LETTER OF APPEAL

Dear Health Care Provider:

We have provided this sample Letter of Appeal to assist with appeal of a denial for ELZONRIS® (tagraxofusp-erzs) Injection for Intravenous (IV) Use. Use of this document does not guarantee coverage for the medication for your patient.

To use this letter, please copy the text from the next page and paste it onto your office letterhead. Be sure to replace all bolded and bracketed text with the appropriate patient-specific information before forwarding your customized letter to your patient's insurance provider. If necessary, please modify the provided fields to more accurately reflect your practice.

Tips for completing the disease and medical history fields:

- Include specific diagnosis codes where appropriate
- List previous therapy, length of therapy, and outcomes (i.e., specify reasons for unsuccessful results)
- Clearly state the rationale for the recommended therapy and why it is appropriate for your patient

Tips for completing the enclosed materials field:

- List and enclose documents that support your rationale for the recommended therapy:
  - Summary of patient's medical records
  - Journal articles
  - Copies of medical correspondence
  - Specific information about the recommended drug or procedure (Prescribing Information, FDA approval letter, treatment guidelines compiled by professional physician organizations)
- Be sure to include all the listed documents with the letter when you send it to your patient's insurance provider

We hope you find this sample Letter of Appeal to be a valuable resource to your practice.

Sincerely,

APPEAL
[Date]

[Name of insurance company]
[Insurance street address]
[City, state, ZIP code]

RE: Appeal for [Patient Name]
Member ID: [Patient ID number]
Date of Birth: [Patient date of birth]
Group Number: [Patient group number]

Dear [insurance contact name]:

I am writing on behalf of my patient, [Patient Name], to request prior authorization for ELZONRIS® (tagraxofusp-erzs) Injection for Intravenous (IV) Use for the treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN).

This letter outlines [Patient Name]'s medical history, prognosis, and treatment rationale.

Summary of Patient History

- [Patient's diagnosis, condition, and treatment history]
- [Previous therapies the patient has undergone for the symptoms associated with disease]
- [Patient's response to past therapies tried and failed]
- [Brief description of the patient's recent symptoms and conditions]

[Summarize your professional opinion of the patient's likely prognosis or disease progression without treatment with ELZONRIS].

Based on the above considerations, I am confident you will agree that ELZONRIS is medically necessary for my patient. If you have any further questions, please feel free to call me at [Phone #] to discuss.

Thank you in advance for your immediate attention to this request. Sincerely,
[Signature] [Name]

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

Please see full Prescribing Information, including Boxed WARNING.

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.