



November 12, 2014

## Stemline Therapeutics Reports Third Quarter 2014 Financial Results and Provides Corporate Update

NEW YORK, Nov. 12, 2014 (GLOBE NEWSWIRE) -- Stemline Therapeutics, Inc. (Nasdaq:STML), a clinical stage biopharmaceutical company developing novel drugs targeting cancer stem cells (CSCs) and tumor bulk, today reported financial results for the quarter ended September 30, 2014 and provided a corporate update.

Ivan Bergstein, M.D., Stemline's Chief Executive Officer, commented, "This third quarter marked an extremely productive period for Stemline as we initiated and are actively enrolling patients in trials with SL-401 in BPDCN and relapsed/refractory AML, as well as with SL-701 in adult brain cancer. We've also recently opened another study with SL-401 in an earlier stage of AML." He continued, "We anticipate significant upcoming milestones, with trial updates expected during 1H15 and throughout 2015, as we continue to pursue our objective of building a leading commercial-stage biopharmaceutical company."

### Business Highlights

- **Actively enrolling patients in SL-401 trial of BPDCN and relapsed/refractory AML.** During the quarter, Stemline treated its first patients and is actively enrolling in a multicenter, open-label trial of SL-401 in blastic plasmacytoid dendritic cell neoplasm (BPDCN) and relapsed/refractory acute myeloid leukemia (AML). Target enrollment is approximately 60 patients, and includes a brief lead-in that transitions into a larger expansion stage for each indication.
- **Opened additional SL-401 trial.** During the quarter, Stemline opened another SL-401 trial. This open-label multicenter trial will enroll patients with AML who are in first complete remission (CR) following their first course of induction chemotherapy, but display evidence of minimal residual disease (MRD) in their bone marrow and remain at high risk for relapse. Target enrollment is approximately 33 patients, and includes a brief lead-in that transitions into a larger expansion stage in this indication.
- **Actively enrolling patients in SL-701 trial of adult second-line GBM.** Stemline continues to actively enroll and treat patients in its multicenter, open-label study of SL-701 in adult second-line glioblastoma multiforme (GBM). Target enrollment is approximately 100 patients.
- **Additional SL-401 trials planned in other IL-3R+ cancers.** Stemline is planning additional SL-401 trials in other malignancies including several uncommon stem cell-derived myeloproliferative disorders.
- **Abstracts accepted at upcoming leading oncology conferences.** Stemline scientific abstracts were accepted for presentation at the Society for Neuro-Oncology (SNO) (SL-701 clinical trial design); the San Antonio Breast Cancer Symposium (StemScreen drug discovery platform in breast cancer); and the American Society of Hematology (ASH) (preclinical data from SL-401 in IL-3R+ cancers including myeloma, SL-501 in Hodgkin's and Non-Hodgkin's lymphoma, and SL-101 in AML).
- **Further expanded intellectual property portfolio.** A recent addition to Stemline's patent estate around the therapeutic targeting of IL-3R (CD123) was granted in the United States. This U.S Patent covers the use of naked monoclonal antibodies that target CD123 in AML. This patent joins additional Stemline issued patents from its family in the U.S and abroad that cover both naked antibodies as well as antibody-drug conjugates (ADCs) directed to CD123 as a method of treating certain hematologic diseases. In addition, Stemline has other broad patents around therapeutic antibodies to cancer stem cell (CSC) cell surface targets in general, as well as patents around its specific IL-3R-targeted agents, SL-401 and SL-501.

### Third Quarter 2014 Financial Results Review

Stemline ended the third quarter of 2014 with \$65.0 million in cash, cash equivalents and investments as compared to \$69.5 million as of June 30, 2014, which reflects a cash burn of \$4.5 million for the quarter. Existing cash, cash equivalents and investments are expected to fund operations for at least the next two years. The company ended the third quarter of 2014 with 13.3 million shares outstanding.

For the third quarter of 2014, Stemline had a net loss of \$6.9 million, or \$0.53 per share, compared with a net loss of \$5.6 million, or \$0.45 per share, for the same period in 2013. The net loss for the first nine months of 2014 was \$21.9 million, or \$1.69 per share, as compared with a net loss of \$16.5 million, or \$1.74 per share, for the nine-month period ended September

30, 2013.

Research and development expense was \$5.0 million for the third quarter of 2014, an increase of \$1.7 million or 50% compared with \$3.3 million for the same period in 2013. The higher costs were primarily attributable to the ramp up in development activities for the SL-401 and SL-701 clinical programs which included manufacturing and regulatory activities coupled with the initiation and execution of clinical trials as compared to the same period in the prior year.

General and administrative expense was \$2.0 million for the third quarter of 2014, which reflects a decrease of \$0.3 million, or 11% compared with \$2.3 million for the same period in 2013. This decrease in costs was primarily attributable to a reduction in consulting and advisory fees.

