

# SECURITIES AND EXCHANGE COMMISSION

## FORM FWP

Filing under Securities Act Rules 163/433 of free writing prospectuses

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### SUBJECT COMPANY

#### STEMLINE THERAPEUTICS INC

CIK: [1264587](#) | IRS No.: **450522567** | State of Incorporation: **DE** | Fiscal Year End: **1231**  
Type: **FWP** | Act: **34** | File No.: **333-180515** | Film No.: **13521360**  
SIC: **2834** Pharmaceutical preparations

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**Issuer Free Writing Prospectus**

**Dated January 9, 2013**

**Filed Pursuant to Rule 433**

**Registration No. 333-180515**

**Stemline Therapeutics, Inc.**

**Free Writing Prospectus**

**We have filed a registration statement (including a prospectus) with the Securities and Exchange Commission (“SEC”) for the offering to which this communication relates. The registration statement has not yet become effective. Before you invest, you should read the prospectus in that registration statement (including the risk factors described therein) and other documents we have filed with the SEC for more complete information about us and the offering. You may get these documents for free by visiting EDGAR on the SEC Web site at [www.sec.gov](http://www.sec.gov).**

**The preliminary prospectus, dated January 8, 2013, is available on the SEC Web site at:  
<http://www.sec.gov/Archives/edgar/data/1264587/000104746913000116/a2210473zs-1a.htm>**

**Alternatively, we or any underwriter participating in the offering will arrange to send you the prospectus if you contact Aegis Capital Corp., Prospectus Department, 810 Seventh Avenue, 11th Floor, New York, NY 10019, telephone: 212-813-1010, e-mail: [prospectus@aegiscap.com](mailto:prospectus@aegiscap.com); Feltl and Company, Inc., Prospectus Department, 800 LaSalle Avenue, Suite 2100, Minneapolis, MN 55402, telephone: 612-492-8800, e-mail: [prospectus@feltd.com](mailto:prospectus@feltd.com); or Sunrise Securities Corp., 600 Lexington Avenue, 23rd Floor, New York, NY 10022, telephone: 212-421-1616, email: [prospectus@sunrisecorp.com](mailto:prospectus@sunrisecorp.com).**

On December 7, 2012, we issued the following press release.



**Stemline Therapeutics, Inc.**

**Press Release**

**Stemline Therapeutics, Inc. Announces Presentations of SL-401 Updated Clinical Trial Results in Acute Myeloid Leukemia (AML) and Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN) and SL-101 Preclinical Efficacy Data Against Hodgkin’s Lymphoma at the 54th Annual Meeting of the American Society of Hematology (ASH)**

NEW YORK, Dec. 7, 2012 /PRNewswire/ – Stemline Therapeutics, Inc. today announced that two studies featuring SL-401 updated clinical trial results in acute myeloid leukemia (AML) and other hematologic malignancies, including blastic plasmacytoid dendritic cell neoplasm (BPDCN), and SL-101 preclinical activity against Hodgkin’s lymphoma have been selected for presentation at the upcoming 54<sup>th</sup> Annual Meeting of the American Society of Hematology (ASH) to be held in Atlanta, GA from December 8-11, 2012. Stemline and its collaborators from MD Anderson Cancer Center and Scott and White Memorial Hospital will present the posters.

The updated clinical trial results for SL-401, a novel biologic targeted therapy directed to the interleukin-3 receptor (IL-3R), demonstrated that the drug was well-tolerated at clinically active doses and showed single agent anti-tumor activity in heavily pretreated patients with AML, as well as in patients with high risk myelodysplastic syndrome (MDS) and relapsed/refractory blastic plasmacytoid dendritic cell neoplasm (BPDCN). In particular, a single cycle of SL-401 demonstrated single agent activity in patients with relapsed or refractory AML, including two durable complete responses (CRs) of eight and >25 months duration, respectively, and multiple

additional cases of leukemia blast reductions. An overall survival (OS) benefit was also notable among patients treated with only one cycle of SL-401 who were  $\geq$ 3rd-line therapy for AML (n=35); the median OS was 3.6 months (95% CI: 2.3, 6.1 months), which is more than double the historical median OS results of 1.5 months for third-line AML patients treated with

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standard of care. Moreover, at therapeutically relevant doses defined as the MTD (16.6  $\mu$ g/kg/day) or one or two dose levels below the MTD (9.4 or 12.5  $\mu$ g/kg/day), the median OS among patients treated with only one cycle of SL-401 who were  $\geq$ 3rd-line for AML (n = 16) was 5.6 months (95% CI: 2.5, 10.8 months), which is more than triple the historical median OS results of 1.5 months for third-line AML patients treated with standard of care.

