Stemline Therapeutics Reports First Quarter 2017 Financial Results

May 10, 2017

NEW YORK, May 10, 2017 (GLOBE NEWSWIRE) -- Stemline Therapeutics, Inc. (Nasdaq:STML), a clinical-stage biopharmaceutical company developing novel therapeutics for oncology indications of unmet medical need, announced today financial results for the quarter ended March 31, 2017. The company also reviewed clinical and regulatory events from the past quarter, and outlined key upcoming milestones:

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

- During the quarter, we announced completion of enrollment in the Stage 3 cohort of the Phase 2 trial. Stage 3 enrolled 13 patients, and statistical analysis will be conducted on evaluable first-line BPDCN patients.
- Depending on the data from the trial, we plan to use the results generated, along with other relevant data, to support the potential filing of a Biologics License Application (BLA) for approval in BPDCN. A possible BLA filing could begin in 4Q17 or 1Q18.
- To ensure ongoing patient access to SL-401, we are enrolling both first-line and relapsed/refractory BPDCN patients under the current protocol in a Stage 4 cohort.
- We plan to provide an update on Stage 1 and 2 patients mid-year at an upcoming hematology-focused medical conference and on Stage 3 patients in the second half of the year.

Additional Clinical Trials

- Clinical trials evaluating SL-401 are ongoing in additional indications including certain myeloproliferative neoplasms (MPN), acute myeloid leukemia (AML) in complete remission with minimal residual disease, and relapsed/refractory multiple myeloma, and we expect to provide updates on these studies later this year and into next year.
- SL-801 is being evaluated in a Phase 1 dose escalation trial of advanced solid tumor patients, and we recently opened the sixth dosing cohort. SL-701 has completed dosing in a Phase 2 trial in second-line glioblastoma. Updates from both of these studies are expected later this year and into next year.

First Quarter 2017 Financial Results Review
Stemline ended the first quarter of 2017 with $105.8 million in cash, cash equivalents and investments, as compared to $67.6 million as of December 31, 2016, which reflects a cash increase of $38.2 million for the quarter. The $38.2 million increase in cash represents the $48.2 million in net cash proceeds received from the company's follow-on public offering during January 2017 offset by a $10.0 million cash burn for operating activities during the first quarter 2017. The company ended the first quarter of 2017 with 25.1 million shares outstanding.

For the first quarter of 2017, Stemline had a net loss of $14.6 million, or $0.67 per share, compared with a net loss of $9.0 million, or $0.51 per share, for the same period in 2016.

Research and development expenses were $9.6 million for the first quarter of 2017, which reflects an increase of $3.1 million, or 47%, compared with $6.5 million for the first quarter of 2016. The higher costs are primarily driven by an increase of $2.3 million in manufacturing development expenses to support our upcoming potential BLA filing for SL-401. The manufacturing development costs include process characterization and process development work relating to the manufacture of drug substance and drug product for SL-401. Additionally, we incurred an increase in costs due to higher compensation expense as a result of increased headcount. Partially offsetting these higher expenses was a decrease in clinical trial costs for SL-701 resulting from the study attaining full patient enrollment during 2016.

General and administrative expenses were $5.4 million for the first quarter of 2017, which reflects an increase of $2.5 million, or 87%, compared with $2.9 million for the first quarter of 2016. The increase in expense was attributable to higher legal and audit fees of $1.9 million as a result of the class action lawsuits filed against us arising from our January 2017 follow-on public offering. Additionally, the higher costs were driven by $0.5 million in commercial-related pre-launch expenses in support of preparing for a potential product launch 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 oncology indications of unmet medical need. A Phase 2 pivotal trial with SL-401, a targeted therapy directed to the interleukin-3 receptor (CD123), has completed enrollment of patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN) in the Stage 3 cohort, and patients continue to be followed. SL-401 has been granted Breakthrough Therapy Designation (BTD) for the treatment of BPDCN. Additional Phase 1/2 trials with SL-401 are enrolling patients with other malignancies including high-risk myeloproliferative neoplasms (MPN) and acute myeloid leukemia (AML) in remission with minimal residual disease (MRD). A Phase 1/2 trial of SL-401 in combination with pomalidomide is enrolling patients with relapsed/refractory multiple myeloma. A Phase 1 dose escalation trial with SL-801, a novel oral small molecule reversible inhibitor of XPO1, is enrolling patients with advanced solid tumors. A Phase 2 trial with SL-701, an immunotherapy designed to activate the immune system to attack tumors, has completed dosing and patients with second-line glioblastoma are being followed for 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 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.

Table 1. Stemline Therapeutics, Inc. - Balance Sheets

	March 31, 2017 (Unaudited)	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	$ 57,129,787	$ 10,316,064
Short-term investments	32,524,812	36,562,900
Prepaid expenses and other current assets	516,510	290,747
Total current assets	90,171,109	47,169,711
Furniture and fixtures, net	21,579	22,531
Long-term investments	16,140,705	20,714,551
Other Assets	212,305	212,305
Total assets	$ 106,545,698	$ 68,119,098
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 12,535,261	$ 9,284,514
Current portion of deferred revenue	598,798	898,199
Other current liabilities	71,100	71,100
Total current liabilities	13,205,159	10,253,813
Other liabilities	124,425	142,200
Total liabilities	13,329,584	10,396,013
Stockholders' equity:		
Preferred stock $0.0001 par value, 5,000,000 shares authorized, none issued and outstanding at March 31, 2017 and December 31, 2016	—	—
Common stock $0.0001 par value, 33,750,000 shares authorized at March 31, 2017 and December 31, 2016, 25,096,214 shares issued and outstanding at March 31, 2017 and 19,219,223 shares issued and outstanding at December 31, 2016	2,510	1,922
Additional paid-in capital	244,319,102	193,563,572
Accumulated other comprehensive loss	(92,192)	(99,802)
Accumulated deficit	(151,013,306)	(135,742,607)
Total stockholders' equity	93,216,114	57,723,085
Total liabilities and stockholders' equity	$ 106,545,698	$ 68,119,098

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

	Three Months Ended March 31,	
	2017	2016
Revenues:		
Grant revenue	$ 299,401	$ 205,651
Operating expenses:		
Research and development	9,620,324	6,532,730
General and administrative	5,367,775	2,866,122
Total operating expenses	14,988,099	9,398,852

Loss from operations	(14,688,698)	(9,193,201)
Interest income	122,688	144,657
Net loss	$ (14,566,010)	$ (9,048,544)
Net loss per common share:		
Basic and Diluted	$ (0.67)	$ (0.51)
Weighted-average shares outstanding: Basic and Diluted	21,810,559	17,716,012

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