

Stemline In-Licenses Worldwide Rights to Novel Selective RET Inhibitor (SL-1001); Expands Oncology Pipeline

March 11, 2019

NEW YORK, March 11, 2019 (GLOBE NEWSWIRE) -- Stemline Therapeutics, Inc. (Nasdaq: STML), a commercial-stage biopharmaceutical company focused on the development and commercialization of novel oncology therapeutics, announced today that it has exclusively licensed worldwide rights to develop and commercialize a novel, oral, selective small molecule RET (rearranged during transfection) kinase inhibitor from the CRT Pioneer Fund LP, a £70 million specialist oncology investment fund managed by Sixth Element Capital, a UK based fund manager. The RET inhibitor was rationally designed by scientists at Cancer Research UK Manchester Institute at the University of Manchester (United Kingdom). The preclinical compound has been designated SL-1001 and is expected to enter the clinic in 2020.

RET kinase genetic alterations have been found in a diverse range of cancers and, we believe, is a clinically validated target in multiple indications. SL-1001 is an oral RET kinase inhibitor that has demonstrated potent, selective, preclinical anti-cancer activity, both in vitro and in vivo, in RET-driven tumor models.

"SL-1001 is an ideal strategic fit for us, given its targeted mechanism of action and potential for streamlined development," commented Stemline's CEO, Ivan Bergstein. He continued, "Building upon our team's proven track record of success, culminating with the recent ELZONRIS approval, we intend to advance SL-1001 swiftly through the clinical and regulatory process with an eye towards achieving our goal of helping more patients succeed in their fight against cancer."

Robert James, Managing Partner at Sixth Element Capital said, "We are delighted to have partnered SL-1001 with Stemline. We are confident that Stemline's skills and resources will take the project forward rapidly and offer an alternative treatment option to patients with cancer driven by RET kinase".

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 acute myeloid leukemia (AML). Additional pipeline candidates include: SL-701 (immunotherapeutic; Phase 2 in glioblastoma patients completed), SL-801 (XPO1 inhibitor; Phase 1 in advanced solid tumor patients ongoing), SL-901 (novel kinase inhibitor; prior abbreviated European Phase 1, IND-enabling studies ongoing), and SL-1001 (novel RET kinase inhibitor, IND-enabling studies pending).

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. 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 acute myeloid leukemia (AML).

About BPDCN

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

About Sixth Element Capital LLP and the CRT Pioneer Fund

Sixth Element Capital LLP (6EC) is a UK based fund manager, which manages the CRT Pioneer Fund. 6EC's experienced partners focus on creative and collaborative novel financing solutions designed to fund and manage innovative science in order to bring new therapeutic products and technologies to market, creating long term value and benefit to stakeholders. The CRT Pioneer Fund is a specialist oncology investment fund established by 6EC in 2012. The £70 million fund is dedicated to investments in oncology development programmes in Europe. The fund was established to bridge the investment gap between cancer drug discovery and early clinical development. For more information, please see www.sixthelementcapital.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 of our MAA submission to the EMA; 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; inadequate market penetration of our products; 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 produce, maintain or increase sales of ELZONRIS;

the company's ability to develop and/or 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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