Stemline Therapeutics Inc Logo

Stemline Therapeutics Highlights Recent Clinical and Regulatory Developments and Details Upcoming Milestones following its Annual Shareholder Meeting

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NEW YORK, July 08, 2019 (GLOBE NEWSWIRE) -- Stemline Therapeutics, Inc. (Nasdaq: STML), a commercial-stage biopharmaceutical company focused on the development and commercialization of novel oncology therapeutics, following its annual shareholder meeting, highlights recent clinical and regulatory developments, and details other upcoming events.

- ELZONRIS® clinical data were presented at the 2019 American Society of Clinical Oncology (ASCO) annual meeting in Chicago, Illinois and the 24thCongress of the European Hematology Association (EHA) in Amsterdam, Netherlands. Presentations highlighted updated results from ongoing Phase 2 clinical trials in chronic myelomonocytic leukemia (CMML) and myelofibrosis (MF), as well as final results of the pivotal trial in blastic plasmacytoid dendritic cell neoplasm (BPDCN). In addition, ELZONRIS preclinical results in systemic sclerosis, an autoimmune disorder in which $CD123^+$ plasmacytoid dendritic cells (pDCs) play a role in disease pathogenesis, were presented at the Annual European Congress of Rheumatology (EULAR) in Madrid, Spain.

- As previously announced, an additional single-arm cohort of patients with previously-treated CMML, Stage 3, will be added to the currently enrolling trial. In the first part of Stage 3 (Stage 3a), enrichment strategies and certain efficacy endpoints (including spleen size reduction) will be assessed for inclusion in the confirmatory cohort (Stage 3b), that will aim to provide the primary evidence of efficacy to support potential registration. We expect to open enrollment of the new cohort in 4Q19.

- Stemline continues to build out a European commercial infrastructure in advance of potential approval by the European Medicines Agency (EMA). A scientific advisory group meeting is planned for September, and the ELZONRIS marketing authorization application (MAA) review will proceed on a standard timeline. We expect an opinion by the Committee for Medicinal Products for Human Use (CHMP) later this year. If successful, Stemline is targeting a commercial launch in Europe in 1Q20.

- In an ongoing market expansion effort, corporate and investigator-sponsored clinical trials with ELZONRIS in additional indications are ongoing in myelofibrosis (MF) and acute myeloid leukemia (AML) and others are planned to roll out later this year and next.

- Stemline continues to advance its clinical-stage assets, including SL-801 (a reversible inhibitor of XPO1). XPO1 is a clinically validated target in oncology, and the FDA recently approved an XPO1 inhibitor in patients with relapsed/refractory multiple myeloma. Stemline is also developing its preclinical assets SL-1001 (RET kinase inhibitor) and SL-901 (kinase inhibitor).

- Stemline will provide further details on commercial and clinical progress during its second quarter financial results teleconference in early August. Call-in details will be provided in advance of the call.

About ELZONRIS®

ELZONRIS® (tagraxofusp-erzs), a CD123-directed cytotoxin, is approved by the U.S. Food and Drug Administration (FDA) and commercially available in the U.S. for the treatment of adult and pediatric patients, two years or older, with blastic plasmacytoid dendritic cell neoplasm (BPDCN). For full prescribing information in the U.S., visit www.ELZONRIS.com. In Europe, a marketing authorization application (MAA) is under review by the European Medicines Agency (EMA). 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, as well as other markers. For more information, please visit the BPDCN disease awareness website at www.bpdcninfo.com.

About CD123

CD123 is a cell surface target expressed on a wide range of myeloid tumors including blastic plasmacytoid dendritic cell neoplasm (BPDCN), certain myeloproliferative neoplasms (MPNs) including chronic myelomonocytic leukemia (CMML) and myelofibrosis (MF), acute myeloid leukemia (AML) (and potentially enriched in certain AML subsets), myelodysplastic syndrome (MDS), and chronic myeloid leukemia (CML). CD123 has also been reported on certain lymphoid malignancies including multiple myeloma (MM), acute lymphoid leukemia (ALL), hairy cell leukemia (HCL), Hodgkin's lymphoma (HL), and certain Non-Hodgkin's lymphomas (NHL). In addition, CD123 has been detected on some solid tumors as well as autoimmune disorders including cutaneous lupus and scleroderma.

About Stemline Therapeutics

Stemline Therapeutics, Inc. is a commercial-stage biopharmaceutical company focused on the development and commercialization of novel oncology therapeutics. ELZONRIS® (tagraxofusp), a targeted therapy directed to CD123, is FDA-approved and commercially available in the U.S. for the treatment of adult and pediatric patients, two years or older, with blastic plasmacytoid dendritic cell neoplasm (BPDCN). In Europe, a marketing authorization application (MAA) is under review by the European Medicines Agency (EMA). 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). For more information, please visit the company's website at www.stemline.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 U.S. launch and commercialization; the success of our MAA submission to the EMA and potential launch in Europe; the success and timing of our clinical trials and preclinical studies for our product and product candidates, including ELZONRIS in additional indications and our other pipeline 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 product 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 payors) 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 product and product candidates; delays, interruptions, or failures in the manufacture and supply of our product 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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