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Stemline Therapeutics Presents SL-401 Lead-in Results from its Ongoing Phase 2 Trial in AML in Remission with MRD and Phase 2 Trial in High-Risk Myeloproliferative Neoplasms (MPN) at ASH

NEW YORK, Dec. 06, 2016 (GLOBE NEWSWIRE) -- Stemline Therapeutics, Inc. (Nasdaq:STML) announced today the presentation of SL-401 lead-in data from its ongoing Phase 2 trial in acute myeloid leukemia (AML) in remission with minimal residual disease (MRD) and ongoing Phase 2 trial in high-risk myeloproliferative neoplasms (MPN) at the 2016 American Society of Hematology (ASH) Annual Meeting. The AML/MRD results were delivered via oral presentation by Andrew A. Lane, M.D., Ph.D., from the Dana-Farber Cancer Institute (Boston, MA) and the MPN results were presented by Mrinal S. Patnaik, M.D. from the Mayo Clinic (Rochester, MN).

The full presentations are available on the Stemline website, under the "Scientific Presentations" tab (see: http://www.stemline.com/scientific-presentations.asp).

Safety Overview

- SL-401 was found to be safe and well tolerated, and side effects were predictable and manageable. The lead-in dose escalation stages of both Phase 2 studies (3 x 3 design) were completed without dose limiting toxicity (DLT) and a maximum tolerated dose (MTD) was not reached in either study (n=9 patients in AML/MRD lead-in; n=9 patients in MPN lead-in). 12 ug/kg/day was the highest tested dose in both studies and is currently the dose level being used in the expansion stage of both studies.

Efficacy Overview

- **AML/MRD -** Early signs of efficacy in the AML study included an MRD+ AML patient who sustained a decrease in MRD, determined locally, treated at 12 ug/kg/day who then went on to stem cell transplant. The expansion stage is currently enrolling and, for uniformity, will utilize a central facility for MRD analysis.

- **MPN -** Early signs of efficacy in the MPN study including a patient with chronic myelomonocytic leukemia (CMML) who sustained a bone marrow complete response (BMCR) and reduction in spleen size. The expansion stage is currently enrolling CMML as well as additional MPN types including myelofibrosis, mastocytosis, and primary eosinophilic disorder.

Andrew A. Lane, M.D., Ph.D., lead author on the AML study, commented, "Given the unacceptably high relapse rates seen in AML, MRD has emerged as an important predictor of relapse with CD123 as a key target for therapy. The preliminary results seen with SL-401 in this setting are promising. We look forward to enrolling patients in the expansion stage of the trial as we continue to optimize and refine methods to assess and follow MRD."

Mrinal S. Patnaik, M.D., lead author on the MPN study, noted, "The early data from the dose escalation portion of the trial suggests SL-401 can be dosed safely in this patient population. Additionally, we are observing encouraging signs of clinical activity in several patients. We look forward to enrolling patients in the expansion stage of the trial."

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 potentially pivotal Phase 2 trial 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; 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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