About ELZONRIS™ (tagraxofusp-erzs)
ELZONRIS is a prescription medicine used to treat blastic plasmacytoid dendritic cell neoplasm (BPDCN) in adults and pediatric patients 2 years and older.

IMPORTANT SAFETY INFORMATION
ELZONRIS can cause serious side effects, including:

• **Capillary Leak Syndrome (CLS).** ELZONRIS can cause fluid to leak from small blood vessels into your body’s tissues. This is called “Capillary Leak Syndrome.” CLS can quickly cause you to have symptoms that may become life-threatening or fatal (ie, lead to death). **Get emergency medical help immediately if you develop any of the following symptoms:**
  - fast weight gain
  - swelling of your face, arms, hands, legs, or feet
  - shortness of breath or difficulty breathing
  - low blood pressure (dizziness or lightheadedness, headache, feeling tired, or shortness of breath)

Please see Important Safety Information throughout this booklet, as well as the enclosed full Prescribing Information, including Boxed WARNING.
Your guide to treatment with ELZONRIS

Your healthcare provider has chosen ELZONRIS to treat your BPDCN. This booklet provides you with helpful information and resources to help before and during your treatment.

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Understanding BPDCN

What is BPDCN?
Blastic plasmacytoid dendritic cell neoplasm (BPDCN) is a cancer that affects your blood and the soft tissue inside your bones, which is called bone marrow. It can also affect other parts of your body, such as your lymph nodes, spleen, central nervous system, and skin.

How is BPDCN diagnosed?
To diagnose BPDCN, your healthcare provider will biopsy your skin, lymph nodes, or bone marrow. A biopsy means your healthcare provider will remove tissue from your skin, lymph nodes, or bone marrow, and look at it under a microscope.

One thing healthcare providers should look for in all of these tests is cd123, which is a type of protein found on BPDCN cells.

What is ELZONRIS?
ELZONRIS is the only approved treatment for BPDCN. ELZONRIS is an IV (intravenous) infusion. A healthcare professional will administer ELZONRIS through a needle in your vein.

How does ELZONRIS work?
ELZONRIS works by finding and killing BPDCN cells. It is designed to target cd123, which is located on the surface of BPDCN cells, and cause cell death.

What is the goal of treatment?
The goal of treatment is to get rid of as many BPDCN cells as possible. People respond differently to treatment with ELZONRIS. For some, ELZONRIS may get rid of all BPDCN cells in the body while others may only get rid of some BPDCN cells in the body.

Some people can get a stem cell transplant as part of their treatment plan after ELZONRIS. Talk to your healthcare provider about what this means, and if this is a possibility for you.

IMPORTANT SAFETY INFORMATION (cont’d)
Your healthcare provider will check your weight and test your blood before you receive each dose of ELZONRIS and as needed during treatment.

- **Hypersensitivity reactions** may occur with ELZONRIS. Symptoms may include rash, itching (pruritus), wheezing, or swelling in your face, including around your eyes and/or in and around your mouth.
Your treatment with ELZONRIS

Before you begin treatment
You will receive medicines about an hour before each ELZONRIS treatment to help reduce possible side effects of ELZONRIS. Talk to your treatment team if you have questions about these medicines.
Your treatment team will take blood for routine tests before each dose. This will also help them see how your blood, liver, and kidneys are working during treatment.
Your treatment team will also check your weight and vital signs before each dose. Vital signs are blood pressure, heart rate, temperature, and breathing rate.

Tell your treatment team about:
All of the medicines you take, including prescription medicines, over-the-counter medicines, herbal supplements, and vitamins
ELZONRIS may harm your unborn baby. If there is a possibility that you may become pregnant during treatment, you should use birth control while you are on ELZONRIS, and for 1 week or more after the last dose.
ELZONRIS may cause fetal harm when administered to a pregnant woman. All pregnancies have a risk of birth defect, loss, or other adverse outcomes.
You should not breastfeed while you are on ELZONRIS. It is not known if ELZONRIS passes into breast milk.

Your treatment team will discuss your dosing schedule details with you

IMPORTANT SAFETY INFORMATION (cont’d)
• Liver damage is usually detected through blood tests. Symptoms may include feeling tired (fatigue), loss of appetite, yellowing of your skin or the whites of your eyes (jaundice), or upper right abdominal pain or discomfort
Your healthcare provider will periodically test your blood while you are on ELZONRIS to check for liver damage.

IMPORTANT SAFETY INFORMATION (cont’d)
Contact your healthcare provider immediately if you have any of these symptoms.
Getting medical treatment right away may help keep these problems from becoming more serious.
If you have any side effects during treatment with ELZONRIS, your healthcare provider may hold your treatment for a period of time or completely stop your treatment with ELZONRIS.

Please see Important Safety Information throughout this booklet, as well as the enclosed full Prescribing Information, including Boxed WARNING.
During treatment with ELZONRIS

**HOW:**
Through a needle in your vein (IV infusion)

**HOW LONG:**
Each dose will take 15 minutes

**HOW MUCH:**
Your dose of ELZONRIS is based on your weight

Each cycle of ELZONRIS treatment is 21 days

You will receive ELZONRIS daily on days 1 to 5 of each treatment cycle. Your healthcare provider may decide to extend this dosing period up to day 10 of the treatment cycle.

- Your healthcare provider may delay a dose if your blood tests or vital signs show that it would be safer to wait. They may also decide it is safer to skip a dose.
- You may have at least 11 days without treatment.
- Your healthcare provider will then decide if and when you will receive another 21-day cycle of treatment.

You will receive your first cycle of treatment in the hospital.

- Your treatment team will monitor your reaction to ELZONRIS for 24 hours after the last dose of cycle 1.

