



Synta Announces Continuation of the SYMMETRYSM Trial Based on Evaluation of Independent Data Monitoring Committee

December 18, 2008

LEXINGTON, Mass.--(BUSINESS WIRE)--Dec. 18, 2008--Synta Pharmaceuticals Corp. (NASDAQ: SNTA) announced today the recommendation from the independent Data Monitoring Committee (DMC) that is overseeing the Company's Phase 3 clinical investigation of elesclomol in metastatic melanoma, the SYMMETRYSM trial. Based on a review of the safety data and a non-futility analysis, the DMC has recommended that the trial should continue.

Elesclomol is an investigational first-in-class oxidative stress inducer that triggers apoptosis (programmed cell death) in cancer cells. Elesclomol is being developed under a global collaboration agreement between Synta Pharmaceuticals and GlaxoSmithKline and is not approved for marketing by the U.S. Food and Drug Administration (FDA) or any other similar regulatory body in any country.

As previously announced, Synta expects to complete enrollment of the SYMMETRY trial in January or February 2009 and conduct the primary endpoint analysis shortly thereafter.

SYMMETRY Trial Design

The SYMMETRY trial is enrolling patients with stage IV metastatic melanoma who have not received prior chemotherapy but who may have already been treated with non-chemotherapeutic agents such as biologics. Approximately 630 patients are being enrolled in the blinded, randomized, controlled study, which is being conducted at approximately 150 centers worldwide. Patients are randomized (1:1) to elesclomol (213 mg/m²) plus paclitaxel (80 mg/m²) or paclitaxel alone (80 mg/m²) and receive three weekly treatments and one week without treatment per each four week cycle. If tolerated, treatment continues until disease progression. Patients are stratified according to LDH levels, M-grade status and prior treatment history. Response is assessed using modified RECIST criteria at baseline and every eight weeks from the date of randomization, with radiology scans being assessed by independent, blinded, reviewers at a central site. The primary endpoint of the trial is progression-free survival (PFS); secondary endpoints include overall survival and response rate. No crossover is allowed from the paclitaxel control arm to the combination arm following disease progression, in order to facilitate the assessment of overall survival.

The control arm treatment, the combination arm treatment, the doses, the schedule, and the primary endpoint - PFS - are the same as in the prior, Phase 2b melanoma trial. The Phase 3 SYMMETRY trial design has been reviewed and agreed to by the FDA under the Special Protocol Assessment process.

About Elesclomol

Elesclomol is an investigational first-in-class oxidative stress inducer that triggers apoptosis

(programmed cell death) in cancer cells. Cancer cells operate at high levels of reactive oxygen species, or oxidative stress. Elesclomol acts by increasing the level of oxidative stress in cancer cells even further, beyond sustainable levels, inducing apoptosis. This mechanism of action, called oxidative stress induction, represents a novel way of selectively targeting and killing cancer cells.

In a double-blind, randomized, controlled Phase 2b clinical trial in 81 patients with stage IV metastatic melanoma, elesclomol in combination with paclitaxel met the primary endpoint, doubling the median time patients survived without their disease progressing, compared to paclitaxel alone ($p = 0.035$). The most common adverse events in the elesclomol plus paclitaxel group included fatigue, alopecia, constipation, nausea, hypoaesthesia, arthralgia, insomnia, diarrhea, and anemia.

A pivotal Phase 3 clinical trial of elesclomol in combination with paclitaxel in patients with stage IV metastatic melanoma (the SYMMETRYSM trial) is ongoing. Information about the SYMMETRY trial can be found at www.symmetrymelanomastudy.com, or www.clinicaltrials.gov, (NCI identifier # NCT00522834).

A Phase 1/2 trial of elesclomol in combination with docetaxel in patients with metastatic, hormone-refractory prostate cancer was initiated in 2008. Trials in other indications, and in combination with other agents, are planned.

Elesclomol has received Fast Track and Orphan Drug designation from the FDA for metastatic melanoma. The Phase 3 SYMMETRY trial design has been reviewed and agreed to by the FDA under the Special Protocol Assessment process.

About Metastatic Melanoma

Melanoma, the most deadly form of skin cancer, arises from melanocytes, the pigment-producing cells of the skin. According to the American Cancer Society, melanoma accounts for approximately five percent of all skin cancers but causes about 75% of all skin cancer-related deaths. An estimated 60,000 people will be diagnosed and nearly 8,200 people will die from melanoma this year in the U.S. alone. If diagnosed and surgically removed while localized in the outermost skin layer, melanoma is potentially curable; however, for patients with metastatic disease the prognosis is poor, with limited available treatments and an expected survival of only six to nine months. The incidence of melanoma has increased more rapidly than any other cancer during the past ten years. The FDA has not approved a novel, small molecule drug for the treatment of metastatic melanoma in over 30 years.

About Synta Pharmaceuticals

Synta Pharmaceuticals Corp. is a biopharmaceutical company focused on discovering, developing, and commercializing small molecule drugs to extend and enhance the lives of patients with severe medical conditions, including cancer and chronic inflammatory diseases. Synta has a unique chemical compound library, an integrated discovery engine, and a diverse pipeline of clinical- and preclinical-stage drug candidates with distinct mechanisms of action and novel chemical structures. All Synta drug candidates were invented by Synta scientists using our compound library and discovery capabilities. For more information, please visit www.syntapharma.com.

Safe Harbor Statement

This media release may contain forward-looking statements about Synta Pharmaceuticals Corp. Such forward-looking statements can be identified by the use of forward-looking terminology such as "will", "would", "should", "expects", "anticipates", "intends", "plans", "believes", "may", "estimates", "predicts", "projects", or similar expressions intended to identify forward-looking statements. Such statements, including statements relating to the timing and progress of our clinical and preclinical programs, including the expected timing of completion of the enrollment of the SYMMETRY trial and the primary endpoint analysis, reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such forward-looking statements, including those described in "Risk Factors" of our Form 10-K for the year ended December 31, 2007 as filed with the Securities and Exchange Commission. Synta undertakes no obligation to publicly update forward-looking statements, whether because of new information, future events or otherwise, except as required by law.

CONTACT: Synta Pharmaceuticals Corp.
Rob Kloppenburg, 781-541-7125
or
MacDougall Biomedical Communications
Doug MacDougall, 781-235-3060

Source: Synta Pharmaceuticals Corp.