Stemline Therapeutics Announces Completion of Enrollment in Stage 3 of the SL-401 Pivotal Trial in BPDCN

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NEW YORK, March 23, 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 that enrollment of Stage 3 in the SL-401 pivotal trial in blastic plasmacytoid dendritic cell neoplasm (BPDCN) has been completed. The company also reviewed key milestones for the SL-401 program over the coming year.

Completes Stage 3 Enrollment
Stemline has completed enrollment of the Stage 3 cohort of the SL-401 pivotal trial in BPDCN. Stage 3 enrolled 13 first-line BPDCN patients; statistical analysis will be based on evaluable first-line patients. The registration pathway was previously agreed upon with the U.S. Food and Drug Administration (FDA). Depending on the data from the trial, Stemline plans to use the results generated to support the potential filing of a Biologics License Application (BLA) for full approval in first-line BPDCN, and is targeting possible BLA filing in the second half of this year.

This multicenter, pivotal trial has enrolled 47 BPDCN patients at seven centers in the U.S. The 47 BPDCN patients were comprised of 32 first-line patients (29 dosed at 12 ug/kg/day) and 15 relapsed/refractory patients dosed at 12 ug/kg/day. Stemline plans to provide a clinical update on patients enrolled in Stages 1 and 2 at a medical conference around mid-year, with top-line data from Stage 3 expected in the second half of 2017. To ensure ongoing patient access to SL-401, Stemline plans to continue to enroll both first-line and relapsed/refractory BPDCN patients under the current protocol.

SL-401 received Breakthrough Therapy Designation (BTD) by the FDA in August 2016.

BLA Preparation and Pre-Commercial Activities Underway
Stemline's clinical, preclinical, manufacturing, and regulatory teams are working toward a timely and comprehensive potential BLA filing. Ongoing efforts include compiling the necessary supportive data and assembling the BLA modules, including clinical, clinical pharmacology, non-clinical, and CMC (chemistry, manufacturing, and controls). In parallel, the commercial team is working to define the BPDCN market landscape, including factors related to patient flow, market access and pricing considerations, all with an eye toward setting the stage for a successful launch of SL-401, if approved.

"I am very proud of the entire Stemline team and our clinical investigators, who helped to make this key milestone possible," said Ivan Bergstein, M.D., Chief Executive Officer of Stemline. Dr. Bergstein continued, "Completing enrollment in our pivotal trial is an important step toward our goal of bringing to market a novel treatment for patients suffering from BPDCN, a devastating disease. We continue to focus on following patients, data collection, and advancing our BLA-targeted efforts on all fronts."

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 pivotal cohort, and patients continue to be followed. SL-401 has been granted Breakthrough Therapy Designation (BTD) for the treatment of BPDCN. 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, 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.

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