Treatment cycle 2 and all additional treatment cycles may be in the hospital or in an outpatient clinic.

- Your treatment team should observe you for 4 hours after each dose.

**Keep all of your medical appointments**

As with any medicine, it is important to follow the schedule set by your healthcare provider. If you miss an appointment, call your healthcare provider as soon as possible to reschedule.

**Watch your weight**

Your weight gives your treatment team important information during your treatment. Fast weight gain can be a sign of CLS (capillary leak syndrome), a serious side effect.

- Weigh yourself daily, and write down your weight every day.
- Weigh yourself at the same time every morning, without clothes, with the scale on a hard surface.

**Get emergency medical help immediately if you develop any of the following symptoms**

- Fast weight gain
- Swelling of your face, arms, hands, legs, or feet
- Shortness of breath
- Low blood pressure (dizziness or lightheadedness, headache, feeling tired, or shortness of breath)

See page 13 of this booklet for a list of resources to help you during your treatment with ELZONRIS.

**IMPORTANT SAFETY INFORMATION (cont’d)**

The most common side effects of ELZONRIS include CLS, nausea, feeling tired (fatigue), swelling in your legs or feet, fever, and weight gain.

These are not all of the possible side effects of ELZONRIS. If any new side effects start or an existing one gets worse, contact your healthcare provider immediately. For more information, talk to your treatment team.
About ELZONRIS™ (tagraxofusp-erzs)
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Your healthcare provider will periodically test your blood while you are on ELZONRIS to check for liver damage.

Contact your healthcare provider immediately if you have any of these symptoms.

Getting medical treatment right away may help keep these problems from becoming more serious.

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The most common side effects of ELZONRIS include CLS, nausea, feeling tired (fatigue), swelling in your legs or feet, fever, and weight gain.

These are not all of the possible side effects of ELZONRIS. If any new side effects start or an existing one gets worse, contact your healthcare provider immediately. For more information, talk to your treatment team.

Be sure to tell your treatment team about:

- all of your medical conditions, including if you
  - are pregnant or plan to become pregnant. ELZONRIS may harm your unborn baby
  - are breastfeeding or plan to breastfeed. It is not known if ELZONRIS passes into breast milk. You and your healthcare provider should decide if you will receive ELZONRIS or breastfeed. You should not do both

You can report any side effects to Stemline Therapeutics, Inc. at 1-877-332-7961 or contact the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see full Prescribing Information, including **Boxed WARNING**, for ELZONRIS to learn more.
Sign up for patient support: Stemline ARC™

You may be able to receive support by signing up for Stemline ARC. Talk to your treatment team about which programs you might be eligible for. They can guide you through the process.

Your dedicated Nurse Advocate is here to help

Our Nurse Advocates are here to help support you as you begin your treatment journey. Every Nurse Advocate is oncology certified and will provide personalized education, helpful tools, and resources. It is important to remember that Nurse Advocate support is not intended to replace discussions between you and your healthcare provider.

Before treatment starts, you will receive several calls from your Nurse Advocate to go over support services including financial assistance, provide education, confirm your first treatment appointment, and verify your insurance coverage.

During treatment cycles, your Nurse Advocate will call with treatment updates, reminders, and additional education.

Following each treatment cycle, your Nurse Advocate will call to check in with you and provide additional guidance, including support to help you transition from inpatient to outpatient treatment, when applicable.

For questions or more information about Stemline ARC, call 1-833-4-STEMLINE (1-833-478-3654) from 8:00 AM to 8:00 PM ET, Monday through Friday

Helpful resources

Resources are available to help you during your treatment. The resources below can give you more information about your cancer and its treatment.*

- American Cancer Society
  cancer.org
- Leukemia & Lymphoma Society
  lls.org
- CancerCare®
  cancercare.org
- National Cancer Institute
  cancer.gov
- Cancer Support Community
  cancersupportcommunity.org
- National Organization for Rare Disorders
  rarediseases.org

Use the links below to learn about the importance of eating nutritious food during your treatment, as well as for recipes and helpful hints.

- American Cancer Society
- National Cancer Institute

Talk to your treatment team if you have questions about your care

*Information provided by Stemline Therapeutics is meant for educational purposes only. It is not meant to replace your healthcare provider’s medical advice or treatment. The organizations listed above are independent from Stemline Therapeutics. Stemline has listed these organizations only as a convenience and according to the permissions granted by their respective terms of use. Each organization has its own terms and conditions and privacy policy that should be reviewed if you choose to contact any of them.
**Talk to your treatment team**

Write down any questions, comments, or concerns about BPDCN or ELZONRIS that you’d like to remember.

**NOTES**

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Please see Important Safety Information throughout this booklet, as well as the enclosed full Prescribing Information, including Boxed WARNING.
HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use ELZNORISTM safely and effectively. See full prescribing information for ELZNORIS.

ELZNORIS (tagraxofusp-erzs) injection, for intravenous use
Initial U.S. Approval: 2018

WARNING: CAPILLARY LEAK SYNDROME
See full prescribing information for complete boxed warning.

