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Stemline Therapeutics Reports Second Quarter 2015 Financial Results

NEW YORK, Aug. 10, 2015 (GLOBE NEWSWIRE) -- Stemline Therapeutics, Inc. (Nasdaq:STML), a clinical stage biopharmaceutical company developing novel oncology drugs that primarily target cancer stem cells (CSCs) and tumor bulk, today reported financial results for the quarter ended June 30, 2015.

Ivan Bergstein, M.D., Stemline's Chief Executive Officer, commented, "This quarter, we began enrollment in the expansion stage of our SL-401 pivotal trial in BPDCN, a highly aggressive malignancy of unmet medical need. This follows completion of the lead-in stage of this trial, wherein we evaluated multiple cycle SL-401 administration at escalating doses in first-line and relapsed/refractory BPDCN as well as relapsed/refractory AML. In the lead-in, we established a dose and schedule for the expansion stage, and observed major objective responses, including complete responses, some with gross clearance of bulky disease in multiple organ systems in BPDCN. We are encouraged by both the lack of cumulative side effects and cases of ongoing efficacy seen thus far with multiple cycles. The expansion stage focuses on relapsed/refractory BPDCN patients, which we believe could support registration. We look forward to updating and reporting detailed data at upcoming medical conferences."

Dr. Bergstein continued, "With the expansion stage of our BPDCN pivotal trial underway, we continue to pursue additional opportunities to expand SL-401's potential in other malignancies, and have opened trials in early and late stage AML and high-risk myeloproliferative neoplasms. We also continue to advance and position our other pipeline candidates, SL-701 and SL-801. With a strong cash position and multiple programs advancing in a variety of indications, we remain well positioned to achieve our objective of building a leading commercial stage biopharmaceutical company."

Second Quarter 2015 Financial Results Review

Stemline ended the second quarter of 2015 with \$109.0 million in cash, cash equivalents and investments, as compared to \$58.6 million as of December 31, 2014. In the first quarter of 2015, the Company completed an equity offering raising \$68.6 million in gross cash proceeds on the sale of 4.4 million common shares.

For the second quarter of 2015, Stemline had a net loss of \$10.2 million, or \$0.58 per share, compared with a net loss of \$6.0 million, or \$0.47 per share, for the same period in 2014.

Research and development expenses were \$8.2 million for the second quarter of 2015, which reflects an increase of \$4.1 million compared with \$4.1 million for the second quarter of 2014. The higher expenses during the second quarter were primarily attributable to the SL-401 clinical program due largely to the ramp up of patient accrual.

General and administrative expenses were \$2.2 million for the second quarter of 2015, which reflects an increase of \$0.2 million compared with \$2.0 million for the second quarter of 2014. The higher costs were primarily attributable to an increase in stock based compensation expense relating to administrative employees.

About Stemline Therapeutics

Stemline Therapeutics, Inc. is a clinical stage biopharmaceutical company developing novel oncology therapeutics that primarily target cancer stem cells (CSCs) and tumor bulk. Stemline is developing two clinical stage product candidates, SL-401 and SL-701, and a pipeline of preclinical candidates that includes SL-801. SL-401 is a targeted therapy directed to the interleukin-3 receptor (IL-3R) present on CSCs and tumor bulk of a wide range of hematologic cancers. Several multicenter clinical trials with SL-401 are currently open in a variety of indications. Patients are currently being enrolled in the expansion stage of the SL-401 pivotal trial in relapsed/refractory blastic plasmacytoid dendritic cell neoplasm (BPDCN). This follows recent completion of the lead-in stage of this trial that enrolled first-line and relapsed/refractory BPDCN and relapsed/refractory acute myeloid leukemia (AML) patients at escalating doses and confirmed the dose and schedule for the expansion stage. A previous Phase 1/2 trial with SL-401 demonstrated major responses, including complete responses (CRs), in both first-line and relapsed/refractory BPDCN as well as relapsed/refractory AML (*Frankel et al. Blood 124, 2014*). Clinical studies with SL-401 are also open in additional hematologic indications including acute myeloid leukemia (AML) in first complete remission with minimal residual disease (MRD), relapsed/refractory AML, and four types of advanced high-risk myeloproliferative neoplasms (MPN), including systemic mastocytosis, advanced symptomatic hypereosinophilic disorder, myelofibrosis, and chronic myelomonocytic leukemia. SL-701, an immunotherapy designed to activate the immune system to attack tumors, is being developed in adult patients with second-line glioblastoma multiforme (GBM). SL-801, a novel oral small molecule reversible

