
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
WASHINGTON, D.C. 20549

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934**

Date of report (Date of earliest event reported): **December 21, 2018**

Stemline Therapeutics, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-35619
(Commission File Number)

45-0522567
(IRS Employer Identification No.)

**750 Lexington Avenue
Eleventh Floor
New York, New York 10022**
(Address of Principal Executive Offices)

(646) 502-2311
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act.
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act.
- Pre-commencement communications pursuant to Rule 14d-2b under the Exchange Act.
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act.

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter). Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 Other Events.

On December 21, 2018, Stemline Therapeutics, Inc. (the “Company”) announced that the U.S. Food and Drug Administration has granted approval of ELZONRIS™ (tagraxofusp; SL-401) for the treatment of patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN) in adult and pediatric patients two years and older, in both treatment-naïve and previously-treated populations. ELZONRIS is the first treatment approved for BPDCN and the first approved CD-123 targeted therapy.

The Company intends to host a conference call to discuss the approval of ELZONRIS for the treatment of BPDCN on Friday, December 21, 2018, at 4:30 p.m. EST. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is furnished herewith:

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press release issued by Stemline Therapeutics, Inc., dated December 21, 2018.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: December 21, 2018

Stemline Therapeutics, Inc.
(Registrant)

By /s/ Kenneth Hoberman
Kenneth Hoberman
Chief Operating Officer



FDA Approves ELZONRIS™ (tagraxofusp), the First Treatment for Blastic Plasmacytoid Dendritic Cell Neoplasm and First CD123-Targeted Therapy

- ELZONRIS is approved to treat adult and pediatric patients with both treatment-naïve and previously-treated BPDCN
- Conference call scheduled for Friday, December 21, 2018 at 4:30 PM ET: Toll Free: (888) 254-3590 or (323) 994-2093; Confirmation Code: 6383213

NEW YORK, December 21, 2018 (GLOBE NEWSWIRE) — Stemline Therapeutics, Inc. (NASDAQ:STML), a biopharmaceutical company focused on the development and commercialization of novel oncology therapeutics, announced today that the U.S. Food and Drug Administration (FDA) has granted approval of ELZONRIS™ (tagraxofusp-erzs; SL-401) for the treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN) in adult and pediatric patients two years and older, in both treatment-naïve and previously-treated populations. ELZONRIS is the first treatment approved for BPDCN and the first approved CD123-targeted therapy.

BPDCN is an aggressive, orphan hematologic malignancy with historically poor outcomes and is an area of unmet medical need. BPDCN may present with features similar to, and can be mistaken for, certain diseases including acute myeloid leukemia, non-Hodgkin's lymphoma, acute lymphocytic leukemia, myelodysplastic syndromes, and chronic myelomonocytic leukemia, as well as other malignancies with skin manifestations. BPDCN typically presents in the bone marrow and/or skin, and may also involve lymph nodes and viscera. The diagnosis of BPDCN is based on the immunophenotypic diagnostic triad of CD123, CD4, and CD56. For more information, see the BPDCN disease education website at www.bpdcninfo.com.

"Today's approval of tagraxofusp is a major step forward for people with BPDCN, their families and the medical community," said Naveen Pemmaraju, M.D., Associate Professor at The University of Texas MD Anderson Cancer Center, and a principal investigator on the tagraxofusp clinical trial. "CD123 is expressed in BPDCN and a number of other hematologic malignancies. The approval of tagraxofusp, a CD123-targeted therapy, represents a new standard of care for patients with BPDCN."

CD123 is a key marker in identifying BPDCN and is a rapidly emerging target for therapeutic research in a variety of cancers. ELZONRIS is designed to specifically target CD123, and, within a triad of signature markers, enables proper diagnosis.

"Tagraxofusp represents an unprecedented leap forward in the treatment of BPDCN, an aggressive malignancy with no approved therapeutic options until now," said Andrew Lane, M.D., Ph.D., Assistant Professor at Harvard Medical School and Dana-Farber Cancer Institute and a principal investigator on the tagraxofusp clinical trial. "I have witnessed firsthand the significant responses a number of my patients experienced with tagraxofusp and a proportion of responders were able to receive a stem-cell transplant following remission."

ELZONRIS was granted Breakthrough Therapy Designation (BTD) and Orphan Drug Designation (ODD), and the ELZONRIS Biologics License Application (BLA) was evaluated under Priority Review by the FDA.