Capillary Leak Syndrome (CLS), which may be life-threatening or fatal if not properly managed, can occur in patients receiving ELZNORIS. (5.1)

INDICATIONS AND USAGE
ELZNORIS 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. (1)

DOSAGE AND ADMINISTRATION
• Premedicate with an H1-histamine antagonist, acetaminophen, corticosteroid and H2-histamine antagonist prior to each ELZNORIS infusion. (2.1)
• Administer ELZNORIS intravenously at 12 mcg/kg over 15 minutes once daily on days 1 to 5 of a 21-day cycle. (2.1)
• Administer the first cycle of ELZNORIS in the inpatient setting. Subsequent cycles may be administered in the inpatient or appropriate outpatient setting. (2.1)
• Additional important preparation and administration information is in full prescribing information. See full prescribing information for instructions on preparation and administration. (2.3, 2.4)

Dosage Forms and Strengths
Injection: 1,000 mcg in 1 mL in a single-dose vial. (3)

CONTRAINDICATIONS
None. (4)

WARNINGS AND PRECAUTIONS
• Hypersensitivity: Monitor patients for signs/symptoms and treat appropriately. (5.2)
• Hepatotoxicity: Monitor ALT and AST. Interrupt ELZNORIS if the transaminases rise to greater than 5 times the upper limit of normal. (5.3)

ADVERSE REACTIONS
Most common adverse reactions (incidence ≥ 30%) are capillary leak syndrome, nausea, fatigue, peripheral edema, pyrexia and weight increase. (6.1)

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

USE IN SPECIFIC POPULATIONS
Lactation: Advise women not to breastfeed (8.2)

See 17 for PATIENT COUNSELING INFORMATION

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Revised: 12/2018
1 INDICATIONS AND USAGE
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.

2 DOSAGE AND ADMINISTRATION

2.1 Recommended Dose
- Administer ELZONRIS at 12 mcg/kg intravenously over 15 minutes once daily on days 1 to 5 of a 21-day cycle. The dosing period may be extended for dose delays up to day 10 of the cycle. Continue treatment with ELZONRIS until disease progression or unacceptable toxicity.
- Prior to the first dose of the first cycle, ensure serum albumin is greater than or equal to 3.2 g/dL before administering ELZONRIS.
- Premedicate patients with an H1-histamine antagonist (e.g., diphenhydramine hydrochloride), H2-histamine antagonist (e.g., ranitidine), corticosteroid (e.g., 50 mg intravenous methylprednisolone or equivalent) and acetaminophen (or paracetamol) approximately 60 minutes prior to each ELZONRIS infusion.
- Administer Cycle 1 of ELZONRIS in the inpatient setting with patient observation through at least 24 hours after the last infusion.
- Administer subsequent cycles of ELZONRIS in the inpatient setting or in a suitable outpatient ambulatory care setting that is equipped with appropriate monitoring for patients with hematopoietic malignancies undergoing treatment. Observe patients for a minimum of 4 hours following each infusion.

2.2 Dose Modifications
Monitor vital signs and check albumin, transaminases, and creatinine prior to preparing each dose of ELZONRIS. See Table 1 for recommended dose modifications and Table 2 for CLS management guidelines.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Severity Criteria</th>
<th>Dose Modification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum albumin</td>
<td>Serum albumin &lt; 3.5 g/dL or reduced ≥ 0.5 g/dL from value measured prior to initiation of the current cycle</td>
<td>See CLS Management Guidelines (Table 2)</td>
</tr>
<tr>
<td>Body weight</td>
<td>Body weight increase ≥ 1.5 kg over pretreatment weight on prior treatment day</td>
<td>See CLS Management Guidelines (Table 2)</td>
</tr>
<tr>
<td>Aspartate aminotransferase (AST)</td>
<td>ALT or AST increase &gt; 5 times the upper limit of normal</td>
<td>Withhold ELZONRIS until transaminase elevations are ≤ 2.5 times the upper limit of normal.</td>
</tr>
<tr>
<td>or alanine aminotransferase (ALT)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Serum creatinine</td>
<td>Serum creatinine &gt; 1.8 mg/dL (159 micromol/L) or creatinine clearance &lt; 60 mL/minute</td>
<td>Withhold ELZONRIS until serum creatinine resolves to ≤ 1.8 mg/dL (159 micromol/L) or creatinine clearance ≥ 60 mL/minute.</td>
</tr>
<tr>
<td>Parameter</td>
<td>Severity Criteria</td>
<td>Dose Modification</td>
</tr>
<tr>
<td>------------------------</td>
<td>------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Systolic blood pressure</td>
<td>Systolic blood pressure ≥ 160 mmHg or ≤ 80 mmHg</td>
<td>Withhold ELZONRIS until systolic blood pressure is &lt; 160 mmHg or &gt; 80 mmHg.</td>
</tr>
<tr>
<td>Heart rate</td>
<td>Heart rate ≥ 130 bpm or ≤ 40 bpm</td>
<td>Withhold ELZONRIS until heart rate is &lt; 130 bpm or &gt; 40 bpm.</td>
</tr>
<tr>
<td>Body temperature</td>
<td>Body temperature ≥ 38°C</td>
<td>Withhold ELZONRIS until body temperature is &lt; 38°C.</td>
</tr>
<tr>
<td>Hypersensitivity</td>
<td>Mild or moderate</td>
<td>Withhold ELZONRIS until resolution of any mild or moderate hypersensitivity reaction. Resume ELZONRIS at the same infusion rate.</td>
</tr>
<tr>
<td></td>
<td>Severe or life-threatening</td>
<td>Discontinue ELZONRIS permanently.</td>
</tr>
</tbody>
</table>

