Stemline Therapeutics Inc Logo

Stemline Therapeutics Announces Preliminary 2019 Net Revenues for ELZONRIS® (tagraxofusp) and Highlights Commercial and Clinical Growth Drivers

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NEW YORK, Jan. 13, 2020 (GLOBE NEWSWIRE) -- Stemline Therapeutics, Inc. (Nasdaq: STML), a commercial-stage biopharmaceutical company focused on the development and commercialization of novel oncology therapeutics, today announced preliminary net revenues for 2019, as well as outlined key BPDCN market successes and upcoming commercial and clinical milestones.

Unaudited preliminary 2019 results include:

- $43.2 million in estimated ELZONRIS net revenues for the year-ended December 31, 2019
- $11.8 million in estimated ELZONRIS net revenues for the fourth quarter of 2019

The above financial information is based on preliminary unaudited information, is subject to adjustment, and does not present all information necessary for an understanding of the Company's full-year and fourth quarter financial results for 2019. Stemline expects to report complete audited 2019 financial results on or before March 16, 2020.

Robert Francomano, Chief Commercial Officer of Stemline, stated, "We are very pleased with the solid uptake seen in the first year of the ELZONRIS launch, as we continue to successfully create, penetrate and grow a new market in BPDCN. Given the orphan nature and unique features of this disease, we believe patient starts were subject to significant quarterly variance – a phenomena that will likely continue throughout 2020. We are actively implementing a host of tactics to expand and further penetrate this emerging market."

Ivan Bergstein, CEO of Stemline, commented, "2019 was a transformational year for Stemline as we launched ELZONRIS, the first and only CD123 targeted agent and first agent ever approved for patients with BPDCN. We continue to pursue growth opportunities not only in BPDCN but also in a number of malignancies where targeting CD123 could provide therapeutic benefit. We look forward to data readouts in CMML, MF, and AML, including in patient subsets with high CD123, later this year and on into next year. Given our continued commercial and clinical progress, we look forward to a productive 2020 and beyond."

Corporate Highlights and Key Commercial and Clinical Milestones

BPDCN

- $43.2 million in estimated, unaudited, net revenues for ELZONRIS in 2019
- Marketing Authorization Application (MAA) under review by European Medicines Agency (EMA) for potential approval in the E.U.
- Phase 1/2 trial of ELZONRIS in patients with BPDCN in the maintenance setting, post-stem cell transplant (SCT), has regulatory authorization to proceed; targeting treatment of the first patient in ~1Q20

Chronic Myelomonocytic Leukemia (CMML)

- The CMML expansion cohort, Stage 3a, is open for enrollment of two patient populations: relapsed/refractory patients, and first-line, poor prognosis patients not expected to benefit from first line cytoreductive treatment
- Results from Stage 3a is expected to inform the design of the subsequent Stage 3b confirmatory cohort for potential registration
- We expect to report initial data from this trial in ~4Q20

Myelofibrosis (MF)

- The MF cohort of the ongoing trial has been expanded to include 20-25 additional patients
- We are evaluating relapsed/refractory patients and specific subsets of patients, including patients with monocytosis, thrombocytopenia, and CD123 positivity.
- We expect to report updated data from this trial in ~4Q20

Acute Myeloid Leukemia (AML)

- A Phase 1/2 trial of ELZONRIS in combination with other agents in patients with relapsed/refractory AML, treatment-naive AML unfit for chemotherapy, and high-risk myelodysplastic syndrome (MDS) is currently enrolling patients. We expect to provide data updates later this year.

About ELZONRIS®

ELZONRIS® (tagraxofusp), 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 and 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: felezonexor (SL-801) (XPO1 inhibitor; Phase 1 in advanced solid tumor patients ongoing), SL-1001 (novel RET kinase inhibitor, IND-enabling studies ongoing), SL-701 (immunotherapeutic; Phase 2 in glioblastoma patients completed), and SL-901 (novel kinase inhibitor; prior abbreviated European Phase 1, IND-enabling studies ongoing). 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 risk that our actual revenue for the fourth quarter and year ended December 31, 2019 may differ materially from our estimated results for these periods as a result of the completion of year-end closing procedures or the audit of our financial statements; 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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