Stemline Therapeutics Inc Logo

Stemline Therapeutics Announces Submission of European Marketing Authorization Application (MAA) for ELZONRIS™

January 7, 2019

NEW YORK, Jan. 07, 2019 (GLOBE NEWSWIRE) -- Stemline Therapeutics, Inc. (NASDAQ:STML), a biopharmaceutical company focused on the development and commercialization of novel oncology therapeutics, announced today that it has submitted the marketing authorization application (MAA) for ELZONRIS (tagraxofusp) to the European Medicines Agency (EMA). The MAA seeks approval for treating patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN). In November 2018, the EMA granted the ELZONRIS MAA accelerated assessment.

On December 21, 2018, ELZONRIS was approved by the U.S. Food and Drug Administration (FDA) for the treatment of BPDCN in adult and pediatric patients, two years and older, in both treatment-naïve and previously-treated populations. ELZONRIS is the first treatment approved for BPDCN and the first approved CD123-targeted therapy.

“The submission of the ELZONRIS MAA is another major step forward for providing this important targeted treatment to patients, globally,” said Ivan Bergstein, M.D., CEO of Stemline Therapeutics. “We look forward to working closely with the EMA to ensure this treatment is available to patients as quickly as possible. In parallel, our commercial team is continuing its ongoing effort to raise awareness of both CD123 testing and BPDCN worldwide. Potential European approval offers us an opportunity to significantly increase the number of patients who may benefit from ELZONRIS.”

About ELZONRIS™
ELZONRIS (tagraxofusp), a CD123-directed cytotoxin, was approved by the Food and Drug Administration (FDA) on December 21, 2018 for the treatment of adult and pediatric patients, two years and older, with blastic plasmacytoid dendritic cell neoplasm (BPDCN). In November 2018, the European Medicines Agency (EMA) granted ELZONRIS accelerated assessment to the marketing authorization application (MAA), which was submitted to the EMA in January 2019. ELZONRIS is also being evaluated in additional clinical trials in other indications including chronic myelomonocytic leukemia (CMML), myelofibrosis (MF) and other CD123 positive diseases.

About BPDCN
Blastic plasmacytoid dendritic cell neoplasm (BPDCN) is an aggressive hematologic malignancy with historically poor outcomes and an area of unmet medical need. The BPDCN cell of origin is the plasmacytoid dendritic cell (pDC) precursor. BPDCN typically presents in the bone marrow and/or skin and may also involve lymph nodes and viscera. The diagnosis of BPDCN is based on the immunophenotypic diagnostic triad of CD123, CD4, and CD56. For more information, please visit the BPDCN disease awareness website at www.bpdcninfo.com.

About Stemline Therapeutics
Stemline Therapeutics, Inc. is a biopharmaceutical company focused on the development and commercialization of novel oncology therapeutics. In December 2018, the FDA approved ELZONRIS, a targeted therapy directed to CD123, for the treatment of adult and pediatric patients, two years and older, with blastic plasmacytoid dendritic cell neoplasm (BPDCN). In November 2018, the European Medicines Agency (EMA) granted accelerated assessment to the marketing authorization application (MAA) of ELZONRIS in patients with BPDCN, which was submitted to the EMA in January 2019. ELZONRIS is also being evaluated in clinical trials in additional indications including chronic myelomonocytic leukemia (CMML), myelofibrosis (MF) and others. Other Stemline clinical candidates include SL-801, a novel oral small molecule reversible inhibitor of XPO1, which is currently in a Phase 1 trial of patients with advanced solid tumors and recent data was presented at the European Society of Medical Oncology (ESMO) annual conference; and SL-701, an immunotherapeutic which has completed a Phase 2 trial in patients with second-line glioblastoma and recent data were presented at the Society for Neuro-Oncology (SNO) annual conference.

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 MAA submission to the EMA CHMP; 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, EMA, 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; the possibility that results of clinical trials are not predictive of safety and efficacy results of our product candidates in broader patient populations or of our products if approved; our plans to develop and commercialize our product candidates, including, but not limited to delays in arranging satisfactory manufacturing capabilities and establishing commercial infrastructure for ELZONRIS; product efficacy or safety concerns resulting in product recalls or regulatory action; the risk that estimates regarding the number of patients with the diseases that our products and product candidates may treat are inaccurate; our products not gaining acceptance among patients (and providers or third party payers) for certain indications (due to cost or otherwise); the risk that third party payors (including governmental agencies) will not reimburse for the use of ELZONRIS at acceptable rates or at all; the company’s ability to maintain or increase sales of ELZONRIS; the company’s ability to develop and commercialize ELZONRIS; the adequacy of our pharmacovigilance and drug safety reporting processes; our available cash and investments; our ability to obtain and maintain intellectual property protection for our products and product candidates; delays, interruptions, or failures in the manufacture and supply of our products and product candidates; the performance of third-party businesses, including, but not limited to, 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.

Contact:

Investors:
Stemline Therapeutics, Inc.
750 Lexington Avenue
Eleventh Floor
New York, NY 10022

Tel: 646-502-2307
Email: investorrelations@stemline.com

Source: Stemline Therapeutics, Inc.