Table 2. CLS Management Guidelines

<table>
<thead>
<tr>
<th>Time of Presentation</th>
<th>CLS Sign/Symptom</th>
<th>Recommended Action</th>
<th>ELZONRIS Dosing Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior to first dose of ELZONRIS in cycle 1</td>
<td>Serum albumin &lt; 3.2 g/dL</td>
<td>Administer ELZONRIS when serum albumin ≥ 3.2 g/dL.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Serum albumin &lt; 3.5 g/dL</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Serum albumin reduced by ≥ 0.5 g/dL from the albumin value measured prior to ELZONRIS dosing initiation of the current cycle</td>
<td>Administer 25g intravenous albumin (q12h or more frequently as practical), and manage fluid status as indicated clinically (e.g., generally with intravenous fluids and vasopressors if hypotensive and with diuretics if normotensive or hypertensive), until body weight increase has resolved (i.e. the increase is no longer ≥ 1.5 kg greater than the previous day’s predose weight).</td>
<td>Interrupt ELZONRIS dosing until the relevant CLS sign/symptom has resolved.1</td>
</tr>
<tr>
<td></td>
<td>A predose body weight that is increased by ≥ 1.5 kg over the previous day’s predose weight</td>
<td>Administer 25g intravenous albumin (q12h or more frequently as practical) until serum albumin is ≥ 3.5 g/dL.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Edema, fluid overload and/or hypotension</td>
<td>Administer 1 mg/kg of methylprednisolone (or an equivalent) per day, until resolution of CLS sign/symptom or as indicated clinically.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>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.</td>
<td></td>
</tr>
</tbody>
</table>

1 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/symptoms have not resolved or the patient required measures to treat hemodynamic instability (e.g. 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.
2.3 Preparation for Administration

Assure the following components required for dose preparation and administration are available prior to thawing ELZONRIS:

- One empty 10 mL sterile vial
- 0.9% Sodium Chloride Injection, USP (sterile saline)
- Three 10 mL sterile syringes
- One 1 mL sterile syringe
- One mini-bifuse Y-connector
- Microbore tubing
- One 0.2 micron polyethersulfone in-line filter

- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Thawed ELZONRIS appearance should be a clear, colorless liquid that may contain a few white to translucent particles.

- Prior to dose preparation thaw at room temperature, between 15°C and 25°C (59°F and 77°F), for 15 to 30 minutes in original carton, and verify thaw visually. Thawed vials may be held at room temperature for approximately 1 hour prior to dosage preparation. Do not force thaw. Do not refreeze vial once thawed.

- Use aseptic technique for preparation of the ELZONRIS dose.

- A 2-step process is required for preparation of the final ELZONRIS dose:
  - **Step 1** - Prepare 10 mL of 100 mcg/mL ELZONRIS
    - Using a sterile 10 mL syringe, transfer 9 mL of 0.9% Sodium Chloride Injection, USP to an empty sterile 10 mL vial.
    - Gently swirl the ELZONRIS vial to mix the contents, remove the cap, and using a sterile 1 mL syringe, withdraw 1 mL of thawed ELZONRIS from the product vial.
    - Transfer the 1 mL of ELZONRIS into the 10 mL vial containing the 0.9% Sodium Chloride Injection. Gently invert the vial at least 3 times to mix the contents. Do not shake vigorously.
    - Following dilution the final concentration of ELZONRIS is 100 mcg/mL.
  - **Step 2** – Prepare the ELZONRIS infusion set.
    - Calculate the required volume of diluted ELZONRIS (100 mcg/mL) according to patient’s weight.
    - Draw up the required volume into a new syringe (if more than 10 mL of diluted ELZONRIS (100 mcg/mL) is required for the calculated patient dose, repeat step 1 with a second vial of ELZONRIS). Label the ELZONRIS syringe.
    - Prepare a separate syringe with at least 3 mL of 0.9% Sodium Chloride Injection, USP (saline flush) to be used to flush the administration set once the ELZONRIS dose is delivered.
    - Label the saline flush syringe.
    - Connect the saline flush syringe to one arm of the Y-connector and ensure the clamp is closed.
    - Connect the product syringe to the other arm of the Y-connector and ensure the clamp is closed.
    - Connect the terminal end of the Y-connector to the microbore tubing.
    - Remove the cap from the supply side of the 0.2 micron filter and attach it to the terminal end of the microbore tubing.
    - Unclamp the arm of the Y-connector connected to the saline flush syringe. Prime the Y-connector up to the intersection (do not prime the full infusion set with saline). Re-clamp the Y-connector line on the saline flush arm.
    - Remove the cap on the terminal end of the 0.2 micron filter and set it aside. Unclamp the arm of the Y-connector connected to the product syringe, and prime the entire infusion set, including the filter. Recap the filter, and re-clamp the Y-connector line on the product side. The infusion set is now ready for delivery for dose administration.

- Administer ELZONRIS within 4 hours. During this 4-hour window, the prepared dose should remain at room temperature.
• Do not reuse excess ELZONRIS. Any excess material should be thrown away immediately following infusion.

2.4 Administration
• Establish venous access and maintain with sterile 0.9% Sodium Chloride Injection, USP.
• Administer the prepared ELZONRIS dose via infusion syringe pump over 15 minutes. The total infusion time will be controlled using a syringe pump to deliver the entire dose and the saline flush over 15 minutes.
• Insert the ELZONRIS syringe into the syringe pump, open the clamp on the ELZONRIS side of the Y-connector and deliver the prepared ELZONRIS dose.
• Once the ELZONRIS syringe has been emptied, remove it from the pump and place the saline flush syringe in the syringe pump.
• Open the clamp on the saline flush side of the Y-connector and resume infusion via the syringe pump at the pre-specified flow to push remaining ELZONRIS dose out of the infusion line to complete delivery.

3 DOSAGE FORMS AND STRENGTHS
Injection: 1,000 mcg in 1 mL clear colorless solution in a single-dose vial.

4 CONTRAINDICATIONS
None.

5 WARNINGS AND PRECAUTIONS

5.1 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 55% (52/94), including Grade 1 or 2 in 46% (43/94), Grade 3 in 6% (6/94), Grade 4 in 1% (1/94) and 2 fatal events (2/94, 2%). 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 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 [see Dose Modifications (2.2)].

