Stemline Therapeutics Presents SL-401 Updated Stage 1 and 2 Data from Ongoing Pivotal Trial in BPDCN and Safety Experience Across Multiple Indications, Today at EHA

June 23, 2017

NEW YORK, June 23, 2017 (GLOBE NEWSWIRE) -- Stemline Therapeutics, Inc. (Nasdaq:STML), a clinical-stage biopharmaceutical company developing novel therapeutics for difficult to treat cancers, announced the presentation today of updated clinical data from Stages 1 and 2 of the ongoing SL-401 pivotal Phase 2 clinical trial in blastic plasmacytoid dendritic cell neoplasm (BPDCN), along with safety data from the entire SL-401 clinical program, at the 22ndCongress of the European Hematology Association (EHA) being held in Madrid, Spain.

A summary of the presentation is as follows:

- Stages 1 and 2 enrolled 32 BPDCN patients, of which 19 were first-line and 13 patients were relapsed/refractory.
- Median age was 72 years (range 29-85 years).
- The most common treatment-related adverse events (TRAEs) with SL-401 across BPDCN and other indications (n=134 patients) were hypoalbuminemia (43%), transaminitis (43%), and thrombocytopenia (26%), by investigator-assessment. TRAEs included capillary leak syndrome (18%), of which 3 cases were grade 5 (2.2%), as previously reported.
- The overall response rate (ORR) for Stage 1 and 2 BPDCN patients (n=32) was 84%, with a complete response (CR) rate of 59%, by investigator-assessment.
- Eight BPDCN patients who achieved remission on SL-401 (for ~2.5 to ~6 months duration) were subsequently bridged to stem cell transplant, including one relapsed/refractory patient.
- In first-line BPDCN patients treated at 12 ug/kg/day (n=16), the median overall survival (OS) has not been reached.

The full presentation will be available on the Stemline website (www.stemline.com), under the "Scientific Presentations" tab, following delivery of today's presentation at EHA.

Stage 3 is fully enrolled (n=13 first-line BPDCN patients) and data will be reported, along with further updated Stage 1 and 2 data, in 2H17. Depending on the results of this ongoing Phase 2 trial, the largest prospective study ever conducted in this indication (n=45 patients), we intend to file a BLA for SL-401 in BPDCN in 4Q17/1Q18.

About Stemline Therapeutics
Stemline Therapeutics, Inc. is a clinical stage biopharmaceutical company developing novel therapeutics for difficult to treat cancers. 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 cohort, and patients continue to be treated and followed. SL-401 has been granted Breakthrough Therapy Designation (BTD) for the treatment of BPDCN. Additional Phase 1/2 trials with SL-401 are enrolling patients with other malignancies including myeloproliferative neoplasms (MPN) (chronic myelomonocytic leukemia [CMML] and myelofibrosis [MF]) 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 with SL-801, a novel oral small molecule reversible inhibitor of XPO1, is enrolling patients with advanced solid tumors. 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.

Contact
Investor Relations
Stemline Therapeutics, Inc.750 Lexington Avenue
Eleventh Floor
New York, NY 10022
Tel: 646-502-2307
Email: investorrelations@stemline.com

Primary Logo

Stemline Therapeutics