



November 8, 2016

Stemline Therapeutics Reports Third Quarter 2016 Financial Results and Highlights Recent Regulatory and Clinical Progress

NEW YORK, Nov. 08, 2016 (GLOBE NEWSWIRE) -- Stemline Therapeutics, Inc. (Nasdaq:STML) today reported financial results for the quarter ended September 30, 2016.

Ivan Bergstein, M.D., Stemline's Chief Executive Officer, commented, "A key highlight of the quarter was the FDA granting SL-401 Breakthrough Therapy designation for the treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN), a deadly malignancy of the immune system of unmet medical need. We also continue to make significant progress across our entire pipeline, resulting in seven presentations, including an oral presentation of updated Phase 2 trial results of SL-401 in BPDCN, at the upcoming American Society of Hematology (ASH) annual meeting."

Dr. Bergstein concluded, "We look forward to gaining further clarity around our BPDCN registration pathway and timelines in the near-term, and have begun to build-out our pre-commercial infrastructure in preparation for success. Importantly, our strong cash position provides us with the resources to reach important clinical, regulatory and commercial milestones across our many programs."

Third Quarter 2016 Financial Results Review

Stemline ended the third quarter of 2016 with \$74.3 million in cash, cash equivalents and investments, as compared to \$81.2 million as of June 30, 2016, which reflects a cash burn of \$6.9 million for the quarter.

For the third quarter of 2016, Stemline had a net loss of \$9.9 million, or \$0.56 per share, compared with a net loss of \$9.2 million, or \$0.53 per share, for the same period in 2015.

Research and development expenses were \$7.2 million for the third quarter of 2016, which reflects a decrease of \$0.1 million, or 2%, compared with \$7.3 million for the third quarter of 2015.

General and administrative expenses were \$3.2 million for the third quarter of 2016, which reflects an increase of \$1.0 million, or 43%, compared with \$2.2 million for the third quarter of 2015. The increase in expense was primarily attributable to higher non-cash stock based compensation and payroll costs relating to employees.

About Stemline Therapeutics

Stemline Therapeutics, Inc. is a clinical stage biopharmaceutical company developing novel oncology therapeutics. Stemline is developing three clinical stage product candidates, SL-401, SL-801, and SL-701. SL-401 is a targeted therapy directed to the interleukin-3 receptor (CD123) present on a wide range of malignancies. SL-401 is being advanced through a potentially pivotal Phase 2 trial in patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN), an indication for which SL-401 has been granted Breakthrough Therapy Designation (BTD) by the FDA. SL-401 has demonstrated high overall response rates (ORR), with multiple complete responses (CRs), in both first-line and relapsed refractory patients, and response-driven outcomes including treatment duration and frequency of bridge to transplant have been trending favorably. SL-401 is also being advanced through Phase 1/2 trials of patients with additional malignancies including acute myeloid leukemia (AML) in remission with minimal residual disease (MRD), high risk myeloproliferative neoplasms (MPN), and relapsed/refractory multiple myeloma (in combination with pomalidomide). SL-801 is a novel oral small molecule reversible inhibitor of XPO1 that has demonstrated broad *in vivo* and *in vitro* preclinical activity in a wide array of solid and hematologic malignancies. A Phase 1 trial with SL-801 is open and enrolling patients with advanced solid tumors, and a Phase 1 trial in hematologic malignancies is planned. SL-701 is an immunotherapy designed to activate the immune system to attack tumors. A Phase 2 trial with SL-701 in adult patients with second-line glioblastoma multiforme (GBM) is ongoing. For more information about Stemline Therapeutics, please 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

	September 30, 2016		December 31, 2015	
	(Unaudited)			
Assets				
Current assets:				
Cash and cash equivalents	\$	9,127,991	\$	13,376,196
Short-term investments		41,375,137		32,663,245
Prepaid expenses and other current assets		523,612		651,889
Total current assets		51,026,740		46,691,330
Furniture and fixtures, net		23,482		95,661
Long-term investments		23,818,645		51,428,632
Other Assets		212,305		—
Total assets	\$	75,081,172	\$	98,215,623
Liabilities and stockholders' equity				
Current liabilities:				
Accounts payable and accrued expenses	\$	7,917,969	\$	8,632,873
Current portion of deferred grant revenue		1,197,600		822,604
Total current liabilities		9,115,569		9,455,477
Deferred grant revenue, net of current portion		—		616,949
Other liabilities		159,975		31,241
Total liabilities		9,275,544		10,103,667
Stockholders' equity:				
Preferred stock \$0.0001 par value, 5,000,000 shares authorized, none issued and outstanding at September 30, 2016 and December 31, 2015		—		—
Common stock \$0.0001 par value, 33,750,000 shares authorized at September 30, 2016 and December 31, 2015. 19,151,652 shares issued and outstanding at September 30, 2016 and 18,235,020 shares issued and outstanding at December 31, 2015		1,916		1,825
Additional paid-in capital		191,584,735		185,703,423
Accumulated other comprehensive loss		(47,512)		(153,690)
Accumulated deficit		(125,733,511)		(97,439,602)
Total stockholders' equity		65,805,628		88,111,956
Total liabilities and stockholders' equity	\$	75,081,172	\$	98,215,623

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Revenues:				
Grant revenue	\$ 299,401	\$ 205,651	\$ 741,953	\$ 448,509
Operating expenses:				
Research and development	7,176,960	7,340,859	20,585,659	21,575,743
General and				

administrative	3,187,869	2,234,991	8,914,630	6,197,694
Total operating expenses	<u>10,364,829</u>	<u>9,575,850</u>	<u>29,500,289</u>	<u>27,773,437</u>
Loss from operations	(10,065,428)	(9,370,199)	(28,758,336)	(27,324,928)
Other income	1,378	—	11,736	1,609
Interest income	<u>132,006</u>	<u>137,123</u>	<u>417,113</u>	<u>259,064</u>
Net loss before income taxes	(9,932,044)	(9,233,076)	(28,329,487)	(27,064,255)
Income tax benefit	<u>8,822</u>	<u>—</u>	<u>35,578</u>	<u>—</u>
Net loss	<u><u>\$ (9,923,222)</u></u>	<u><u>\$ (9,233,076)</u></u>	<u><u>\$ (28,293,909)</u></u>	<u><u>\$ (27,064,255)</u></u>
Net loss per common share:				
Basic and Diluted	\$ (0.56)	\$ (0.53)	\$ (1.59)	\$ (1.57)
Weighted-average shares outstanding:				
Basic and Diluted	17,831,022	17,515,895	17,777,675	17,196,840

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