5.2 Hypersensitivity Reactions
ELZONRIS can cause severe hypersensitivity reactions. In patients receiving ELZONRIS in clinical trials, hypersensitivity reactions were reported in 46% (43/94) of patients treated with ELZONRIS and were Grade ≥ 3 in 10% (9/94). Manifestations of hypersensitivity reported in ≥ 5% of patients include rash, pruritus, stomatitis, and wheezing. Monitor patients for hypersensitivity reactions during treatment with ELZONRIS. Interrupt ELZONRIS infusion and provide supportive care as needed if a hypersensitivity reaction should occur [see Dose Modifications (2.2)].
5.3 Hepatotoxicity
Treatment with ELZONRIS was associated with elevations in liver enzymes. In patients receiving ELZONRIS in clinical trials, elevations in liver enzymes occurred in 88% (83/94) of patients, including Grade 1 or 2 in 48% (45/94), Grade 3 in 36% (34/94), and Grade 4 in 4% (4/94). 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 [see Dose Modifications (2.2)].

6 ADVERSE REACTIONS

The following serious adverse drug reactions are described elsewhere in the labeling:
- Capillary Leak Syndrome [see Warnings and Precautions (5.1)]
- Hypersensitivity Reactions [see Warnings and Precautions (5.2)]
- Hepatotoxicity [see Warnings and Precautions (5.3)]

6.1 Clinical Trials Experience
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Safety of ELZONRIS was assessed in a single-arm clinical trial that included 94 adults with newly-diagnosed or relapsed/refractory myeloid malignancies, including 58 with BPDCN, treated with ELZONRIS 12 mcg/kg daily for 5 days of a 21-day cycle. The overall median number of cycles administered was 2 (range, 1-43), and 4 in patients with BPDCN (range, 1-43).

Two (2%) patients had fatal adverse reaction, both capillary leak syndrome. Overall, 10 (11%) patients discontinued treatment with ELZONRIS due to an adverse reaction; the most common adverse reactions resulting in treatment discontinuation were hepatic toxicities and CLS.

Table 3 summarizes the common (≥ 10%) adverse reactions with ELZONRIS in patients with myeloid malignancies. The rate of any given adverse reaction or lab abnormality was derived from all the reported events of that type.

<table>
<thead>
<tr>
<th>Table 3. Adverse Reactions in ≥ 10% of Patients Receiving 12 mcg/kg of ELZONRIS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vascular disorders</td>
</tr>
<tr>
<td>Capillary leak syndrome&lt;sup&gt;1&lt;/sup&gt;</td>
</tr>
<tr>
<td>Hypotension</td>
</tr>
<tr>
<td>Hypertension</td>
</tr>
<tr>
<td>Gastrointestinal disorders</td>
</tr>
<tr>
<td>Nausea</td>
</tr>
<tr>
<td>Constipation</td>
</tr>
<tr>
<td>Vomiting</td>
</tr>
<tr>
<td>Diarrhea</td>
</tr>
</tbody>
</table>

N=94
<table>
<thead>
<tr>
<th>Medical Conditions</th>
<th>All Grades %</th>
<th>Grade ≥ 3 %</th>
</tr>
</thead>
<tbody>
<tr>
<td>General disorders and administration site conditions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatigue</td>
<td>45</td>
<td>7</td>
</tr>
<tr>
<td>Peripheral edema</td>
<td>43</td>
<td>1</td>
</tr>
<tr>
<td>Pyrexia</td>
<td>43</td>
<td>0</td>
</tr>
<tr>
<td>Chills</td>
<td>29</td>
<td>1</td>
</tr>
<tr>
<td>Investigations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weight increase</td>
<td>31</td>
<td>0</td>
</tr>
<tr>
<td>Nervous system disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td>29</td>
<td>0</td>
</tr>
<tr>
<td>Dizziness</td>
<td>20</td>
<td>0</td>
</tr>
<tr>
<td>Metabolism and nutrition disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Decreased appetite</td>
<td>24</td>
<td>0</td>
</tr>
<tr>
<td>Blood and lymphatic system disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Febrile neutropenia</td>
<td>20</td>
<td>18</td>
</tr>
<tr>
<td>Musculoskeletal and connective tissue disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Back pain</td>
<td>20</td>
<td>2</td>
</tr>
<tr>
<td>Pain in extremity</td>
<td>10</td>
<td>2</td>
</tr>
<tr>
<td>Respiratory, thoracic and mediastinal disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dyspnea</td>
<td>19</td>
<td>2</td>
</tr>
<tr>
<td>Cough</td>
<td>14</td>
<td>0</td>
</tr>
<tr>
<td>Epistaxis</td>
<td>14</td>
<td>1</td>
</tr>
<tr>
<td>Oropharyngeal pain</td>
<td>12</td>
<td>0</td>
</tr>
<tr>
<td>Psychiatric disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insomnia</td>
<td>17</td>
<td>0</td>
</tr>
<tr>
<td>Anxiety</td>
<td>15</td>
<td>0</td>
</tr>
<tr>
<td>Confusional state</td>
<td>11</td>
<td>0</td>
</tr>
<tr>
<td>Cardiac disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tachycardia</td>
<td>17</td>
<td>0</td>
</tr>
<tr>
<td>Skin and subcutaneous tissue disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Petechiae</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>Pruritus</td>
<td>10</td>
<td>0</td>
</tr>
<tr>
<td>Renal and urinary disorders</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hematuria</td>
<td>10</td>
<td>0</td>
</tr>
</tbody>
</table>

1 Capillary leak syndrome defined as any event reported as CLS during treatment with ELZONRIS or the occurrence of at least 2 of the following CLS manifestations within 7 days of each other: hypoalbuminemia (including albumin value less than 3.0 g/dL), edema (including weight increase of 5 kg or more), hypotension (including systolic blood pressure less than 90 mmHg).

