Stemline Therapeutics Announces Presentation of ELZONRIS™ (tagraxofusp; SL-401) Preclinical Data in Systemic Sclerosis, an Autoimmune Disorder, at EULAR Congress

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NEW YORK, June 15, 2018 (GLOBE NEWSWIRE) -- Stemline Therapeutics, Inc. (Nasdaq:STML), a clinical-stage biopharmaceutical company developing novel oncology therapeutics, announced today that ELZONRIS™ (tagraxofusp; SL-401) preclinical data in the autoimmune disorder systemic sclerosis were delivered via poster presentation at the Annual European Congress of Rheumatology (EULAR) in Amsterdam.

The poster, entitled “SL-401, a Novel Targeted Therapy Directed to the Interleukin-3 Receptor (CD123), Kills Plasmacytoid Dendritic Cells (pDCs) from Systemic Sclerosis Patients”, was presented today. Preclinical data demonstrated the activity of ELZONRIS against potentially pathogenic plasmacytoid dendritic cells (pDCs), suggesting a novel approach for the treatment of systemic sclerosis and certain other autoimmune disorders.

Notably, the CD123+ pDC is the cell of origin of the malignancy blastic plasmacytoid dendritic cell neoplasm (BPDCN) an indication for which ELZONRIS™ (tagraxofusp; SL-401), a novel targeted therapy directed to CD123, has been granted breakthrough therapy designation (BTD). ELZONRIS has successfully completed a pivotal trial in BPDCN, and a rolling Biologics License Application (BLA) submission is underway.

Presentation Highlights and Conclusions

- Plasmacytoid dendritic cells (pDCs), from which the malignancy BPDCN is derived, are immune cells that express CD123, secrete IFN-α, and play a role in inflammation and pathogenesis observed in certain autoimmune diseases including systemic sclerosis (SSc)
- SL-401 is cytotoxic against CD123+ pDCs
- Concurrent with pDC depletion, a reduction in secreted IFNα and IL-6 was observed in cell culture supernatant
- Depletion of pDCs or attenuation of pDC function may represent a novel mechanism of action for the treatment of patients with SSc
- As such, these data present a potentially novel approach of targeting pDCs and inflammation in the treatment of SSc and warrant further investigation

A copy of the full presentation will be available on Stemline’s website (www.stemline.com) under the Scientific Presentations tab.

About ELZONRIS™ (tagraxofusp; SL-401)
ELZONRIS™ (tagraxofusp; SL-401) is a novel targeted therapy directed to CD123, a cell surface receptor expressed on a range of malignancies. ELZONRIS has successfully completed a pivotal trial in blastic plasmacytoid dendritic cell neoplasm (BPDCN), an indication for which it was granted Breakthrough Therapy Designation (BTD). A rolling Biologics License Application (BLA) submission is underway. ELZONRIS is also being evaluated in additional clinical trials in other indications including chronic myelomonocytic leukemia (CMML), myelofibrosis (MF), and acute myeloid leukemia (AML).

About BPDCN
Please visit the BPDCN disease awareness website: www.bpdcninfo.com.

About Stemline Therapeutics
Stemline Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing novel oncology therapeutics. Stemline is developing three clinical stage product candidates, ELZONRIS™ (tagraxofusp; SL-401), SL-801, and SL-701. ELZONRIS is a targeted therapy directed to the interleukin-3 receptor (CD123) present on a range of malignancies. ELZONRIS 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. ELZONRIS 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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