## About Stemline Therapeutics

Stemline Therapeutics, Inc. is a clinical stage biopharmaceutical company developing novel therapeutics that target both cancer stem cells (CSCs) and tumor bulk. Stemline is currently developing two clinical stage product candidates, SL-401 and SL-701. SL-401 is a targeted therapy directed to the interleukin-3 receptor (IL-3R). A multicenter clinical trial with SL-401 is currently open and accruing patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN) and advanced acute myeloid leukemia (AML). An additional clinical trial with SL-401 is currently open in patients with AML who are in first complete remission (CR) with minimal residual disease (MRD), which is associated with a high relapse rate. Stemline is also planning SL-401 trials in additional hematologic cancers including several uncommon, stem cell-derived myeloproliferative disorders. Previously, SL-401 demonstrated single-agent activity, including multiple durable complete responses (CRs), in a Phase 1/2 trial in several indications including BPDCN and relapsed/refractory AML. SL-701 is an enhanced immunotherapy designed to activate the immune system to attack tumors. A multicenter clinical trial with SL-701 is currently open and accruing adult patients with glioblastoma multiforme (GBM) in first recurrence. Previously, an earlier version of the therapy demonstrated clinical activity, including durable CRs and partial responses (PRs), in Phase 1/2 trials in adults and children with advanced brain cancers. For more information about Stemline Therapeutics, visit [www.stemline.com](http://www.stemline.com).

## 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 preclinical studies and clinical trials, including site initiation, internal review board approval, scientific review committee approval, and patient accrual; our plans to develop and commercialize our product candidates; our available cash; our ability to obtain and maintain intellectual property protection for our product candidates; the ability of our product candidates to successfully perform in clinical trials; 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.

**Table 1. Stemline Therapeutics, Inc. - Balance Sheets**

	September 30, 2014 (Unaudited)	December 31, 2013
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 28,489,426	\$ 44,200,420
Short-term investments	16,002,407	—
Related party receivable	—	199,615
Prepaid expenses and other current assets	735,896	292,916
Total current assets	45,227,729	44,692,951
Furniture and fixtures, net	268,333	383,333
Long-term investments	20,531,546	40,204,912
Total assets	\$ 66,027,608	\$ 85,281,196

**Liabilities and stockholders' equity**

Current liabilities:

Accounts payable and accrued expenses	\$ 4,399,103	\$ 5,013,808
Total current liabilities	4,399,103	5,013,808
Deferred grant revenue	429,428	643,000
Total liabilities	<u>4,828,531</u>	<u>5,656,808</u>

Stockholders' equity:

Preferred stock \$0.0001 par value, 5,000,000 shares authorized, none issued and outstanding at September 30, 2014 and December 31, 2013	—	—
Common stock \$0.0001 par value, 33,750,000 shares authorized at September 30, 2014 and December 31, 2013, 13,270,232 shares issued and outstanding at September 30, 2014 and 13,095,726 shares issued and outstanding at December 31, 2013	1,327	1,310
Additional paid-in capital	114,445,189	111,032,619
Accumulated other comprehensive gain (loss)	16,108	(43,775)
Accumulated deficit	<u>(53,263,547)</u>	<u>(31,365,766)</u>
Total stockholders' equity	<u>61,199,077</u>	<u>79,624,388</u>
Total liabilities and stockholders' equity	<u>\$ 66,027,608</u>	<u>\$ 85,281,196</u>

**Table 2. Stemline Therapeutics, Inc. - Statements of Operations (Unaudited)**

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2014</u>	<u>2013</u>	<u>2014</u>	<u>2013</u>
Revenues:				
Grant revenue	<u>\$71,429</u>	<u>—</u>	<u>\$213,858</u>	<u>—</u>
Operating expenses:				
Research and development	4,979,291	\$ 3,323,662	16,186,735	\$ 10,569,909
General and administrative	<u>2,008,957</u>	<u>2,253,652</u>	<u>6,024,182</u>	<u>5,492,545</u>
Total operating expenses	<u>6,988,248</u>	<u>5,577,314</u>	<u>22,210,917</u>	<u>16,062,454</u>
Loss from operations	(6,916,819)	(5,577,314)	(21,997,059)	(16,062,454)
Other income	2,810	—	3,443	30,649
Other expense	(11,284)	—	(30,354)	—
Interest expense	—	—	—	(505,037)
Interest income	<u>40,136</u>	<u>3,790</u>	<u>126,189</u>	<u>7,034</u>
Net loss from operations	<u>(6,885,157)</u>	<u>(5,573,524)</u>	<u>(21,897,781)</u>	<u>(16,529,808)</u>
Net loss attributable to common stockholders	<u>\$ (6,885,157)</u>	<u>\$ (5,573,524)</u>	<u>\$ (21,897,781)</u>	<u>\$ (16,529,808)</u>
Net loss attributable to common stockholders per common share:				
Basic and Diluted	\$ (0.53)	\$ (0.45)	\$ (1.69)	\$ (1.74)
Weighted-average shares outstanding:				
Basic and Diluted	12,950,027	12,471,472	12,922,117	9,520,179

CONTACT: Investor Relations

Stemline Therapeutics, Inc.

750 Lexington Avenue

Eleventh Floor

New York, NY 10022

Tel: 646-502-2307

Email: [investorrelations@stemline.com](mailto:investorrelations@stemline.com)



Source: Stemline Therapeutics, Inc.

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