Table 4 summarizes the clinically-important laboratory abnormalities that occurred in ≥ 10% patients with myeloid malignancies treated with ELZONRIS.
Table 4. Selected Laboratory Abnormalities in Patients Receiving 12 mcg/kg of ELZONRIS

<table>
<thead>
<tr>
<th></th>
<th>Treatment-Emergent Laboratory Abnormalities</th>
<th>All Grades %</th>
<th>Grade ≥ 3 %</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Hematology</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Platelets decrease</td>
<td></td>
<td>67</td>
<td>53</td>
</tr>
<tr>
<td>Hemoglobin decrease</td>
<td></td>
<td>60</td>
<td>35</td>
</tr>
<tr>
<td>Neutrophils decrease</td>
<td></td>
<td>37</td>
<td>31</td>
</tr>
<tr>
<td><strong>Chemistry</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glucose increase</td>
<td></td>
<td>87</td>
<td>20</td>
</tr>
<tr>
<td>ALT increase</td>
<td></td>
<td>82</td>
<td>30</td>
</tr>
<tr>
<td>AST increase</td>
<td></td>
<td>79</td>
<td>37</td>
</tr>
<tr>
<td>Albumin decrease</td>
<td></td>
<td>77</td>
<td>0</td>
</tr>
<tr>
<td>Calcium decrease</td>
<td></td>
<td>57</td>
<td>2</td>
</tr>
<tr>
<td>Sodium decrease</td>
<td></td>
<td>50</td>
<td>10</td>
</tr>
<tr>
<td>Potassium decrease</td>
<td></td>
<td>39</td>
<td>4</td>
</tr>
<tr>
<td>Phosphate decrease</td>
<td></td>
<td>30</td>
<td>11</td>
</tr>
<tr>
<td>Creatinine increase</td>
<td></td>
<td>27</td>
<td>0</td>
</tr>
<tr>
<td>Alkaline phosphatase increase</td>
<td></td>
<td>26</td>
<td>1</td>
</tr>
<tr>
<td>Potassium increase</td>
<td></td>
<td>21</td>
<td>2</td>
</tr>
<tr>
<td>Magnesium decrease</td>
<td></td>
<td>20</td>
<td>0</td>
</tr>
<tr>
<td>Magnesium increase</td>
<td></td>
<td>14</td>
<td>3</td>
</tr>
<tr>
<td>Bilirubin increase</td>
<td></td>
<td>14</td>
<td>0</td>
</tr>
<tr>
<td>Glucose decrease</td>
<td></td>
<td>11</td>
<td>0</td>
</tr>
<tr>
<td>Sodium increase</td>
<td></td>
<td>10</td>
<td>0</td>
</tr>
</tbody>
</table>

6.2 **Immunogenicity**

As with all therapeutic proteins, there is potential for immunogenicity. The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of the incidence of antibodies to ELZONRIS with the incidences of antibodies to other products may be misleading.

Immune response to ELZONRIS was evaluated by assessment of serum binding reactivity against ELZONRIS (anti-drug antibodies; ADA) and neutralizing antibodies by inhibition of functional activity. Immune response to ELZONRIS was assessed using two immunoassays. The first assay detected reactivity directed against ELZONRIS (ADA), and the second assay detected reactivity against the interleukin-3 (IL-3) portion of ELZONRIS. Two cell-based assays were used to investigate the presence of neutralizing antibodies by inhibition of a cell-based functional activity.
The presence of ADA had a clinically significant effect on the pharmacokinetics of tagraxofusp-erzs [see Clinical Pharmacology (12.2)]. In 130 patients treated with ELZONRIS in 4 clinical trials:

- 96% (115/120) of patients evaluable for the presence of pre-existing ADA at baseline before treatment were confirmed positive with 21% being positive for the presence of neutralizing antibodies. The high prevalence of ADA at baseline was anticipated due to diphtheria immunization.

- 99% (107/108) of patients evaluable for treatment-emergent ADA tested positive with most patients showing an increase in ADA titer by the end of Cycle 2 of ELZONRIS.

- 85% (86/101) of ADA-positive patients evaluable for the presence of neutralizing antibodies were neutralizing antibody-positive.

- 68% (73/108) of patients evaluable for treatment-emergent anti-IL-3 antibodies tested positive with most patients testing positive by Cycle 3 of ELZONRIS.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Based on its mechanism of action, ELZONRIS has the potential for adverse effects on embryo-fetal development [see Clinical Pharmacology (12.1)]. There are no available data on ELZONRIS use in pregnant women to inform a drug-associated risk of adverse developmental outcomes. Animal reproduction or developmental toxicity studies have not been conducted with tagraxofusp-erzs. Advise pregnant women of the potential risk to the fetus.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4%, and 15% to 20%, respectively.

8.2 Lactation

Risk Summary

No data are available regarding the presence of ELZONRIS in human milk, the effects on the breastfed child, or the effects on milk production. Because of the potential for serious adverse reactions in breastfed children from ELZONRIS, breast feeding is not recommended during treatment and for 1 week after the last dose.

8.3 Females and Males of Reproductive Potential

Based on its mechanism of action, ELZONRIS may cause fetal harm when administered to a pregnant woman [see Use in Specific Populations (8.1)].

Pregnancy Testing:
Conduct pregnancy testing in females of reproductive potential within 7 days prior to initiating ELZONRIS treatment.