"We are incredibly thankful to the patients, their families and physicians who participated in our clinical trials, and proud of our exceptional team here at Stemline, all of whom played critical roles in bringing this breakthrough treatment to fruition," said Ivan Bergstein, M.D., chief executive officer of Stemline Therapeutics. "Stemline is proud to provide the first approved treatment for BPDCN, and we are committed to making ELZONRIS available to patients."

Stemline intends to bring ELZONRIS to patients with BPDCN globally. In November 2018, the European Medicines Agency (EMA) granted accelerated assessment to the upcoming ELZONRIS Marketing Authorization Application (MAA) submission, which is expected in the first quarter of 2019.

Stemline's Comprehensive Patient Access Program

ELZONRIS will be commercially available for appropriate people with BPDCN in early 2019. Stemline is committed to helping patients with BPDCN access ELZONRIS through the Stemline ARC™ program. Stemline ARC is a comprehensive access program designed to provide support, information and assistance to patients prescribed ELZONRIS. Dedicated oncology nurse advocates are available to provide personalized education about BPDCN and ELZONRIS to patients and their caregivers, and connect them with helpful tools and resources. Stemline ARC offers a copay assistance program for patients with commercial insurance who qualify. Stemline is also partnering with patient advocacy groups to support the needs of patients with BPDCN.

Patients, physicians, pharmacists and other healthcare professionals in the U.S. will be able to access the program by contacting 1-833-478-3654 or by visiting www.stemlineARC.com in early 2019.

ELZONRIS Clinical Trial Design

The ELZONRIS BPDCN clinical trial was the largest prospective trial ever conducted in this disease. This multicenter, multi-cohort, open-label, single-arm, clinical trial (STML-401-0114; NCT 02113982) enrolled 47 patients with BPDCN, including 32 treatment-naïve and 15 previously-treated patients, at seven sites in the U.S. Patients received ELZONRIS intravenously on days 1-5 of a 21-day cycle for multiple consecutive cycles. The trial consisted of three stages: Stage 1 (lead-in, dose escalation), Stage 2 (expansion) and Stage 3 (pivotal, confirmatory). Patients were also enrolled in an additional cohort (Stage 4) to enable uninterrupted access to ELZONRIS.

ELZONRIS Efficacy and Safety

Approval was based on a multicenter, multicohort, open-label, single-arm clinical trial (STML-401-0114; NCT 02113982) in patients with treatment-naïve or previously-treated BPDCN. In the Stage 3 (pivotal) cohort, 13 patients with treatment-naïve BPDCN received ELZONRIS at the labeled dose and schedule. Efficacy was based on the rate of complete response or clinical complete response (CR/CRc), with CRc defined as complete response with residual skin abnormality not indicative of active disease. In this pivotal cohort, the CR/CRc rate was 53.8 percent (7/13) (95% CI: 25.1, 80.8). The median duration of CR/CRc was not reached (range: 3.9 to 12.2 months).

The safety of ELZONRIS was assessed in 94 adults with treatment-naïve or previously-treated myeloid malignancies treated with ELZONRIS at the labeled dose and schedule. The most common adverse reactions (incidence $\geq 30\%$) were capillary leak syndrome (CLS), nausea, fatigue, peripheral edema, pyrexia, and weight increase. The most common laboratory abnormalities (incidence $\geq 50\%$) were decreases in albumin, platelets, hemoglobin, calcium, sodium, and increases in glucose, alanine aminotransferase (ALT) and aspartate aminotransferase (AST).

ELZONRIS Overall Clinical Program in BPDCN

Clinical data from Study STML-401-0114 (NCT 02113982) were presented at the American Society of Hematology (ASH) annual meeting earlier this month. In 29 treatment-naïve patients who received ELZONRIS at 12 mcg/kg/day, the overall response rate (ORR) was 90 percent (26/29) (95% CI: 72.6, 97.8). In these patients, the CR/CRc rate was 72 percent (21/29) (95% CI: 52.8, 87.3) with a median duration of CR/CRc not reached (range: 1.3 to 32.2 months). Forty-five percent (13/29) of these patients were bridged to stem cell transplant (SCT), following remission on ELZONRIS.

The median overall survival (OS), among 29 treatment-naïve patients who received ELZONRIS at 12 mcg/kg/day was not reached (range: 0.2 to 42.0 months, with median follow-up of 23.0 months [range: 0.2 to 41+ months]).

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.

The ELZONRIS label contains a boxed warning for CLS, which may be life-threatening or fatal and can occur in patients receiving ELZONRIS. Physicians are advised to monitor for signs and symptoms of CLS and take actions as recommended in the full prescribing information.

