PRE-ADMINISTRATION PARAMETERS Tracking Tool

ELZONRIS®
(tagraxofusp-erzs) Injection

INDICATION

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

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.

This information is intended as educational and should not replace a healthcare professional's judgment or clinical expertise.

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BEFORE INITIATING TREATMENT

Review the treatment requirements below and record values where appropriate to ensure the patient meets all requirements prior to ELZONRIS administration. ELZONRIS is administered once daily on days 1 to 5 of a 21-day cycle. The dosing cycle may be extended for dose delays up to day 10 of the cycle.

Patient's name _____ **Date of birth** _____ **Cycle number** _____

PRIOR TO FIRST DOSE: CYCLE 1[1]

☐ Ensure patient has adequate cardiac function[a] ☐ Ensure patient has serum albumin ≥ 3.2 g/dL

[a]In clinical studies, patients had a normal left ventricular ejection fraction ≥ institutional lower limit of normal as measured by multigated acquisition scan or 2-dimensional echocardiography within 28 days prior to start of therapy and no clinically significant abnormalities on a 12-lead electrocardiogram.[2]

FOR ALL DOSES[1]	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7	DAY 8	DAY 9	DAY 10
Date (month/day)	___/___	___/___	___/___	___/___	___/___	___/___	___/___	___/___	___/___	___/___
Parameter										
Body weight (kg)										
Systolic blood pressure (mmHg)										
Heart rate (bpm)										
Body temperature (C°)										
Serum albumin (g/dL)										
Aspartate aminotransferase (AST)										
Alanine aminotransferase (ALT)										
Serum creatinine (mg/dL)										

Alert the treating physician immediately if any parameters defined above exceed the limits for dose modification per the Recommended Dose Modification Guidelines and CLS Management Guidelines on the next page.

RECOMMENDED ELZONRIS DOSAGE MODIFICATIONS[1]

Parameter	Severity Criteria	Dosage Modification
Body weight	Body weight increase ≥ 1.5 kg over pretreatment weight on prior treatment day	See CLS Management Guidelines below
Systolic blood pressure	Systolic blood pressure ≥ 160 mmHg or ≤ 80 mmHg	Withhold ELZONRIS until systolic blood pressure is < 160 mmHg or > 80 mmHg
Heart rate	Heart rate ≥ 130 bpm or ≤ 40 bpm	Withhold ELZONRIS until heart rate is < 130 bpm or > 40 bpm
Body temperature	Body temperature ≥ 38°C	Withhold ELZONRIS until body temperature is < 38°C
Serum albumin	Serum albumin < 3.5 g/dL or reduced ≥ 0.5 g/dL from value measured prior to initiation of the current cycle	See CLS Management Guidelines below
AST or ALT	AST or ALT increase > 5 times the upper limit of normal	Withhold ELZONRIS until transaminase elevations are ≤ 2.5 times the upper limit of normal
Serum creatinine	Serum creatinine > 1.8 mg/dL (159 micromol/L) or creatinine clearance < 60 mL/minute	Withhold ELZONRIS until serum creatinine resolves to ≤ 1.8 mg/dL (159 micromol/L) or creatinine clearance ≥ 60 mL/minute
Hypersensitivity reactions	Mild or moderate	Withhold ELZONRIS until resolution of any mild or moderate hypersensitivity reaction. Resume ELZONRIS at the same infusion rate
	Severe or life-threatening	Discontinue ELZONRIS permanently

CAPILLARY LEAK SYNDROME (CLS) MANAGEMENT GUIDELINES[1]