Contraception:
Advise females to use acceptable contraceptive methods during ELZONRIS treatment and for at least 1 week after the last dose of ELZONRIS.
8.4 Pediatric Use
The safety and effectiveness of ELZONRIS for treatment of BPDCN have been established in pediatric patients 2 years of age and older (no data for pediatric patients less than 2 years of age). Use of ELZONRIS in these age groups is supported by evidence from an adequate and well-controlled study of ELZONRIS in adults with BPDCN and additional safety data from three pediatric patients with BPDCN, including 1 child (2 years to < 12 years old) and 2 adolescents (12 years to < 17 years old), treated with ELZONRIS at the recommended dosage. The safety profile of ELZONRIS in the pediatric patients was similar to that seen in the adults. Efficacy for pediatric patients is extrapolated from the results of STML-401-0114 [see Clinical Studies 14.1, 14.2].

8.5 Geriatric Use
Of the 94 patients who received ELZONRIS at the labeled dose in STML-401-0114, 23% were 75 years and older. The older patients experienced a higher incidence of altered mental status (including confusional state, delirium, mental status changes, dementia, and encephalopathy) than younger patients.

11 DESCRIPTION
Tagraxofusp-erzs, a CD123-directed cytotoxin, is a fusion protein comprised of a recombinant human interleukin-3 (IL-3) and truncated diphtheria toxin (DT). Tagraxofusp-erzs has an approximate molecular weight of 57,695 Daltons. Tagraxofusp-erzs is constructed by recombinant DNA technology and produced in Escherichia coli cells.

ELZONRIS (tagraxofusp-erzs) injection is a preservative-free, sterile, clear, colorless solution that may contain a few white to translucent particles and requires dilution prior to intravenous infusion. ELZONRIS is supplied at a concentration of 1,000 mcg/mL in a single-dose vial. Each mL of ELZONRIS contains 1,000 mcg tagraxofusp-erzs, sodium chloride (4.38 mg), sorbitol (50 mg), tromethamine (2.42 mg) and Water for Injection, USP and pH is 7.5.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action
Tagraxofusp-erzs is a CD123-directed cytotoxin composed of recombinant human interleukin-3 (IL-3) and truncated diphtheria toxin (DT) fusion protein that inhibits protein synthesis and causes cell death in CD123-expressing cells.

12.2 Pharmacokinetics
Following administration of tagraxofusp-erzs 12 mcg/kg via 15-minute infusion in patients with BPDCN, the mean (SD) area under the plasma drug concentration over time curve (AUC) was 231 (123) hr·mcg/L and maximum plasma concentration (Cmax) was 162 (58.1) mcg/L.

Distribution
Mean (SD) volume of distribution of tagraxofusp-erzs is 5.1 (1.9) L in patients with BPDCN.

Elimination
Mean (SD) clearance is 7.1 (7.2) L/hr in patients with BPDCN. Mean (SD) terminal half-life of tagraxofusp-erzs is 0.7 (0.3) hours.
Anti-Product Antibody Formation Affecting Pharmacokinetics
Pharmacokinetic data obtained following doses given in Cycle 3 showed increased titers of anti-drug antibodies and reduced free ELZONRIS concentration in most plasma samples. Following administration of tagraxofusp-erzs 12 mcg/kg via 15-minute infusion in patients with pre-existing anti-drug antibodies, the mean (SD) volume of distribution of tagraxofusp-erzs is 21.2 (25.4) L, clearance is 13.9 (19.4) L/hr, AUC is 151 (89.2) hr·mcg/L and Cmax is 80.0 (82.2) mcg/L.

Specific Populations
No clinically significant differences in the pharmacokinetics of tagraxofusp-erzs were observed based on age (22 to 84 years), sex, mild to moderate renal impairment (eGFR 30 to 89 mL/min/1.73 m², estimated by MDRD), mild (total bilirubin ≤ ULN and AST >ULN, or total bilirubin 1 to 1.5 times ULN and any AST) or moderate (total bilirubin >1.5 to 3 times ULN and any AST) hepatic impairment or body weight after adjusting dose by body weight. The effect of severe renal impairment (eGFR 15 to 29 mL/min/1.73 m²), or severe hepatic impairment (total bilirubin >3 times ULN and any AST) on tagraxofusp-erzs pharmacokinetics is unknown.

Drug Interaction Studies
No drug-drug interaction studies have been conducted with ELZONRIS.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
No studies have been conducted to assess the carcinogenic or genotoxic potential of tagraxofusp. Animal fertility studies have not been conducted with tagraxofusp-erzs.

13.2 Animal Toxicology and/or Pharmacology
At human equivalent doses greater than or equal to 1.6 times the recommended dose based on body surface area, severe kidney tubular degeneration/necrosis was observed in cynomolgus monkeys. At human equivalent doses equal to the recommended dose, degeneration/necrosis of the choroid plexus in the brain was observed in cynomolgus monkeys. The reversibility of this finding was not assessed at lower doses, but the finding was irreversible and became progressively more severe at a human equivalent dose 1.6 times the recommended dose, 3 weeks after dosing stopped.

