

INDICATION

 ELZONRIS is a CD123-directed cytotoxin for the treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN) in adults and in pediatric patients 2 years and older

IMPORTANT SAFETY INFORMATION

Boxed WARNING: CAPILLARY LEAK SYNDROME

 Capillary Leak Syndrome (CLS), which may be life-threatening or fatal, can occur in patients receiving ELZONRIS. Monitor for signs and symptoms of CLS and take actions as recommended

WARNINGS AND PRECAUTIONS

Capillary Leak Syndrome

• ELZONRIS can cause capillary leak syndrome (CLS), which may be lifethreatening or fatal if not properly managed. The overall incidence of CLS in clinical trials was 55% in patients receiving ELZONRIS, including 46% in Grades 1 or 2, 6% in Grade 3, 1% in Grade 4, and 2 fatal events. Common signs and symptoms (incidence ≥ 20%) associated with CLS that

were reported during treatment with ELZONRIS include hypoalbuminemia, edema, weight gain, and hypotension

- Before initiating therapy with ELZONRIS, ensure that the patient has adequate cardiac function and serum albumin is ≥ 3.2 g/dL
- During treatment with ELZONRIS, ensure that serum albumin levels are
 ≥ 3.5 g/dL and have not been reduced by ≥ 0.5 g/dL from the albumin
 value measured prior to dosing initiation of the current cycle. Monitor
 serum albumin levels prior to the initiation of each dose or more often as
 indicated clinically thereafter. Additionally, assess patients for other signs
 or symptoms of CLS, including weight gain, new onset or worsening edema
 including pulmonary edema, hypotension, or hemodynamic instability
- Counsel patients to seek immediate medical attention should signs or symptoms of CLS occur at any time

Hypersensitivity Reactions

• ELZONRIS can cause severe hypersensitivity reactions. Grade 3 or higher events were reported in 10% of patients in clinical trials. Monitor patients for hypersensitivity reactions during treatment with ELZONRIS.

Interrupt ELZONRIS infusion and provide supportive care as needed if a hypersensitivity reaction should occur. If the reaction is severe, discontinue ELZONRIS permanently

Hepatotoxicity

- Elevations in liver enzymes can occur with ELZONRIS. Grade 3 or higher elevations in liver enzymes occurred in approximately 40% of patients in clinical trials
- Monitor alanine aminotransferase (ALT) and aspartate aminotransferase (AST) prior to each infusion with ELZONRIS. Temporarily withhold ELZONRIS if the transaminases rise to greater than 5 times the upper limit of normal (ULN) and resume treatment upon normalization or when resolved

ADVERSE REACTIONS:

The most common adverse reactions in the clinical trials (incidence \geq 30%) are capillary leak syndrome, nausea, fatigue, peripheral edema, pyrexia, and weight increase. The most common laboratory abnormalities (incidence \geq 50%) are decreases in albumin, platelets, hemoglobin, calcium, sodium, and increases in glucose, ALT, and AST.

Please see representative for full Prescribing Information, including Boxed WARNING, or visit ELZONRIS.com/hcp.

To report SUSPECTED ADVERSE REACTIONS, contact Stemline Therapeutics, Inc. at 1-877-332-7961 or contact the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

References: 1. Pagano L, Valentini CG, Grammatico S, Pulsoni A. Blastic plasmacytoid dendritic cell neoplasm: diagnostic criteria and therapeutical approaches. *Br J Haematol*. 2016;174(2):188-202. 2. Laribi K, Denizon N, Besançon A, et al. Blastic plasmacytoid dendritic cell neoplasm: from origin of the cell to targeted therapies. *Biol Blood Marrow Transplant*. 2016;22(8):1357-1367. 3. Riaz W, Zhang L, Horna P, Sokol L. Blastic plasmacytoid dendritic cell neoplasm: update on molecular biology, diagnosis, and therapy. *Cancer Control*. 2014;21(4):279-289. 4. León-Martínez G, Meillón-García L, Morales-Polanco M, Soler-Montecinos L, Ortiz-Hidalgo C. Unusual morphologic presentations of blastic plasmacytoid dendritic cell neoplasm: report of two cases misdiagnosed as melanoma and leprosy. *Int J Surg Pathol*. 2014;22(1):76-82. 5. Pemmaraju N, Konopleva M. Treating blastic plasmacytoid dendritic cell neoplasm. *The Hematologist* website. http://www.hematology.org/Thehematologist/Ask/8927.aspx. Published August 28, 2018. Accessed January 22, 2019. 6. Facchetti F, Cigognetti M, Fisogni S, Rossi G, Lonardi S, Vermi W. Neoplasms derived from plasmacytoid dendritic cells. *Mod Pathol*. 2016;29(2):98-111. 7. Frankel AE, Woo JH, Ahn C, et al. Activity of SL-401, a targeted therapy directed to interleukin-3 receptor, in blastic plasmacytoid dendritic cell neoplasm patients. *Blood*. 2014;124(3):385-392. 8. Pagano L, Valentini CG, Pulsoni A, et al. Blastic plasmacytoid dendritic cell neoplasm with leukemic presentation: an Italian multicenter study. *Haematologica*. 2013;98(2):239-246. 9. Pemmaraju N. Novel pathways and potential therapeutic strategies for blastic plasmacytoid dendritic cell neoplasm (BPDCN): CD123 and beyond. *Curr Hematol Malig Rep*. 2017;12(6):510-512. 10. Data on file. Stemline Therapeutics, Inc. 11. ELZONRIS [prescribing information]. New York, NY, US: Stemline Therapeutics, Inc.; December 2018.



