Stemline Therapeutics Inc Logo

Stemline Therapeutics Announces ASCO Presentation of ELZONRIS Phase 2 Clinical Data in CMML and MF; Provides Next Steps for CMML Program

June 3, 2019

NEW YORK, June 03, 2019 (GLOBE NEWSWIRE) -- Stemline Therapeutics, Inc. (Nasdaq: STML), a commercial-stage biopharmaceutical company focused on the development and commercialization of novel oncology therapeutics, announced that ELZONRIS™ (tagraxofusp) Phase 2 clinical data in chronic myelomonocytic leukemia (CMML) and myelofibrosis (MF) data are being presented today at the 2019 American Society of Clinical Oncology (ASCO) annual meeting, being held from May 31-June 4, 2019, at McCormick Place in Chicago, Illinois.

ELZONRIS (tagraxofusp) is FDA-approved for the treatment of patients, adults and pediatric 2 years and older, with blastic plasmacytoid dendritic cell neoplasm (BPDCN), and is commercially available in the U.S.

Details on the presentations are as follows:

Results from Ongoing Phase 1/2 Clinical Trial of Tagraxofusp (SL-401) in Patients with Relapsed/Refractory Chronic Myelomonocytic Leukemia (CMML)

- Abstract: 7059
- Session: Hematologic Malignancies – Leukemia, Myelodysplastic Syndromes, and Allotransplant
- Presenter: Mrinal M. Patnaik, MBBS; Mayo Clinic
- Date: Monday, June 3
- Time: 8:00 to 11:00 AM CT

Results from Ongoing Phase 1/2 Clinical Trial of Tagraxofusp (SL-401) in Patients with Intermediate or High Risk Relapsed/Refractory Myelofibrosis (MF)

- Abstract: 7058
- Session: Hematologic Malignancies – Leukemia, Myelodysplastic Syndromes, and Allotransplant
- Presenter: Naveen Pemmaraju, MD; The University of Texas MD Anderson Cancer Center
- Date: Monday, June 3
- Time: 8:00 to 11:00 AM CT

Please visit our Stemline corporate booth (#19156) during the 2019 ASCO annual meeting.

Stemline Provides Further Details on Next Steps for the ELZONRIS CMML Program
Given the encouraging clinical data generated from the ELZONRIS Phase 2 trial in patients with CMML, combined with feedback and guidance from the Food and Drug Administration (FDA), Stemline intends to open a Stage 3 cohort of the currently enrolling 0314 trial to serve as the pivotal program for ELZONRIS in patients with CMML. The planned primary endpoint is overall response rate (ORR); in addition, if certain other endpoints, including spleen size, are shown to have clinical benefit in the initial, Stage 3a, portion of the new cohort, then these endpoints could contribute to the primary evidence of efficacy in the final, Stage 3b, portion of the pivotal program. CD123 levels will also be evaluated in Stage 3a for potential enrichment in 3b.

Stage 3 will enroll patients with previously-treated CMML, and will be a single-arm, non-randomized trial designed to support potential registration. The protocol is currently being designed, and we expect to provide further details, including sample size, during 3Q19, with an expectation of opening the new cohort to enrollment later this year.

Ivan Bergstein, M.D., CEO of Stemline Therapeutics, commented “With ELZONRIS now FDA-approved and commercially available for patients with BPDCN, our focus is on both ensuring patient access to ELZONRIS in the commercial setting as well as broadening the potential for ELZONRIS in additional indications. With this in mind, we are very excited to advance another ELZONRIS clinical program toward a potential second approval, this time in CMML, an aggressive and underserved malignancy.”

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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