved tagraxofusp-erzs infusion for treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN) in adults and in pediatric patients aged 2 years and older.

According to FDA, prior to this approval, there had been no FDA-approved therapies for BPDCN. The standard of care had been intensive chemotherapy followed by bone marrow transplantation.

BPDCN is an aggressive and rare disease of the bone marrow and blood that can affect multiple organs, including the lymph nodes and the skin. It often presents as leukemia or evolves into acute leukemia. The disease is more common in men than women and in patients aged 60 and older.

Efficacy of tagraxofusp-erzs was studied in two cohorts of patients in a single-arm clinical trial. The first trial cohort enrolled 13 patients with untreated BPDCN, and 7 patients (54%) achieved complete remission (CR) or CR with a skin abnormality not indicative of active disease (CRc). The second cohort included 15 patients with relapsed or refractory BPDCN. One patient achieved CR, and one patient achieved CRc.

Common adverse effects reported by patients in clinical trials were capillary leak syndrome, nausea, fatigue, peripheral edema, fever, chills, and weight increase. Most common laboratory abnormalities were decreases in lymphocytes, albumin, platelets, hemoglobin, and calcium, and increases in glucose and liver enzymes (ALT and AST). Health care providers are advised to monitor liver enzyme levels and for signs of intolerance to the infusion.

Women who are pregnant or breastfeeding should not take tagraxofusp-erzs because it may cause harm to a developing fetus or newborn baby.

The labeling contains a boxed warning to alert health professionals and patients about the increased risk of capillary leak syndrome, which may be life-threatening or fatal.

Medication Monitor Categories:
New Drug Approvals