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Stemline Therapeutics Announces Oral Presentation of SL-701 Phase 2 Data in Second-Line Glioblastoma at the 21st Annual Meeting of the Society of Neuro-Oncology (SNO)

NEW YORK, Nov. 21, 2016 (GLOBE NEWSWIRE) -- Stemline Therapeutics, Inc. (Nasdaq:STML) announced today the oral presentation of clinical data from its ongoing Phase 2 trial of SL-701 in patients with second-line glioblastoma (GBM). The Phase 2 results were delivered by David A. Reardon, M.D., Clinical Director, Center for Neuro-Oncology, Dana-Farber Cancer Institute and Professor of Medicine, Harvard Medical School, at the Society for Neuro-Oncology (SNO) annual meeting in Scottsdale, AZ this past Friday, November 18, at 6:20 PM ET. SL-701 is a subcutaneously delivered immunotherapy designed to generate a long-term T cell response against GBM.

David A. Reardon, M.D., the lead investigator of the study, commented, "We are observing encouraging clinical activity, including major responses, some with promising durability, from the combination of SL-701 and bevacizumab." Dr. Reardon continued, "These preliminary findings are consistent with a potential long-term immunotherapeutic benefit of SL-701 as a large majority of treated patients remain alive and the trial has not reached a median overall survival." Dr. Reardon concluded, "We look forward to following our patients and reporting longer-term survival and response data as the trial matures. In parallel, we are evaluating additional combination regimens and the design of a potential pivotal trial."

SL-701 Phase 2 Trial
The SL-701 Phase 2 trial enrolled second-line GBM patients and was comprised of a single-agent stage (Stage 1; n=46) and a combination stage which evaluated SL-701 with bevacizumab (Stage 2; n=28).

SL-701 was found to be safe and well-tolerated, and demonstrated clinical activity, including major responses, in second-line GBM when used alone or in combination with bevacizumab.

Key efficacy outcomes observed to date with the overall program include:

- Combination activity in second-line GBM
  - SL-701 + poly-ICLC + bevacizumab (Phase 2 trial, Stage 2; n=21 evaluable)
    - Major responses (n=7; 2 complete responses [CR] and 5 partial responses [PR])
      - 4 confirmed with 2^{nd} response assessment
      - 2 with pending 2^{nd} response assessment
      - 1 progressed prior to 2^{nd} response assessment
    - Response duration encouraging, with several responses of 6 months-plus in duration, all ongoing
    - Overall survival appears promising; median not reached and data continue to mature
- Single agent activity in relapsed/refractory GBM
  - SL-701 + GM-CSF + Imiquimod (Phase 2 trial, Stage 1; n=42 evaluable)
    - 1 partial response (PR) of 13^{+} months duration, ongoing
    - 2 stable diseases (SD) of 18^{+} and 20^{+} months duration, both ongoing
  - Earlier versions of SL-701 + poly-ICLC (Phase 1 trial)
    - Major responses in second- and third-line GBM

Patients continue to be followed for response and survival, and additional clinical data updates are expected next year, as well as immunocorrelative analyses.

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

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

response-driven outcomes including 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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