In addition, two of three patients with relapsed/refractory BPDCN sustained two additional durable CRs following a single cycle of SL-401. With these CRs, malignant blasts were no longer detectable in the bone marrow and blood. In addition, in one CR, there was also normalization of hepatic and splenic enlargement, and in the other CR there was resolution of associated malignant skin lesions. SL-401 was well-tolerated at clinically active doses, and had no evidence of treatment-related bone marrow suppression.

In a second study, another agent being developed by Stemline, SL-101, demonstrated preclinical efficacy against lymphoid cancers including Hodgkin' s lymphoma. SL-101 is a novel monoclonal antibody-conjugate that targets CD123 with high affinity. SL-101 demonstrated preclinical anti-cancer activity against several Hodgkin' s lymphoma cell lines, as well as anti-cancer activity against mantle cell lymphoma and T-cell acute lymphoid leukemia. The results of this study warrant further evaluation of SL-101 in lymphoid cancers including Hodgkin' s lymphoma.

Details on the abstracts selected for presentation are as follows:

**SL-401, A Targeted Therapy Directed to the Interleukin-3 Receptor Present On Leukemia Blasts and Cancer Stem Cells, Is Active As a Single Agent in Patients with Advanced AML**

Abstract #: 3625

Lead Author: Marina Konopleva, MD, PhD, University of Texas MD Anderson Cancer Center

Session: 615. Acute Myeloid Leukemia - Therapy, excluding Transplantation: Poster III

Date/Time: Monday, December 10, 2012; 6:00 – 8:00pm ET

Location: Hall B1-B2 (Georgia World Congress Center)

**SL-101, a Novel Monoclonal Antibody-Conjugate That Targets Interleukin-3 Receptor Alpha (CD123), Possesses Preclinical Anti-Tumor Activity Against Hodgkin' s Lymphoma**

Abstract #: 2768

Lead Author: Christopher Brooks, Ph.D., Stemline Therapeutics, Inc.

Session: 625. Lymphoma - Pre-Clinical - Chemotherapy and Biologic Agents: Poster II

Date/Time: Sunday, December 9, 2012; 6:00 – 8:00pm ET

Location: Hall B1-B2 (Georgia World Congress Center)

A copy of the above referenced abstracts can be viewed online through the ASH website at [www.hematology.org](http://www.hematology.org).

**About Stemline Therapeutics, Inc.**

Stemline Therapeutics, Inc. is a clinical stage biopharmaceutical company developing novel oncology therapeutics that target both cancer stem cells (CSCs) as well as the tumor bulk. Among Stemline' s drug candidates are SL-401 and SL-701, both of which have demonstrated single agent clinical activity in Phase 1/2 studies of advanced cancer patients. In a multicenter Phase 1/2 trial in patients with advanced acute myeloid leukemia (AML) and other hematologic malignancies including blastic plasmacytoid dendritic cell neoplasm (BPDCN), SL-401 demonstrated single agent activity, including durable complete responses (CRs), and an overall survival

(OS) improvement relative to historical data in the most heavily pretreated AML patients. SL-401 also induced two additional CRs in patients with relapsed/refractory BPDCN, a rare lymphoma. In addition, SL-401 was well-tolerated and was not toxic to the bone marrow. SL-401 is being advanced into later stage trials in advanced BPDCN and AML. In Phase 1/2 trials, Stemline' s second clinical stage therapeutic, SL-701, has demonstrated single agent activity including durable CRs and partial responses (PRs) in adult patients with refractory or recurrent glioblastoma and pediatric patients with malignant glioma, as well as an OS benefit in adult patients with refractory or recurrent glioblastoma compared with historical data. SL-701 is now poised for later stage trials in pediatric and adult patients with advanced brain cancer. Stemline is also developing a broad portfolio of preclinical small molecules and antibodies

for a variety of solid and hematological cancer types. Many of these compounds have derived from the Company' s proprietary discovery platform, StemScreen®. For more information, please visit the Company' s website at [www.stemline.com](http://www.stemline.com).

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