Stemline Therapeutics Reports Third Quarter 2017 Financial Results

November 9, 2017

NEW YORK, Nov. 09, 2017 (GLOBE NEWSWIRE) -- Stemline Therapeutics, Inc. (Nasdaq:STML), a clinical-stage biopharmaceutical company developing novel therapeutics for difficult to treat cancers, announced today financial results for the quarter ended September 30, 2017. The Company also reviewed recent clinical and regulatory events, and outlined key upcoming milestones:

Pivotal Trial of SL-401 In Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN)

- On October 31, 2017, we announced that the pivotal trial of SL-401 in blastic plasmacytoid dendritic cell neoplasm (BPDCN) met its primary endpoint.
- We anticipate that a Biologics License Application (BLA) submission could begin in the fourth quarter of 2017 or first quarter of 2018.
- We plan to have detailed data on this trial presented at the upcoming 2017 American Society of Hematology (ASH) Annual Meeting, being held December 9-12 in Atlanta, GA.

Additional Clinical Trials – SL-401, SL-801, SL-701

- SL-401 is also being evaluated in ongoing Phase 1/2 trials in additional indications including certain myeloproliferative neoplasms (MPN) (chronic myelomonocytic leukemia [CMML] and myelofibrosis [MF]), acute myeloid leukemia (AML), and multiple myeloma, as a single agent or in combination with other agents. We expect to provide updates on some of these studies at ASH and on into next year.
- SL-801 Phase 1 results in patients with advanced solid tumors were the subject of a presentation at the European Society of Medical Oncology (ESMO) Annual Congress in September. Dose escalation is ongoing, and the trial is currently enrolling patients in the eighth dosing cohort.
- SL-701 has completed dosing in a Phase 2 trial of patients with second-line glioblastoma. We plan to provide an update on the trial at the upcoming Society for Neuro-Oncology (SNO) meeting in November.

Third Quarter 2017 Financial Results Review
Stemline ended the third quarter of 2017 with $79.9 million in cash, cash equivalents and investments, as compared to $93.2 million as of June 30, 2017, which reflects cash expenditures of $13.3 million for the quarter. The company ended the third quarter of 2017 with 25.3 million shares outstanding.

For the third quarter of 2017, Stemline had a net loss of $16.1 million, or $0.68 per share, compared with a net loss of $9.9 million, or $0.56 per share, for the same period in 2016.

Research and development expense was $12.4 million for the quarter ended September 30, 2017, compared with $7.2 million for the quarter ended September 30, 2016, representing an increase of $5.2 million. The higher costs are primarily driven by an increase of $2.4 million in manufacturing expenses to support our upcoming potential BLA filing for SL-401. We also incurred $2.1 million in higher regulatory costs to support our potential BLA filing for SL-401.

General and administrative expense was $4.2 million for the quarter ended September 30, 2017, compared with $3.2 million for the quarter ended September 30, 2016, representing an increase of $1.0 million. The increase in expense was primarily attributable to $0.6 million in higher legal expenses. Additionally, the higher costs were due to $0.2 million of pre-launch expenses in support of a potential commercialization of SL-401 in BPDCN, if marketing approval from the FDA is received.

About Stemline Therapeutics
Stemline Therapeutics, Inc. is a clinical stage biopharmaceutical company developing novel therapeutics for difficult to treat cancers. 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), a cell surface receptor expressed on a variety of malignancies including blastic plasmacytoid dendritic cell neoplasm (BPDCN), a highly aggressive, lethal malignancy of unmet medical need, with no approved therapies. SL-401 was granted Breakthrough Therapy Designation (BTD) by the U.S. Food and Drug Administration (FDA) for the treatment of patients with BPDCN. A pivotal Phase 2 trial with SL-401 in BPDCN has completed enrollment. An additional cohort is currently enrolling BPDCN patients to ensure continued access to SL-401. Additional Phase 1/2 trials with SL-401, including as a single agent or in combination with other agents, are ongoing in patients with other malignancies including myeloproliferative neoplasms (MPN) (focused on chronic myelomonocytic leukemia [CMML] and myelofibrosis [MF]), acute myeloid leukemia (AML), and multiple myeloma. A Phase 1 trial of SL-801, a novel oral small molecule reversible XPO1 inhibitor, is enrolling patients with advanced solid tumors. Results presented at the European Society of Medical Oncology (ESMO) Annual Congress in September 2017 included dose escalation data of SL-801 through 6 dosing cohorts without dose limiting toxicity. The ideal therapeutic dose of SL-801 has not yet been determined and dose escalation/schedule optimization continues. A Phase 2 trial of SL-701, an immunotherapeutic, has completed dosing of patients with second-line glioblastoma and patients are being followed for outcomes including 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 agree with our data, find our data supportive of approval, or 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.

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Table 1. Stemline Therapeutics, Inc. - Balance Sheets

	September 30, 2017 (Unaudited)	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 10,265,356	$ 10,316,064
Short-term investments	55,259,923	36,562,900
Prepaid expenses and other current assets	598,356	290,747
Total current assets	66,123,635	47,169,711
Property and equipment, net	145,968	22,531
Long-term investments	14,348,432	20,714,551
Other Assets	212,305	212,305
Total assets	$ 80,830,340	**$** 68,119,098
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 14,368,329	$ 9,284,514
Current portion of deferred grant revenue	—	898,199
Other current liabilities	96,827	71,100
Total current liabilities	14,465,156	10,253,813
Other liabilities	121,033	142,200
Total liabilities	14,586,189	10,396,013
Stockholders' equity:		
Preferred stock $0.0001 par value, 5,000,000 shares authorized, none issued and outstanding at September 30, 2017 and December 31, 2016	—	—
Common stock $0.0001 par value, 53,750,000 shares authorized at September 30, 2017 and 33,750,000 shares authorized at December 31, 2016. 25,271,907 shares issued and outstanding at September 30, 2017 and 19,219,223 shares issued and outstanding at December 31, 2016	2,527	1,922
Additional paid-in capital	248,855,696	193,563,572
Accumulated other comprehensive loss	(87,683)	(99,802)
Accumulated deficit	(182,526,389)	(135,742,607)
Total stockholders' equity	66,244,151	57,723,085

Total liabilities and stockholders' equity	$ 80,830,340	$ 68,119,098

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	**2016**	**2017**	**2016**
Revenues:				
Grant revenue	$ 299,397	$ 299,401	$ 898,199	$ 741,953
Operating expenses:				
Research and development	12,417,652	7,176,960	33,517,006	20,585,659
General and administrative	4,152,449	3,187,869	14,000,854	8,914,630
Total operating expenses	16,570,101	10,364,829	47,517,860	29,500,289
Loss from operations	(16,270,704)	(10,065,428)	(46,619,661)	(28,758,336)
Other income	381	1,378	381	11,736
Other expense	(3,566)	—	(3,566)	—
Interest income	217,742	132,006	543,753	417,113
Net loss before income taxes	(16,056,147)	(9,932,044)	(46,079,093)	(28,329,487)
Income tax benefit	—	8,822	—	35,578
Net loss	$ (16,056,147)	$ (9,923,222)	$ (46,079,093)	$ (28,293,909)
Net loss per common share:				
Basic and Diluted	$ (0.68)	$ (0.56)	$ (2.01)	$ (1.59)
Weighted-average shares outstanding:				
Basic and Diluted	23,464,505	17,831,022	22,901,883	17,777,675

Source: Stemline Therapeutics, Inc.