# Stemline Therapeutics Announces Positive Data Presentations on SL-701 and SL-801 at ASCO

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NEW YORK, June 05, 2018 (GLOBE NEWSWIRE) -- Stemline Therapeutics, Inc. (Nasdaq:STML), a clinical-stage biopharmaceutical company developing novel oncology therapeutics, announced today that positive data from the SL-701 and SL-801 clinical trials were presented at the 2018 American Society of Clinical Oncology (ASCO) annual meeting in Chicago, IL. The presentations are available on Stemline's website (www.stemline.com) under the Scientific Presentations tab.

**SL-701 – Clinical Highlights**

- The Phase 2 trial of SL-701 in previously treated GBM patients met its primary endpoint of 12-month overall survival (OS-12)
- Long-term survivors: 50% OS-12 with SL-701 + bevacizumab
    - Major responses, including complete responses (CRs), in second-line GBM
    - Well-tolerated, with very manageable side effect profile
- Long-term survivors were comprised largely of patients with target-specific CD8+ T-cell responses
    - Median OS of target-specific CD8+ T cell responders not reached
- Given the major unmet medical need in GBM and promising safety and efficacy data generated to date with SL-701 + bevacizumab, Stemline is considering next steps including leveraging potential immune-related biomarker in registration-directed trial designs

**SL-801 – Clinical Highlights**

- Manageable safety and tolerability profile, largely grade 1-2 adverse events (AEs), to date
- Multiple cases of stable disease (SD) in a heavily pretreated solid tumor patient population
- Pharmacokinetic (PK) analyses suggest dose-dependent increases in exposure
- Ideal therapeutic dose not yet determined as dose escalation continues

Ivan Bergstein, M.D., Stemline's CEO, commented, "Our BPDCN disease awareness campaign is kicking into high gear as we approach the end of ASCO, and we believe that our key messages around BPDCN and CD123 are resonating. Our SL-401 regulatory and pre-launch activities continue to progress, and our timelines remain on track." Dr. Bergstein continued, "Additionally, our SL-701 and SL-801 clinical presentations were very well-received at the conference, and our investigators are excited and engaged. The SL-701 + bevacizumab combination has been well-tolerated and has shown activity, including the emergence of long-term survivors comprised largely of target-specific CD8+ T cell responders. Given the major unmet medical need in GBM and SL-701's promising safety and efficacy data, we are considering next steps, including applying these immune data in registration-directed trial designs. Additionally, we are encouraged by SL-801's tolerability profile as we continue to dose escalate in a heavily pretreated solid tumor patient population of unmet medical need. Enrollment is ongoing, and we look forward to further updates later this year."

**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 range of malignancies. SL-401 has completed a pivotal trial in blastic plasmacytoid dendritic cell neoplasm (BPDCN), for which it was granted breakthrough therapy designation (BTD). The pivotal trial met its primary endpoint, and a rolling Biologics License Application (BLA) submission has been initiated. SL-401 is also being evaluated in clinical trials in additional indications including chronic myelomonocytic leukemia (CMML), myelofibrosis (MF), acute myeloid leukemia (AML), and myeloma. SL-801 is a novel oral small molecule reversible inhibitor of XPO1 that is currently in a Phase 1 trial of patients with advanced solid tumors; dose escalation is ongoing. SL-701, an immunotherapeutic, has completed a Phase 2 trial in patients with second-line glioblastoma; data and next steps for the program are being evaluated.

**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 BLA submission to the FDA; 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 agree with our data, find our data supportive of approval, or 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 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 SEC. 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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