Time of Presentation	CLS Sign/Symptom	Recommended Action	ELZONRIS Dosing Management
Prior to first dose of ELZONRIS in cycle 1	Serum albumin < 3.2 g/dL	Administer ELZONRIS when serum albumin ≥ 3.2 g/dL.	
During ELZONRIS dosing	Serum albumin < 3.5 g/dL	Administer 25g intravenous albumin (q12h or more frequently as practical) until serum albumin is ≥ 3.5 g/dL AND not more than 0.5 g/dL lower than the value measured prior to dosing initiation of the current cycle.	Interrupt ELZONRIS dosing until the relevant CLS sign/symptom has resolved[†].
	Serum albumin reduced by ≥ 0.5 g/dL from the albumin value measured prior to ELZONRIS dosing initiation of the current cycle		
	A predose body weight that is increased by ≥ 1.5 kg over the previous day's predose weight	Administer 25g intravenous albumin (q12h or more frequently as practical), and manage fluid status as indicated clinically (eg, generally with intravenous fluids and vasopressors if hypotensive and with diuretics if normotensive or hypertensive), until body weight increase has resolved (ie, the increase is no longer ≥ 1.5 kg greater than the previous day's predose weight).	
	Edema, fluid overload and/or hypotension	Administer 25g intravenous albumin (q12h, or more frequently as practical) until serum albumin is ≥ 3.5 g/dL. Administer 1 mg/kg of methylprednisolone (or an equivalent) per day, until resolution of CLS sign/symptom or as indicated clinically. Aggressive management of fluid status and hypotension if present, which could include intravenous fluids and/or diuretics or other blood pressure management, until resolution of CLS sign/symptom or as clinically indicated.	

[†]If ELZONRIS dose is held:
- ELZONRIS administration may resume in the same cycle if all CLS signs/symptoms have resolved and the patient did not require measures to treat hemodynamic instability
- ELZONRIS administration should be held for the remainder of the cycle if CLS signs/symptomshave not resolved or the patient required measures to treat hemodynamic instability (eg, required administration of intravenous fluids and/or vasopressors to treat hypotension) (even if resolved), and
- ELZONRIS administration may only resume in the next cycle if all CLS signs/symptoms have resolved, and the patient is hemodynamically stable.

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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

- Capillary leak syndrome (CLS), including life-threatening and fatal cases, has been reported among patients treated with ELZONRIS. In patients receiving ELZONRIS in clinical trials, the overall incidence of CLS was 53% (65/122), including Grade 1 or 2 in 43% (52/122) of patients, Grade 3 in 7% (8/122) of patients, Grade 4 in 1% (1/122) of patients, and four fatalities (3%). The median time to onset was 4 days (range - 1 to 46 days), and all but 5 patients experienced an event in Cycle 1.
- Before initiating therapy with ELZONRIS, ensure that the patient has adequate cardiac function and serum albumin is greater than or equal to 3.2 g/dL. During treatment with ELZONRIS, monitor serum albumin levels prior to the initiation of each dose of ELZONRIS and as indicated clinically thereafter, and assess patients for other signs or symptoms of CLS, including weight gain, new onset or worsening edema, including pulmonary edema, hypotension or hemodynamic instability.

Hypersensitivity Reactions

- ELZONRIS can cause severe hypersensitivity reactions. In patients receiving ELZONRIS in clinical trials, hypersensitivity reactions were reported in 43% (53/122) of patients treated with ELZONRIS and were Grade ≥ 3 in 7% (9/122). Manifestations of hypersensitivity reported in ≥ 5% of patients include rash, pruritus, and stomatitis. Monitor patients for hypersensitivity reactions during treatment with ELZONRIS. Interrupt ELZONRIS infusion and provide supportive care as needed if a hypersensitivity reaction should occur.

Hepatotoxicity

- Treatment with ELZONRIS was associated with elevations in liver enzymes. In patients receiving ELZONRIS in clinical trials, elevations in ALT occurred in 79% (96/122) and elevations in AST occurred in 76% (93/122). Grade 3 ALT elevations were reported in 26% (32/122) of patients. Grade 3 AST elevations were reported in 30% (36/122) and Grade 4 AST elevations were reported in 3% (4/122) of patients. Elevated liver enzymes occurred in the majority of patients in Cycle 1 and were reversible following dose interruption.
- Monitor alanine aminotransferase (ALT) and aspartate aminotransferase (AST) prior to each infusion with ELZONRIS. Withhold ELZONRIS temporarily if the transaminases rise to greater than 5 times the upper limit of normal and resume treatment upon normalization or when resolved.

ADVERSE REACTIONS:

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

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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. ELZONRIS [prescribing information]. New York, NY, US: Stemline Therapeutics, Inc.; November 2022. **2**. Data on file. Stemline Therapeutics, Inc.

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