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 $\geq 20\%$) associated with CLS that were reported during treatment with ELZONRIS include hypoalbuminemia, edema, weight gain, and hypotension.
- Capillary leak syndrome is 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 < 90 mmHg).
- 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 full Prescribing Information.

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.

About ELZONRIS™

ELZONRIS, a CD123-directed cytotoxin, was granted full approval by the FDA for the treatment of adult and pediatric patients, two years and older with blastic plasmacytoid dendritic cell neoplasm (BPDCN), in treatment-naïve and previously-treated settings. In November 2018, the European Medicines Agency (EMA) granted ELZONRIS accelerated assessment for the upcoming marketing authorization application (MAA) submission, which is expected in the first quarter of 2019. ELZONRIS is also being evaluated in additional clinical trials in other indications including chronic myelomonocytic leukemia (CMML), myelofibrosis (MF) and other CD123 positive diseases.

About BPDCN

Blastic plasmacytoid dendritic cell neoplasm (BPDCN) is an aggressive hematologic malignancy with historically poor outcomes and an area of unmet medical need. The BPDCN cell of origin is the plasmacytoid dendritic cell (pDC) precursor. BPDCN typically presents in the bone marrow and/or skin and may also involve lymph nodes and viscera. The diagnosis of BPDCN is based on the immunophenotypic diagnostic triad of CD123, CD4, and CD56. For more information, please visit the BPDCN disease awareness website at www.bpdcninfo.com.

About Stemline Therapeutics

Stemline Therapeutics, Inc. is a biopharmaceutical company focused on the development and commercialization of novel oncology therapeutics. In December 2018, the FDA granted approval to ELZONRIS, a targeted therapy directed to CD123, for the treatment of adult and pediatric patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN). In November 2018, the European Medicines Agency (EMA) granted accelerated assessment to the upcoming marketing authorization application (MAA) submission of ELZONRIS in patients with BPDCN, which is expected in the first quarter of 2019. ELZONRIS is also being evaluated in clinical trials in additional indications including chronic myelomonocytic leukemia (CMML), myelofibrosis (MF) and others. Other Stemline clinical candidates include SL-801, a novel oral small molecule reversible inhibitor of XPO1 currently in a Phase 1 trial of patients with advanced solid tumors (dose escalation is ongoing); and SL-701, an immunotherapeutic which has completed a Phase 2 trial in patients with second-line glioblastoma (data and next steps for the program are being evaluated).

Forward-Looking Statements

Some of the statements included in this press release may be forward-looking statements that involve a number of risks and uncertainties. For those statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. The factors that could cause our actual results to differ materially include: the success and timing of our MAA submission to the EMA CHMP; the success and timing of our clinical trials and preclinical studies for our product candidates, including site initiation, institutional review board approval, scientific review committee approval, patient accrual, safety, tolerability and efficacy data observed, and input from regulatory authorities including the risk that the FDA, EMA, or other ex-U.S. national drug authority ultimately does not agree with our data, find our data supportive of approval, or approve any of our product candidates; the possibility that results of clinical trials are not predictive of safety and efficacy results of our product candidates in broader patient populations or of our products if approved; our plans to develop and commercialize our product candidates, including, but not limited to delays in arranging satisfactory manufacturing capabilities and establishing commercial infrastructure for ELZONRIS; product efficacy or safety concerns resulting in product recalls or regulatory action; the risk that estimates regarding the number of patients with the diseases that our products and product

candidates may treat are inaccurate; our products not gaining acceptance among patients (and providers or third party payers) for certain indications (due to cost or otherwise); the risk that third party payors (including governmental agencies) will not reimburse for the use of ELZONRIS at acceptable rates or at all; the company's ability to maintain or increase sales of ELZONRIS; the company's ability to develop and commercialize ELZONRIS; the adequacy of our pharmacovigilance and drug safety reporting processes; our available cash and investments; our ability to obtain and maintain intellectual property protection for our products and product candidates; delays, interruptions, or failures in the manufacture and supply of our products and product candidates; the performance of third-party businesses, including, but not limited to, manufacturers, clinical research organizations, clinical trial sponsors and clinical trial investigators; and other risk factors identified from time to time in our reports filed with the SEC. Any forward-looking statements set forth in this press release speak only as of the date of this press release. We do not intend to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof.

Contact:

Investors:

Stemline Therapeutics, Inc.
750 Lexington Avenue
Eleventh Floor
New York, NY 10022
Tel: 646-502-2307
Email: investorrelations@stemline.com