14 CLINICAL STUDIES

14.1 First-Line Treatment of Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN)
STML-401-0114 (NCT 02113982; Study 0114) was a multicenter, open-label, single-arm, clinical trial that included a prospective cohort of 13 patients with treatment-naive BPDCN. Treatment consisted of ELZONRIS 12 mcg/kg intravenously over 15 minutes once daily on days 1 to 5 of a 21-day cycle. Patient baseline characteristics are presented in Table 5.
Table 5. Baseline Demographics of Patients with Treatment-Naive BPDCN

<table>
<thead>
<tr>
<th>Parameter</th>
<th>N=13</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender, N (%)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>11 (84.6)</td>
</tr>
<tr>
<td>Female</td>
<td>2 (15.4)</td>
</tr>
<tr>
<td>Age (years), N (%)</td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>65.0</td>
</tr>
<tr>
<td>Minimum, Maximum</td>
<td>22, 84</td>
</tr>
<tr>
<td>ECOG, N (%)</td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>8 (61.5)</td>
</tr>
<tr>
<td>1</td>
<td>5 (38.5)</td>
</tr>
<tr>
<td>BPDCN at Baseline, N (%)</td>
<td></td>
</tr>
<tr>
<td>Skin</td>
<td>13 (100.0)</td>
</tr>
<tr>
<td>Bone Marrow</td>
<td>7 (53.8)</td>
</tr>
<tr>
<td>Peripheral Blood</td>
<td>3 (23.1)</td>
</tr>
<tr>
<td>Lymph Nodes</td>
<td>6 (46.2)</td>
</tr>
<tr>
<td>Viscera</td>
<td>2 (15.4)</td>
</tr>
</tbody>
</table>

The efficacy of ELZONRIS in patients with treatment-naive BPDCN was based on the rate of complete response or clinical complete response (CR/CRc). Key efficacy measures are presented in Table 6. The median time to CR/CRc was 57 days (range: 14 to 107).

Table 6. Efficacy Measures in Patients with Treatment-Naive BPDCN

<table>
<thead>
<tr>
<th>Parameter</th>
<th>N=13</th>
</tr>
</thead>
<tbody>
<tr>
<td>CR/CRc* Rate, N (%)</td>
<td>7 (53.8)</td>
</tr>
<tr>
<td>(95% CI)</td>
<td>(25.1, 80.8)</td>
</tr>
<tr>
<td>Duration of CR/CRc (months)</td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>Not Reached</td>
</tr>
<tr>
<td>Minimum, Maximum</td>
<td>3.9, 12.2</td>
</tr>
<tr>
<td>Duration of follow up (months)</td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>11.5</td>
</tr>
<tr>
<td>Minimum, Maximum</td>
<td>0.2, 12.7</td>
</tr>
</tbody>
</table>

* CRc is defined as complete response with residual skin abnormality not indicative of active disease.

14.2 Relapsed or Refractory Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN)

STML-401-0114 (NCT02113982; Study 0114) was a multicenter, open-label, single-arm, clinical trial that included 15 patients with relapsed or refractory BPDCN. Treatment consisted of ELZONRIS 12 mcg/kg on days 1 to 5 of each 21-day cycle. Patient baseline characteristics are presented in Table 7.
Table 7. Baseline Demographics of Patients with Relapsed or Refractory BPDCN

<table>
<thead>
<tr>
<th>Parameter</th>
<th>(N=15)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender, N (%)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>13 (86.7)</td>
</tr>
<tr>
<td>Female</td>
<td>2 (13.3)</td>
</tr>
<tr>
<td>Age (years)</td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>72</td>
</tr>
<tr>
<td>Minimum, Maximum</td>
<td>44, 80</td>
</tr>
<tr>
<td>ECOG, N (%)</td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>5 (33.3)</td>
</tr>
<tr>
<td>1</td>
<td>10 (66.7)</td>
</tr>
<tr>
<td>BPDCN at Baseline, N (%)</td>
<td></td>
</tr>
<tr>
<td>Skin</td>
<td>13 (86.7)</td>
</tr>
<tr>
<td>Bone marrow</td>
<td>9 (60.0)</td>
</tr>
<tr>
<td>Lymph node</td>
<td>8 (53.3)</td>
</tr>
<tr>
<td>Visceral</td>
<td>4 (26.7)</td>
</tr>
<tr>
<td>Peripheral blood</td>
<td>1 (6.7)</td>
</tr>
</tbody>
</table>

In the 15 patients with relapsed/refractory BPDCN, one patient achieved a CR (duration: 111 days) and one patient achieved a CRc (duration: 424 days).

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied
ELZONRIS (tagraxofusp-erzs) injection is a preservative-free, sterile, clear, colorless, 1,000 mcg in 1 mL solution supplied in a single-dose glass vial. Each carton contains one vial (NDC 72187-0401-1).

16.2 Storage and Handling
Store in freezer between -25°C and -15°C (-13°F and 5°F). Protect ELZONRIS from light by storing in the original package until time of use. Thaw vials at room temperature between 15°C and 25°C (59°F and 77°F) prior to preparation [see Preparation for Administration (2.3)]. Do not refreeze the vial once thawed. Do not use beyond expiration date on container.

17 PATIENT COUNSELING INFORMATION

Capillary Leak Syndrome
Advise patients of the risk of capillary leak syndrome (CLS), and to contact their health care professional for signs and symptoms associated with CLS including new or worsening edema, weight gain, shortness of breath, and/or hypotension after infusion. Advise patients to weigh themselves daily [see Warnings and Precautions (5.1)].

Hypersensitivity
Advise patients of the risk of hypersensitivity reactions, and to contact their healthcare professional for signs and symptoms associated with hypersensitivity reactions including rash, flushing, wheezing and swelling of the face [see Warnings and Precautions (5.2)].
Hepatic Toxicity
Advise patients to report symptoms that may indicate elevated liver enzymes including fatigue, anorexia and/or right upper abdominal discomfort [see Warnings and Precautions (5.3)].

Contraception
Advise females to avoid pregnancy and to use acceptable contraceptive methods during ELZONRIS treatment and for at least 1 week after the last dose of ELZONRIS.

Lactation
Advise women not to breastfeed [see Use in Specific Populations (8.2)].

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