February 2, 2017

Stemline Therapeutics Provides Update on Pivotal BPDCN Trial

NEW YORK, Feb. 02, 2017 (GLOBE NEWSWIRE) -- Stemline Therapeutics, Inc. (Nasdaq:STML), a clinical-stage biopharmaceutical company developing novel oncology therapeutics, provides an update on its ongoing pivotal Phase 2 trial in blastic plasmacytoid dendritic cell neoplasm (BPDCN), using Stemline's experimental compound, SL-401. BPDCN at present has no approved treatment.

On January 18, the Company received a report that a patient death had occurred. The patient had developed capillary leak syndrome (CLS), a known, sometimes fatal, and well-documented side effect of SL-401. The cause of the patient's death has not yet been determined. The safety profile for SL-401 includes CLS, and there have been previous deaths reported in patients with CLS in this trial, which have been disclosed in public presentations. That CLS is an expected complication of the administration of SL-401 has also been identified in filings with the Securities and Exchange Commission (SEC) and U.S. Food and Drug Administration (FDA), as well as in the study's informed consent forms and other information provided to investigators.

As with all study events, the Company has and will continue to report the data to the FDA in accordance with the study protocol and applicable regulations. Stemline plans to provide a clinical and safety update on this cohort when the cohort and data are complete. The pivotal Phase 2 trial with SL-401 in BPDCN is currently ongoing, patient enrollment is ahead of schedule, and patients continue to receive SL-401 in the trial. Our timelines for study completion and BLA submission remain on track.

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.

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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