Stemline Therapeutics Presents SL-801 Phase 1 Data at ESMO 2017

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NEW YORK, Sept. 11, 2017 (GLOBE NEWSWIRE) -- Stemline Therapeutics, Inc. (Nasdaq:STML), a clinical-stage biopharmaceutical company developing novel therapeutics for difficult to treat cancers, announced the presentation of clinical data from the ongoing SL-801 Phase 1 trial in patients with advanced solid tumors. The data were presented at the European Society of Medical Oncology (ESMO) Annual Congress 2017 in Madrid, Spain.

A summary of the SL-801 Phase 1 trial presentation is as follows:

- 24 patients with advanced solid tumors were enrolled.
  -- 75% of patients were third-line or greater, and include colorectal and other gastrointestinal tumors, breast, non-small cell lung cancer, neuroendocrine, genitourinary, and other tumor types.
  -- Six dose levels (5, 10, 20, 30, 35 and 40 mg/day dosed orally on days 1-4 and days 8-11 of a 21 day cycle) have been cleared.
- Manageable safety and tolerability profile.
  -- No dose limiting toxicity (DLT) or maximum tolerated dose (MTD) has been reached.
  -- Most common treatment related adverse events (TRAEs) were grade 1-2, with no grade 4 or 5 events reported.
- Stable disease (SD) was achieved in 37.5% (9/24) of patients, with up to 20% tumor shrinkage noted in some heavily pre-treated patients.
- The ideal therapeutic dose of SL-801 has not yet been determined, as dose escalation continues. The seventh dose cohort (45 mg/day) is currently enrolling.

The full presentation is available on the Stemline website (www.stemline.com), under the "Scientific Presentations" tab.

Ivan Bergstein, M.D., Stemline's CEO, commented, "SL-801 has demonstrated a manageable safety and tolerability profile thus far in the trial. We are also encouraged by multiple cases of stable disease in heavily pretreated solid tumor patients. We continue to increase the dose of SL-801 and plan to provide further data updates throughout next year. In conjunction with the anticipated read-out this year of pivotal data from SL-401, our lead program, in blastic plasmacytoid dendritic cell neoplasm (BPDCN), we view SL-801's promising early data as another key step toward our objective of building a leading commercial stage biopharmaceutical company with a robust and innovative pipeline."

About Stemline Therapeutics
Stemline Therapeutics, Inc. is a clinical stage biopharmaceutical company developing novel therapeutics for difficult to treat cancers. SL-401, our most advanced drug candidate, was granted Breakthrough Therapy Designation (BTD) for the treatment of patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN). BPDCN is a highly aggressive, lethal malignancy of unmet medical need, with no approved therapies. SL-401 is a targeted therapy directed to the interleukin-3 receptor (CD123), a cell surface receptor expressed on BPDCN and a variety of other malignancies. A pivotal Phase 2 trial with SL-401 in BPDCN has completed enrollment in Stages 1, 2 and 3 of the trial. An additional cohort, Stage 4, is currently enrolling BPDCN patients to ensure ongoing access to SL-401. Additional Phase 1/2 trials with SL-401, as a single agent or in combination with other agents, are ongoing in patients with other malignancies including myeloproliferative neoplasms (MPN) (focused on chronic myelomonocytic leukemia [CMML] and myelofibrosis [MF]), acute myeloid leukemia (AML), and multiple myeloma. A Phase 1 trial of SL-801, a novel oral small molecule reversible XPO1 inhibitor, is enrolling patients with advanced solid tumors. A Phase 2 trial of SL-701, an immunotherapeutic, has completed dosing of patients with second-line glioblastoma and patients are being followed for outcomes including 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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