

## Stemline Therapeutics Announces Validation of Marketing Authorization Application (MAA) by the European Medicines Agency (EMA)

January 30, 2019

NEW YORK, Jan. 30, 2019 (GLOBE NEWSWIRE) -- Stemline Therapeutics, Inc. (Nasdaq: STML), a commercial-stage biopharmaceutical company focused on the development and commercialization of novel oncology therapeutics, today announced that the European Medicines Agency (EMA) has completed its validation of the Marketing Authorization Application (MAA) for ELZONRIS™ (tagraxofusp-erzs). Validation of the MAA confirms that the submission is sufficiently complete to begin the formal review process. Stemline submitted the MAA earlier this month seeking approval of ELZONRIS for the treatment of adult patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN). In November 2018, the MAA was granted accelerated assessment.

Under European Union legislation, a medicinal product of major public health interest may be reviewed under an accelerated assessment procedure. Accelerated assessment can significantly reduce the timeframe for the EMA Committee for Medicinal Products for Human Use (CHMP) to review an MAA.

ELZONRIS was approved by the U.S. Food and Drug Administration (FDA) on December 21, 2018 for the treatment of adult and pediatric patients, two years and older, with BPDCN. ELZONRIS is currently commercially available in the U.S.

"The validation of our MAA by the EMA represents another major step forward in our effort to provide patients with BPDCN in Europe access to ELZONRIS as expeditiously as possible," said Ivan Bergstein, M.D., Chief Executive Officer of Stemline Therapeutics. "With ELZONRIS now commercially available in the U.S., we remain committed to increasing access for patients with BPDCN who may benefit from ELZONRIS treatment, worldwide."

### About BPDCN

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.bpdncinfo.com](http://www.bpdncinfo.com).

### 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). For full prescribing information in the U.S., visit [www.ELZONRIS.com](http://www.ELZONRIS.com). In November 2018, the European Medicines Agency (EMA) granted ELZONRIS accelerated assessment to the marketing authorization application (MAA), which was submitted to, and validated by, 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 diseases.

### 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 or 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 for the treatment of patients with BPDCN, which was submitted to, and validated by, 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. Additional Stemline clinical candidates include SL-801 and SL-701. SL-801, a novel oral small molecule reversible inhibitor of XPO1, is currently in a Phase 1 trial of patients with advanced solid tumors. SL-701, an immunotherapeutic, has completed a Phase 2 trial in patients with second-line glioblastoma and next steps are being considered.

### 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.

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