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Advances in BPDCN Treatment: Targeting Its Pathophysiology

ReachMD Announcer:
Welcome to *Project Oncology* on ReachMD. This medical industry feature, titled "Advances in BPDCN Treatment: Targeting Its Pathophysiology," is sponsored by Stemline Therapeutics, Inc., a Menarini Group company.

And now, here's Dr. James Foran. Dr. Foran is a paid consultant for Stemline Therapeutics.

Dr. Foran:
Blastic plasmacytoid dendritic cell neoplasm, or BPDCN, is an aggressive myeloid malignancy with poor prognosis as it has a historical median overall survival of just one year.[1] But in 2018, the FDA approved a therapy specifically to treat BPDCN.

TAGRAXOFUSP, also known as ELZONRIS, is a CD123-directed cytotoxin indicated for the treatment BPDCN in adults and in pediatric patients two years and older.

Note that this does come with a Boxed Warning for capillary leak syndrome, or CLS, which may be life-threatening or fatal, and can occur in patients receiving ELZONRIS. So it's important to monitor for signs and symptoms of CLS and take actions as recommended.

In fact, it's the first and only FDA-approved treatment option that targets BPDCN's pathophysiology.[1,2] For some background, BPDCN is characterized by the overexpression of CD123 in plasmacytoid dendritic cell precursors.[1] And so TAGRAXOFUSP is a CD123-directed therapy consisting of a recombinant human IL-3 fused with a truncated diphtheria toxin payload.[1,2] It's approved for the treatment of frontline and relapsed or refractory BPDCN in adult and pediatric patients two years and older.[1]

Knowing that historically, BPDCN has had a poor prognosis,[1] it's imperative to intervene early in the patient's journey. And TAGRAXOFUSP's use in the clinical setting could potentially change the way we approach treating patients with BPDCN.

But it's also important to note that in a recent trial, the most common adverse events occurring with an incidence of greater than or equal to 20 percent in both patient cohorts were increased ALT or AST, hypoalbuminemia, thrombocytopenia, pyrexia, weight gain, and nausea. There's also that risk for CLS, which again is the basis of the boxed warning. And because it may be life-threatening or fatal we need to monitor for signs and symptoms of CLS and to take actions as recommended.[1,2]

To learn more, please listen to the related audio podcasts, which can be found on ReachMD.com.

I'm Dr. James Foran. And now, please listen to the following Important Safety Information, including the Boxed Warning.

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INDICATION

- ELZONRIS 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.

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) patients, including Grade 1 or 2 in 43% (52/122) patients, Grade 3 in 7% (8/122) patients, Grade 4 in 1% (1/122) 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) patients treated with ELZONRIS and were Grade ≥ 3 in 7% (9/122) patients. 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) patients and elevations in AST occurred in 76% (93/122) patients. Grade 3 ALT elevations were reported in 26% (32/122) patients. Grade 3 AST elevations were reported in 30% (36/122) patients and Grade 4 AST elevations were reported in 3% (4/122) 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.

Please see full Prescribing Information, including the 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.

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REFERENCES

1. Deconinck E, et al. Preliminary results from an observational multicenter study of patients with blastic plasmacytoid dendritic cell neoplasm treated with Tagraxofusp in the European Expanded Access Program. Poster presented at: 65th ASH Annual Meeting & Exposition. December 10-13, 2022: New Orleans, LA.
2. ELZONRIS (tagraxofusp-erzs) [prescribing information]. New York, NY: Stemline Therapeutics; 2018.