January 5, 2017

Stemline Therapeutics Announces Positive FDA Meeting and Agreement on Expedited Pathway to Full Approval of SL-401 in First-Line BPDCN

- ***Ongoing Phase 2 trial with additional small cohort (8-12 patients planned) sufficient for BLA filing for full approval***
- ***Approximately half of new cohort patients already enrolled, with full enrollment expected this quarter***
- ***BLA filing targeted for 2H17, with commercial launch projected for 2018***
- ***Conference call scheduled for tomorrow, Friday, January 6 at 8:00 AM ET***

NEW YORK, Jan. 05, 2017 (GLOBE NEWSWIRE) -- Stemline Therapeutics, Inc. (Nasdaq:STML) announced today an agreement with the U.S. Food and Drug Administration (FDA) on the registration pathway for SL-401 in blastic plasmacytoid dendritic cell neoplasm (BPDCN). To support the filing of a Biologics License Application (BLA) for full approval in first-line BPDCN, Stemline is currently enrolling an additional small cohort, planned for 8-12 first-line BPDCN patients, into its ongoing Phase 2 trial. To date, approximately half of these new patients are enrolled into the study, with full enrollment expected this quarter. Stemline intends to file a BLA in 2H17, which is anticipated to undergo an expedited review given SL-401's Breakthrough Therapy Designation. If successful, Stemline projects a commercial launch of SL-401 in 2018.

Ivan Bergstein, M.D., Stemline's Chief Executive Officer, commented, "We are extremely pleased with the outcome of our meeting with the FDA and the Agency's continued guidance regarding SL-401, which was granted Breakthrough Therapy Designation this past August. The Agency has now provided us with a clear and potentially rapid pathway to obtain full approval of SL-401 in first-line BPDCN, as well as the possibility for review in the relapsed/refractory setting. We are actively enrolling patients who are to be included in the final cohort of the trial and are targeting completion of enrollment this quarter." Dr. Bergstein continued, "In parallel, our operations and regulatory teams are working hard to ensure a timely and comprehensive BLA filing, including addressing additional data requests from the Agency, while our commercial team is setting the stage, if approved, for a successful launch of SL-401. Additionally, we continue to advance SL-401 into other indications in an effort to provide benefit to patients who are battling aggressive cancers."

Conference Call and Webcast
Stemline Therapeutics will host a conference call and audio webcast Friday, January 6, 2017 at 8:00 AM ET. Interested participants and investors may access the conference call by dialing 888-778-9052 (U.S./Canada) or 913-312-0850 (International) and referencing conference ID: 9093286. An audio webcast can also be accessed via the Investor Relations tab of the Stemline Therapeutics website at http://ir.stemline.com.

About Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN)
For more information on BPDCN, please visit Stemline's patient and physician resource site: www.bpdcninfo.com.

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 pivotal Phase 2 program 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 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; 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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