



Stemline Therapeutics Reports Fourth Quarter 2016 Financial Results

NEW YORK, NY, March 16, 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 December 31, 2016. 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)

- SL-401 Phase 2 clinical trial results in patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN) delivered as an oral presentation at the 2016 American Society of Hematology (ASH) annual meeting.
- After receipt of breakthrough therapy designation in 3Q16, Stemline had a successful meeting with the U.S. Food and Drug Administration (FDA) resulting in a defined registration pathway for possible full approval in first-line BPDCN.
 - Stemline is currently enrolling patients in a new cohort (Stage 3) that is expected to enroll approximately 8-12 first-line BPDCN patients.
 - Completion of enrollment of the Stage 3 cohort expected this quarter. We plan to provide clinical results from this cohort in the second half of this year.

Additional Clinical Trials

- SL-401 is being clinically evaluated in several additional indications including certain high-risk myeloproliferative neoplasms (MPN), acute myeloid leukemia (AML) in complete remission with minimal residual disease, and with relapsed/refractory multiple myeloma. SL-801 is being evaluated in a Phase 1 dose escalation trial of advanced solid tumor patients. SL-701 has completed dosing in a Phase 2 trial in second-line glioblastoma. Updates from these studies are expected this year.

Fourth Quarter 2016 Financial Results Review

Stemline ended the fourth quarter of 2016 with \$67.6 million in cash, cash equivalents and investments, as compared to \$74.3 million as of September 30, 2016, which reflects a cash burn of \$6.7 million for the quarter. Subsequent to year end 2016, Stemline completed a follow-on public offering during January 2017 raising \$48.2 million in net cash proceeds bringing total cash, cash equivalents and investments to approximately \$110.0 million as of March 16, 2017.

For the fourth quarter of 2016, Stemline had a net loss of \$10.0 million, or \$0.56 per share, compared with a net loss of \$10.2 million, or \$0.58 per share, for the same period in 2015.

Research and development expenses were \$7.3 million for the fourth quarter of 2016, which reflects a decrease of \$0.6 million, or 8%, compared with \$7.9 million for the fourth quarter of 2015. The lower costs reflect a one-time payroll-related expense in 2015 partially offset by higher non-cash stock based compensation expense in 2016.

General and administrative expenses were \$3.1 million for the fourth quarter of 2016, which reflects an increase of \$0.5 million, or 19%, compared with \$2.6 million for the fourth quarter of 2015. The increase in costs was primarily attributable to higher non-cash stock based compensation expense and the commencement of building infrastructure to support a potential commercial launch of SL-401 for

BPDCN.

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), is enrolling patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN), an indication for which SL-401 has been granted Breakthrough Therapy Designation (BTD). Additional Phase 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 is enrolling patients with advanced tumors with SL-801, a novel oral small molecule reversible inhibitor of XPO1. 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, internal 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 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.

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Table 1. Stemline Therapeutics, Inc. - Balance Sheets

	<u>December 31, 2016</u>	<u>December 31, 2015</u>
Assets		
Current assets:		
Cash and cash equivalents	\$10,316,064	\$13,376,196
Short-term investments	36,562,900	32,663,245
Prepaid expenses and other current assets	290,747	651,889
Total current assets	47,169,711	46,691,330
Furniture and fixtures, net	22,531	95,661
Long-term investments	20,714,551	51,428,632
Other Assets	212,305	—
Total assets	<u>\$68,119,098</u>	<u>\$98,215,623</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	9,284,514	8,632,873
Current portion of deferred grant revenue	898,199	822,604
Other current liabilities	71,100	—
Total current liabilities	10,253,813	9,455,477
Deferred grant revenue, net of current portion	—	616,949
Other liabilities	142,200	31,241
Total liabilities	<u>10,396,013</u>	<u>10,103,667</u>
Stockholders' equity:		
Preferred stock \$0.0001 par value, 5,000,000 shares authorized, none issued and outstanding at December 31, 2016 and 2015	—	—
Common stock \$0.0001 par value, 33,750,000 shares authorized at December 31, 2016 and 2015, 19,219,223 shares issued and outstanding at December 31, 2016 and 18,235,020 shares issued and outstanding at December 31, 2015	1,922	1,825
Additional paid-in capital	193,563,572	185,703,423
Accumulated other comprehensive loss	(99,802)	(153,690)
Accumulated deficit	(135,742,607)	(97,439,602)
Total stockholders' equity	<u>57,723,085</u>	<u>88,111,956</u>
Total liabilities and stockholders' equity	<u>\$68,119,098</u>	<u>\$98,215,623</u>

Table 2. Stemline Therapeutics, Inc. - Statements of Operations

	<u>Three Months Ended December 31,</u>		<u>Twelve Months Ended December 31,</u>	
	<u>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
Revenues:				
Grant revenue	\$ 299,401	\$ 205,651	\$ 1,041,354	\$ 654,160
Operating expenses:				
Research and development	7,284,262	7,882,933	27,869,921	29,458,676
General and administrative	3,142,260	2,631,148	12,056,890	8,828,843
Total operating expenses	<u>10,426,522</u>	<u>10,514,081</u>	<u>39,926,811</u>	<u>38,287,519</u>
Loss from operations	(10,127,121)	(10,308,430)	(38,885,457)	(37,633,359)
Other (expense) income	(299)	—	11,438	1,609
Interest income	128,606	128,824	545,718	387,889
Net loss before income taxes	<u>\$(9,998,814)</u>	<u>\$(10,179,606)</u>	<u>\$(38,328,301)</u>	<u>\$(37,243,861)</u>
Income tax (expense) benefit	(10,282)	—	25,296	—
Net loss	<u>\$(10,009,096)</u>	<u>\$(10,179,606)</u>	<u>\$(38,303,005)</u>	<u>\$(37,243,861)</u>
Net loss per common share:				
Basic and Diluted	\$ (0.56)	\$ (0.58)	\$ (2.15)	\$ (2.15)
Weighted-average shares outstanding:				
Basic and Diluted	17,885,113	17,562,559	17,804,681	17,289,021