

## Stemline Therapeutics Announces Three ELZONRIS Presentations, Including an Oral Presentation in Myelofibrosis, at Upcoming ASH Meeting

November 6, 2019

NEW YORK, Nov. 06, 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 ELZONRIS (tagraxofusp; SL-401), a novel targeted therapeutic directed to CD123, will be featured in three presentations, including an oral presentation of ELZONRIS clinical data in myelofibrosis, at the 2019 American Society of Hematology (ASH) Annual Meeting and Exposition, to be held December 7-10, 2019 in Orlando, FL.

Details on the ASH presentations are as follows:

### Myelofibrosis – Clinical (monotherapy); oral presentation

**Title:** Results from a Phase 1/2 Clinical Trial of Tagraxofusp (SL-401) in Patients with Intermediate, or High Risk, Relapsed/Refractory Myelofibrosis  
**Presenter:** Naveen Pemmaraju, MD; MD Anderson Cancer Center  
**Abstract:** 558  
**Session:** 634. Myeloproliferative Syndromes: Clinical: Emerging and Novel Targeted Therapies  
**Date/Time:** Monday, December 9, 2019 8:15 AM ET  
**Location:** Orange County Convention Center, W304EFGH

### Multiple Myeloma – Clinical (combination therapy); poster presentation

**Title:** Results from Phase 1/2 Trial of Tagraxofusp in Combination with Pomalidomide and Dexamethasone in Relapsed or Refractory Multiple Myeloma  
**Presenter:** Paul G. Richardson, M.D.; Dana-Farber Cancer Institute  
**Abstract:** 3145  
**Session:** 653. Myeloma: Therapy, excluding Transplantation: Poster II  
**Date/Time:** Sunday, December 8, 2019 6:00 PM–8:00 PM ET  
**Location:** Orange County Convention Center, Hall B

### Myeloproliferative Neoplasms – Preclinical (combination therapy); poster presentation

**Title:** Evaluation of Tagraxofusp (SL-401) Alone and in Combination with Ruxolitinib for the Treatment of Myeloproliferative Neoplasms  
**Presenter:** Aishwarya Krishnan, MD; Memorial Sloan Kettering Cancer Center  
**Abstract:** 2967  
**Session:** 635. Myeloproliferative Syndromes: Basic Science: Poster II  
**Date/Time:** Sunday, December 8, 2019 6:00 PM–8:00 PM ET  
**Location:** Orange County Convention Center, Hall B

Ivan Bergstein, M.D., CEO of Stemline Therapeutics, commented, “We are honored that ASH has selected ELZONRIS data as the subject of three presentations, including an oral presentation of clinical trial data in myelofibrosis (MF). Moreover, given the very encouraging trial results to date that we have witnessed, we are expanding the current cohort to enable additional patient enrollment. Two other presentations, including ELZONRIS clinical combination data in patients with multiple myeloma, and ELZONRIS preclinical combination data in myeloproliferative neoplasms, highlight ELZONRIS’ potential utility across indications. In addition, as we now transition our chronic myelomonocytic leukemia (CMML) program to registration-directed, we remain on track to begin enrollment of the Stage 3a cohort in patients with CMML in the coming months, with the goal of reporting data from this cohort, in both the relapsed/refractory and first-line settings, by 2H20.”

### 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](http://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.bpdncinfo.com](http://www.bpdncinfo.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](http://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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Source: Stemline Therapeutics, Inc.