



## Elesclomol Two-Year Survival and Integrated Safety Data Presented at the 33rd Congress of the European Society for Medical Oncology

September 15, 2008

LEXINGTON, Mass.--(BUSINESS WIRE)--Sept. 15, 2008--Synta Pharmaceuticals Corp. (NASDAQ: SNTA) today announced that two-year follow up survival data from its Phase 2b clinical trial in metastatic melanoma were presented at the 33rd Congress of the European Society for Medical Oncology (ESMO) in Stockholm. In addition, an integrated safety analysis from Phase 1 and Phase 2 solid tumor trials of elesclomol plus paclitaxel versus paclitaxel alone was presented. Elesclomol is an investigational drug candidate that triggers programmed cell death (apoptosis) in cancer cells by elevating oxidative stress, and is currently in a global, pivotal Phase 3 trial for metastatic melanoma, with other trials, in other indications, planned. Elesclomol is not yet approved for any indication in any market.

The Phase 2b clinical trial for metastatic melanoma compared the effects of treatment with elesclomol plus paclitaxel (N=53) to treatment with paclitaxel alone (N=28). Follow up showed that:

- Two-year overall survival in the elesclomol plus paclitaxel group was 27%.
- Two-year overall survival in patients initially treated with paclitaxel alone was 21%. Of those patients, 68% received elesclomol plus paclitaxel after disease progression, as allowed by the trial protocol. The two-year overall survival for the crossover group that received elesclomol was 26%. The two-year overall survival for the no-crossover group, patients who never received elesclomol, was 11%.
- Median overall survival and one-year overall survival rates, consistent with higher survival rates in patients who received elesclomol, were unchanged from previously reported data. These results are summarized in the table below:

	Elesclomol + Paclitaxel (N=53)	All patients initially randomized to paclitaxel alone (N=28)	Pac-alone patients who crossed over to elesclomol (N=19)	Pac-alone patients who never received elesclomol (N=9)
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2 Year OS Rate	27%	21%	26%	11%

1 Year OS Rate	49%	43%	53%	22%
Median (months)	11.9	7.8	14.3	5.6

"The incidence of melanoma is increasing however there are few effective treatment options available for patients and their physicians," commented Eric Jacobson, M.D., Senior Vice President and Chief Medical Officer, Synta. "The two-year overall survival rate for patients treated with elesclomol plus paclitaxel is encouraging, consistent with the previously reported one-year and median overall survival rates. Together with the previously reported positive results for the primary endpoint of the study, progression free survival, these overall survival results underscore the potential of elesclomol as an exciting new treatment option for metastatic melanoma patients. The ongoing, international Phase 3 SYMMETRY(SM) clinical trial of elesclomol in metastatic melanoma will provide further data on the potential role of this novel oxidative stress inducer in treating this deadly disease."

Also at the ESMO conference, a poster was presented describing the results from an integrated safety analysis of patients enrolled in Phase 1 and Phase 2 solid tumor studies (melanoma, sarcoma and other solid tumors). The analysis showed that elesclomol plus paclitaxel demonstrated a safety profile similar to that of paclitaxel alone. The observed safety profile across the multiple studies was comparable to the safety profile observed in the Phase 2b melanoma trial.

Metastatic melanoma occurs when melanoma - a cancer that begins in melanocytes, the cells that make skin pigment, or melanin - spreads to other parts of the body.(1,2) Worldwide, approximately 132,000 new diagnoses of melanoma are made each year,(3) of these approximately 48,000 occur in Europe. Stage IV melanoma defines distant metastasis and continues to comprise an ominous prognosis, with a median survival of 6-9 months.(4)

In the past 35 years, the FDA has only approved two types of therapies for metastatic melanoma; however neither of these therapies have been shown to improve patient survival.

#### Elesclomol and Paclitaxel in Stage IV Metastatic Melanoma: 2-year Overall Survival (OS)(5)

The two-year follow-up of the randomized, double-blind, active-controlled, Phase 2b trial in patients with stage IV metastatic melanoma compared overall survival for the combination of elesclomol and paclitaxel versus paclitaxel alone in patients who received one or no prior chemotherapy treatment. A total of 81 patients were enrolled in the trial and were evaluated in this analysis. Patients received either 213 mg/m<sup>2</sup> of elesclomol co-infused with 80 mg/m<sup>2</sup> paclitaxel (n=53) or 80 mg/m<sup>2</sup> of paclitaxel alone (n=28) in four-week cycles (once weekly for three weeks and one week's rest) until disease progression.(5) Disease progression was defined using industry standard RECIST criteria. Patients initially randomized to treatment with paclitaxel alone were eligible for crossover to treatment with elesclomol plus paclitaxel following disease progression.

