



Stemline Therapeutics Reports Second Quarter 2017 Financial Results

August 8, 2017

NEW YORK, Aug. 08, 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 June 30, 2017. The Company also reviewed recent clinical and regulatory events, and outlined key upcoming milestones:

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

- The SL-401 pivotal Phase 2 trial enrolled 45 BPDCN patients in Stages 1, 2 and 3. Stage 3 was prospectively designed to support potential registration.
- During the quarter, we presented updated data from Stages 1 and 2 of the Phase 2 trial at the 22nd Congress of the European Hematology Association (EHA) in Madrid, Spain.
- Analysis of Phase 2 data, inclusive of Stage 3, is ongoing and we remain on track to announce top-line results in 2H17. We are also targeting a medical conference to present more detailed results later this year.
- To ensure ongoing patient access to SL-401, we are enrolling both first-line and relapsed/refractory BPDCN patients in an additional cohort.
- Depending on the data from the trial, we plan to use the results generated, along with other relevant data, to support the filing of a Biologics License Application (BLA) for approval in BPDCN. We continue to anticipate a possible BLA filing could begin in 4Q17 or 1Q18.

Additional Clinical Trials

- Clinical trials evaluating SL-401 are ongoing in additional indications including certain myeloproliferative neoplasms (MPN), acute myeloid leukemia (AML), and multiple myeloma, as a single agent or in combination with other agents. We expect to provide updates on these studies later this year and into next year.
- SL-801, a novel XPO1 inhibitor, is being evaluated in a Phase 1 trial of patients with advanced solid tumors. SL-701 has completed dosing in a Phase 2 trial of patients with second-line glioblastoma. We are targeting medical conferences for updates on both of these studies later this year.

Second Quarter 2017 Financial Results Review

Stemline ended the second quarter of 2017 with \$93.2 million in cash, cash equivalents and investments, as compared to \$105.8 million as of March 31, 2017, which reflects a use of cash of \$12.6 million for the quarter. The company ended the second quarter of 2017 with 25.2 million shares outstanding.

For the second quarter of 2017, Stemline had a net loss of \$15.5 million, or \$0.66 per share, compared with a net loss of \$9.3 million, or \$0.52 per share, for the same period in 2016.

Research and development expenses were \$11.5 million for the second quarter of 2017, which reflects an increase of \$4.6 million, or 67%, compared with \$6.9 million for the second quarter of 2016. The higher costs are primarily driven by an increase of \$2.1 million in manufacturing expenses to support our potential BLA filing for SL-401. We also incurred \$1.2 million in higher costs for regulatory support of our potential BLA filing for SL-401. Additionally, we incurred higher compensation expense as a result of increased headcount.

General and administrative expenses were \$4.5 million for the second quarter of 2017, which reflects an increase of \$1.6 million, or 57%, compared with \$2.9 million for the second quarter of 2016. The increase in expense was primarily attributable to \$0.7 million in pre-launch expenses in support of a potential commercialization of SL-401 in BPDCN, if marketing approval from the FDA is granted. The increase in costs was also driven by \$0.4 million in higher legal expense as a result of the class action lawsuit, as well as a \$0.3 million increase in non-cash stock-based compensation expense.

About Stemline Therapeutics

Stemline Therapeutics, Inc. is a clinical stage biopharmaceutical company developing novel therapeutics for difficult to treat cancers. SL-401 is a targeted therapy directed to the interleukin-3 receptor (CD123), a cell surface receptor overexpressed on BPDCN and a variety of other hematologic cancers. SL-401 was granted Breakthrough Therapy Designation (BTD) for the treatment of patients with BPDCN. A pivotal Phase 2 trial with SL-401 in BPDCN has completed enrollment in Stages 1, 2 and 3 of the trial; to ensure ongoing patient access to SL-401, an additional cohort, Stage 4, is enrolling. Additional Phase 1/2 trials are assessing SL-401 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, as a single agent or in combination with other agents. SL-801, a novel oral small molecule reversible inhibitor of XPO1, is enrolling patients with advanced solid tumors in a Phase 1 trial. SL-701, an immunotherapeutic, has completed dosing of patients with second-line glioblastoma in a Phase 2 trial 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 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

	June 30, 2017 (Unaudited)	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	\$ 8,549,890	\$ 10,316,064
Short-term investments	55,536,100	36,562,900
Prepaid expenses and other current assets	471,880	290,747
Total current assets	64,557,870	47,169,711
Furniture and fixtures, net	45,773	22,531
Long-term investments	29,157,603	20,714,551
Other Assets	212,305	212,305
Total assets	\$ 93,973,551	\$ 68,119,098
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 13,523,018	\$ 9,284,514
Current portion of deferred grant revenue	299,397	898,199
Other current liabilities	71,100	71,100
Total current liabilities	13,893,515	10,253,813
Other liabilities	106,650	142,200
Total liabilities	14,000,165	10,396,013
Stockholders' equity:		
Preferred stock \$0.0001 par value, 5,000,000 shares authorized, none issued and outstanding at June 30, 2017 and December 31, 2016	—	—
Common stock \$0.0001 par value, 53,750,000 shares authorized at June 30, 2017 and 33,750,000 shares authorized at December 31, 2016. 25,180,024 shares issued and outstanding at June 30, 2017 and 19,219,223 shares issued and outstanding at December 31, 2016	2,518	1,922
Additional paid-in capital	246,562,007	193,563,572
Accumulated other comprehensive loss	(120,897) (99,802
Accumulated deficit	(166,470,242) (135,742,607
Total stockholders' equity	79,973,386	57,723,085
Total liabilities and stockholders' equity	\$ 93,973,551	\$ 68,119,098

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2017	2016	2017	2016
Revenues:				
Grant revenue	\$ 299,401	\$ 236,901	\$ 598,802	\$ 442,552
Operating expenses:				
Research and development	11,479,030	6,875,970	21,099,354	13,408,700
General and administrative	4,480,630	2,860,639	9,848,406	5,726,761
Total operating expenses	15,959,660	9,736,609	30,947,760	19,135,461
Loss from operations	(15,660,259) (9,499,708) (30,348,958) (18,692,909

Other income	—	10,359	—	10,359
Interest income	203,323	140,450	326,012	285,107
Net loss before income taxes	(15,456,936)	(9,348,899)	(30,022,946)	(18,397,443)
Income tax benefit	—	26,756	—	26,756
Net loss	\$ (15,456,936)	\$ (9,322,143)	\$ (30,022,946)	\$ (18,370,687)
Net loss per common share:				
Basic and Diluted	\$ (0.66)	\$ (0.52)	\$ (1.33)	\$ (1.03)
Weighted-average shares outstanding:				
	23,412,409	17,785,406	22,615,909	17,750,709
Basic and Diluted				

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