
**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): **March 23, 2017**

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.
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Item 8.01 Other Events.

On March 23, 2017, Stemline Therapeutics, Inc. announced completion of enrollment of the Stage 3 cohort of the SL-401 pivotal trial in blastic plasmacytoid dendritic cell neoplasm (BPDCN).

A copy of such press release is being furnished as Exhibit 99.1 to this report.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is furnished herewith:

Exhibit Number	Description
99.1	Press release issued by Stemline Therapeutics, Inc., dated March 23, 2017.

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: March 24, 2017

Stemline Therapeutics, Inc.
(Registrant)

By /s/ Kenneth Hoberman
Kenneth Hoberman
Chief Operating Officer

INDEX TO EXHIBITS

**Exhibit
Number**

Description

99.1 Press release issued by Stemline Therapeutics, Inc., dated March 23, 2017.



Stemline Therapeutics Announces Completion of Enrollment in Stage 3 of the SL-401 Pivotal Trial in BPDCN

NEW YORK, NY, March 23, 2017 (GLOBE NEWSWIRE)—Stemline Therapeutics, Inc. (Nasdaq: STML), a clinical-stage biopharmaceutical company developing novel therapeutics for oncology indications of unmet medical need, announced today that enrollment of Stage 3 in the SL-401 pivotal trial in blastic plasmacytoid dendritic cell neoplasm (BPDCN) has been completed. The company also reviewed key milestones for the SL-401 program over the coming year.

Completes Stage 3 Enrollment

Stemline has completed enrollment of the Stage 3 cohort of the SL-401 pivotal trial in BPDCN. Stage 3 enrolled 13 first-line BPDCN patients; statistical analysis will be based on evaluable first-line patients. The registration pathway was previously agreed upon with the U.S. Food and Drug Administration (FDA). Depending on the data from the trial, Stemline plans to use the results generated to support the potential filing of a Biologics License Application (BLA) for full approval in first-line BPDCN, and is targeting possible BLA filing in the second half of this year.

This multicenter, pivotal trial has enrolled 47 BPDCN patients at seven centers in the U.S. The 47 BPDCN patients were comprised of 32 first-line patients (29 dosed at 12 ug/kg/day) and 15 relapsed/refractory patients dosed at 12 ug/kg/day. Stemline plans to provide a clinical update on patients enrolled in Stages 1 and 2 at a medical conference around mid-year, with top-line data from Stage 3 expected in the second half of 2017. To ensure ongoing patient access to SL-401, Stemline plans to continue to enroll both first-line and relapsed/refractory BPDCN patients under the current protocol.

SL-401 received Breakthrough Therapy Designation (BTD) by the FDA in August 2016.

BLA Preparation and Pre-Commercial Activities Underway

Stemline's clinical, preclinical, manufacturing, and regulatory teams are working toward a timely and comprehensive potential BLA filing. Ongoing efforts include compiling the necessary supportive data and assembling the BLA modules, including clinical, clinical pharmacology, non-clinical, and CMC (chemistry, manufacturing, and controls). In parallel, the commercial team is working to define the BPDCN market landscape, including factors related to patient flow, market access and pricing considerations, all with an eye toward setting the stage for a successful launch of SL-401, if approved.

"I am very proud of the entire Stemline team and our clinical investigators, who helped to make this key milestone possible," said Ivan Bergstein, M.D., Chief Executive Officer of Stemline. Dr. Bergstein, continued "Completing enrollment in our pivotal trial is an important step toward our goal of bringing to market a novel treatment for patients suffering from BPDCN, a devastating disease. We continue to focus on following patients, data collection, and advancing our BLA-targeted efforts on all fronts."

About Stemline Therapeutics

Stemline Therapeutics, Inc. is a clinical stage biopharmaceutical company developing novel therapeutics for oncology indications of unmet medical need. A Phase 2 pivotal trial with SL-401, a targeted therapy directed to the interleukin-3 receptor (CD123),

has completed enrollment of patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN) in the Stage 3 pivotal cohort, and patients continue to be followed. SL-401 has been granted Breakthrough Therapy Designation (BTD) for the treatment of BPDCN. Additional Phase 2 trials with SL-401 are enrolling patients with other malignancies including high-risk myeloproliferative neoplasms (MPN) and acute myeloid leukemia (AML) in remission with minimal residual disease (MRD). A Phase 1/2 trial of SL-401 in combination with pomalidomide is enrolling patients with relapsed/refractory multiple myeloma. A Phase 1 dose escalation trial is enrolling patients with advanced tumors with SL-801, a novel oral small molecule reversible inhibitor of XPO1. A Phase 2 trial with SL-701, an immunotherapy designed to activate the immune system to attack tumors, has completed dosing and patients with second-line glioblastoma are being followed for survival.

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 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 or other ex-U.S. national drug authority ultimately does not approve any of our product candidates; our plans to develop and commercialize our product candidates; market acceptance of our products; reimbursement available for our products; our available cash and investments; our ability to obtain and maintain intellectual property protection for our product candidates; our ability to manufacture; the performance of third-party 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 Securities and Exchange Commission. 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

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