"Advanced metastatic melanoma is a notoriously hard-to-treat disease - no standard of care exists, single-agent or combination chemotherapies do not impact overall survival, and there are also considerable toxicity and adverse event issues with other approved treatments. These data showcase the promising application of a novel therapeutic approach that may make melanoma, a largely chemo-resistant disease, more sensitive to chemotherapy," said Dr. Steven O'Day, M.D.,

Primary Investigator and Chief of Research and Director of the Melanoma Program at The Angeles Clinic and Research Institute, California.

## Integrated Safety Analysis

Also presented at ESMO were the results from an integrated safety analysis of 239 patients treated with elesclomol plus paclitaxel in 6 completed clinical trials conducted across 54 centers in the United States involving patients with melanoma, sarcoma, and other solid tumors. A control group of 30 patients treated with paclitaxel alone from the randomized, double-blind stages of two of the trials was considered. Results showed that elesclomol plus paclitaxel was associated with no more than 10% of patients having individual adverse events of Grade 3 or higher. The most frequently observed toxicities were consistent with use of paclitaxel alone with a possible slight increase (6% vs. 0%) in neutropenia. Other Grade 3 or higher adverse events included anemia (3%), deep vein thrombosis (3%), fatigue (3%), hyperglycemia (3%), hypophosphatemia (3%), extremity pain (3%), and dyspnea (3%). These results are consistent with previously reported safety data from the Phase 2b clinical trial of elesclomol in metastatic melanoma where the incidents of Grade 3 or higher individual adverse events on the treatment arm were also under 10%.

## About Elesclomol

Elesclomol is a novel, injectable, investigational drug candidate that triggers apoptosis (programmed cell death) in cancer cells. Cancer cells in general and specific types of cancer, such as melanoma, have higher levels of reactive oxygen species, or oxidative stress, than normal cells. When exposed to an oxidative stress inducer like elesclomol, the levels may rise further, beyond sustainable levels, triggering apoptosis in the cancer cell. This mechanism of action, called oxidative stress induction, represents a novel way of selectively targeting and killing cancer cells.

Elesclomol is being developed under a global collaboration agreement between Synta Pharmaceuticals and GlaxoSmithKline.

Elesclomol is not approved for marketing by any regulatory body in any country.

## Ongoing Clinical Trials

Elesclomol is currently in a global, pivotal Phase 3 trial called SYMMETRY(SM). The SYMMETRY study is being conducted at approximately 150 centers worldwide to determine the efficacy of elesclomol in combination with paclitaxel for the treatment of patients with metastatic (Stage IV) melanoma. Elesclomol has received Fast Track and Orphan Drug designation from the FDA for metastatic melanoma, and the Phase 3 SYMMETRY trial has completed the Special Protocol Assessment review process with the FDA. Additional investigations to evaluate elesclomol as a therapy for other cancers are currently being planned. Information about the SYMMETRY trial can be found at [www.symmetrymelanomastudy.com](http://www.symmetrymelanomastudy.com), or [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

## 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. Synta has a partnership with GlaxoSmithKline for the joint development and commercialization of its lead investigational drug candidate, elesclomol, which is in a global, pivotal Phase 3 clinical trial for the treatment of metastatic melanoma. For more information, please visit [www.syntapharma.com](http://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 and financial guidance for 2008, 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.

## References

(1) Melanoma Home Page. National Cancer Institute. <http://www.cancer.gov/cancertopics/types/melanoma> (March 18, 2008).

(2) Melanoma Signs and Symptoms. University of California San Francisco Medical Center. [http://www.ucsfhealth.org/adult/medical\\_services/cancer/skin/conditions/Melanoma/signs.html](http://www.ucsfhealth.org/adult/medical_services/cancer/skin/conditions/Melanoma/signs.html) (March 18, 2008).

(Due to the length of this URL, it may be necessary to copy and paste it into your Internet browser's URL address field. You may also need to remove an extra space in the URL if one exists.)

(3) Melanoma FAQ. World Health Organization. <http://www.who.int/uv/faq/skincancer/en/index1.html> (April 17, 2008).

(4) Tarhini A, Agarwala S. Cutaneous Melanoma: Available therapy for metastatic disease. *Dermatologic Therapy*. 2006; 19:19-25.

(5) O'Day S, Gonzalez R, Weber L, et al. Elesclomol (formerly STA-4783) and paclitaxel in Stage IV metastatic melanoma (MM): 2-year overall survival (OS). 33rd European Society of Medical Oncology Congress, Stockholm, September 2008. Abstract # 7710.

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