inhibitor of XPO1, is currently being advanced toward investigational new drug (IND) filing for clinical development in solid and hematologic cancers. For more information about Stemline Therapeutics, visit 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 clinical trials and preclinical studies for our product candidates, including site initiation, internal review board approval, scientific review committee approval, patient accrual, safety, tolerability and efficacy data observed, and input from regulatory authorities; our plans to develop and commercialize our product candidates; 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.

Table 1. Stemline Therapeutics, Inc. - Balance Sheets

	June 30, 2015	December 31, 2014
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 13,933,233	\$ 25,007,217
Short-term investments	39,937,245	28,976,147
Prepaid expenses and other current assets	<u>2,224,697</u>	<u>1,636,808</u>
Total current assets	56,095,175	55,620,172
Furniture and fixtures, net	153,333	230,000
Long-term investments	<u>55,177,188</u>	<u>4,644,820</u>
Total assets	<u>\$ 111,425,696</u>	<u>\$ 60,494,992</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	<u>\$ 5,844,926</u>	<u>\$ 4,473,842</u>
Total current liabilities	5,844,926	4,473,842
Deferred grant revenue	<u>793,712</u>	<u>607,999</u>
Total liabilities	<u>6,638,638</u>	<u>5,081,841</u>
Stockholders' equity:		
Preferred stock \$0.0001 par value, 5,000,000 shares authorized, none issued and outstanding at June 30, 2015 and December 31, 2014	—	—
Common stock \$0.0001 par value, 33,750,000 shares authorized at June 30, 2015 and December 31, 2014, 17,954,883 shares issued and outstanding at June 30, 2015 and 13,285,232 shares issued and outstanding at December 31, 2014	1,796	1,329
Additional paid-in capital	182,798,121	115,604,563
Accumulated other comprehensive income	14,061	3,000
Accumulated deficit	<u>(78,026,920)</u>	<u>(60,195,741)</u>
Total stockholders' equity	<u>104,787,058</u>	<u>55,413,151</u>
Total liabilities and stockholders' equity	<u>\$ 111,425,696</u>	<u>\$ 60,494,992</u>

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

Three Months Ended June 30, Six Months Ended June 30,

	<u>2015</u>	<u>2014</u>	<u>2015</u>	<u>2014</u>
Revenues:				
Grant revenue	\$ 121,429	\$ 71,429	\$ 242,858	\$ 142,429
Operating expenses:				
Research and development	8,199,397	4,090,590	14,234,884	11,207,446
General and administrative	2,152,638	2,038,011	3,962,703	4,034,294
Total operating expenses	<u>10,352,035</u>	<u>6,128,601</u>	<u>18,197,587</u>	<u>15,241,740</u>
Loss from operations	(10,230,606)	(6,057,172)	(17,954,729)	(15,099,311)
Other income	709	632	1,609	632
Interest income	<u>76,181</u>	<u>43,842</u>	<u>121,941</u>	<u>86,054</u>
Net loss	<u>\$ (10,153,716)</u>	<u>\$ (6,012,698)</u>	<u>\$ (17,831,179)</u>	<u>\$ (15,012,625)</u>
Net loss per common share:				
Basic and Diluted	\$ (0.58)	\$ (0.47)	\$ (1.05)	\$ (1.16)
Weighted-average shares outstanding:				
Basic and Diluted	17,497,976	12,921,898	17,042,631	12,907,931

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