Stemline Therapeutics Announces that FDA Accepts ELZONRIS™ Biologics License Application (BLA) and Grants Priority Review

August 13, 2018

- **Conference call on BLA acceptance and commercial readiness scheduled for Monday, August 13, 2018 at 8:30 AM ET**

NEW YORK, Aug. 13, 2018 (GLOBE NEWSWIRE) -- Stemline Therapeutics, Inc. (Nasdaq: STML), a clinical-stage biopharmaceutical company developing novel oncology therapeutics, announced today that the U.S. Food and Drug Administration (FDA) has accepted for filing the Company's Biologics License Application (BLA) for ELZONRIS™ (tagraxofusp; SL-401) for the treatment of patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN). The FDA also granted Priority Review for the BLA and has set a target action date of February 21, 2019, under the Prescription Drug User Fee Act (PDUFA).

The FDA grants Priority Review to product applications that, if approved, would provide significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications.

ELZONRIS has also been granted Breakthrough Therapy Designation (BTD) and Orphan Drug Designation (ODD) by the FDA.

Ivan Bergstein, M.D., Stemline's CEO, commented, "The acceptance of our BLA for filing and grant of Priority Review represent tremendous milestones for Stemline and the BPDCN patient community. We would like to thank the patients and their families who participated in our clinical trials, as well as recognize the tireless work of our investigators and entire Stemline team. Given both Priority and Breakthrough status, our commercial organization is positioning itself to rapidly launch ELZONRIS, if approved, to ensure this important new treatment reaches patients as quickly as possible."

Conference Call and Webcast
Stemline Therapeutics will host a conference call and audio webcast on Monday, August 13, 2018 at 8:30 AM ET. Interested participants and investors may access the conference call by dialing 844-389-8660 (U.S./Canada) or 478-219-0408 (International) and referencing conference ID: 4762319. An audio webcast can also be accessed via the Investor Relations tab of the Stemline Therapeutics website at http://ir.stemline.com.

About ELZONRIS™ (tagraxofusp; SL-401)
ELZONRIS™ (tagraxofusp; SL-401) is a novel targeted investigational therapy directed to CD123, a cell surface receptor expressed on a range of malignancies. ELZONRIS successfully completed a pivotal trial in patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN), and a Biologics License Application (BLA) in this indication has been accepted for filing and been granted Priority Review by the U.S. Food and Drug Administration (FDA). ELZONRIS has also been granted Breakthrough Therapy Designation (BTD) and Orphan Drug Designation by the FDA. ELZONRIS is also being evaluated in clinical trials in additional indications including chronic myelomonocytic leukemia (CMML), myelofibrosis (MF), and others.

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 Biologics License Application (BLA) has been accepted for filing and granted Priority Review by the FDA. ELZONRIS is also being evaluated in clinical trials in additional indications including chronic myelomonocytic leukemia (CMML), myelofibrosis (MF), and others. 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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