



Elesclomol Study Shows Significant Improvement in Progression-Free Survival for Chemotherapy-Naive Patients With Metastatic Melanoma

May 20, 2008

CHICAGO, May 20, 2008 /PRNewswire via COMTEX News Network/ -- CHICAGO, May 20 /PRNewswire/ -- GlaxoSmithKline and Synta Pharmaceuticals Corp. (Nasdaq: SNTA) today announced positive Phase II clinical data for elesclomol (formerly STA-4783), an investigational agent currently in development for metastatic melanoma. A retrospective analysis showed that stage IV metastatic melanoma patients treated with elesclomol and paclitaxel who had not previously received chemotherapy had a statistically significant improvement in progression-free survival (PFS) compared to patients who received paclitaxel alone.(1) These data will be presented at the 44th Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago. Elesclomol is not yet approved for any indication in any market.

"The incidence of melanoma has continued to rise in recent years and there is an undeniable need to identify effective treatments for patients with metastatic disease," said Paolo Paoletti, M.D., Senior Vice President of the Oncology Medicine Development Center at GSK. "GSK is at the forefront of research to improve the lives of cancer patients, including those with limited treatment options, and we are dedicated to conducting ongoing trials in metastatic melanoma."

"The preliminary clinical data for elesclomol in metastatic melanoma patients are encouraging and underscore the urgent need for new treatments," said Eric Jacobson, M.D., Senior Vice President and Chief Medical Officer, Synta. "These data, combined with earlier clinical and pre-clinical data we have presented for elesclomol, support our belief that oxidative stress induction is a promising new approach to cancer therapy in melanoma and, potentially, other cancer types."

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.(2,3) In the U.S. alone, the percentage of people who develop melanoma - the deadliest form of skin cancer - has more than doubled in the past 30 years, and about 60,000 people are diagnosed with melanoma and 8,000 will die from it in 2008.(4,5,6) Worldwide, approximately 132,000 new diagnoses are made each year.(7) Currently, there are no approved therapies that have been shown to improve survival for patients with metastatic melanoma.(8)

Phase II Trial of Elesclomol and Paclitaxel in Stage IV Metastatic Melanoma: A Subgroup Analysis By Prior Chemotherapy (Abstract # 9036) Presentation date/time: May 31, 2008, 2:00 PM - 6:00 PM

This retrospective subgroup analysis of a randomized, double-blind, active-controlled, Phase II trial in patients with stage IV metastatic melanoma evaluated the rates of progression-free survival and overall survival for the combination of elesclomol and paclitaxel versus paclitaxel alone in patients who received one prior chemotherapy treatment with those who were chemotherapy-naive. A total of 81 patients evaluated in this analysis either received 213 mg/m² of elesclomol co-infused with 80 mg/m² paclitaxel or 80 mg/m² of paclitaxel alone in four-week cycles (once weekly for three weeks and one week's rest) until disease progression.(1)

Patients who had not received prior chemotherapy and were given a combination of elesclomol and paclitaxel (n=24), compared to patients who were given paclitaxel alone (n=8):

Experienced a 69 percent reduction in the risk of progression or death

Lived an average of almost six months longer (15.9 months versus 10.0 months)

Had a longer median progression-free survival (7.1 months versus 1.8 months; p=0.020).(1)

"Metastatic melanoma is an aggressive disease, and patients currently have few treatment options," said investigator David Lawson, M.D., Emory University School of Medicine. "Identifying novel therapies like elesclomol represent the future of treating this hard-to-treat disease."

Data for patients on the elesclomol and paclitaxel arm who had one prior chemotherapy showed a trend toward results similar to patients who had received no prior chemotherapy; however these data were not statistically significant. Specifically, after receiving one prior chemotherapy, the median PFS was 2.8 months for patients receiving elesclomol and paclitaxel (n=29) versus 1.8 months for patients on paclitaxel alone (n=20; p=0.552), and OS was 9.0 months for patients on elesclomol and paclitaxel versus 7.8 months for patients on paclitaxel alone.(1)

Regardless of prior chemotherapy, the most common adverse events in the elesclomol plus paclitaxel group included fatigue, alopecia, constipation, nausea, hypoesthesia, arthralgia, insomnia, diarrhea and anemia. The most serious adverse events (Grade 3 or higher) for the combination arm were similar to those seen in the paclitaxel-only arm and included neutropenia, back pain, fatigue and neuropathy.(1)

About Elesclomol

Elesclomol is a novel, injectable, investigational drug candidate that triggers apoptosis (programmed cell death) in cancer cells. Cancer cells operate at high levels of reactive oxygen species, or oxidative stress. Elesclomol is believed to act 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.

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

Ongoing Clinical Trials

GlaxoSmithKline and Synta Pharmaceuticals are currently studying elesclomol in a global, pivotal Phase III 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.(9) Elesclomol has received Fast Track and Orphan Drug designation from the FDA for metastatic melanoma, and the Phase III SYMMETRY trial has completed a Special Protocol Assessment process with the FDA. Additional investigations to evaluate elesclomol as a therapy for other cancers are currently being planned.(9)

GSK in Oncology

GSK Oncology is dedicated to producing innovations in cancer that will make profound differences in the lives of patients. Through GSK's revolutionary 'bench to bedside' approach, we are transforming the way treatments are discovered and developed, resulting in one of the most robust pipelines in the oncology sector. Our worldwide research in oncology includes collaborations with more than 160 cancer centres. GSK is closing in on cancer from all sides with a new generation of patient focused cancer treatments in prevention, supportive care, chemotherapy and targeted therapies.

About GlaxoSmithKline

GlaxoSmithKline - one of the world's leading research-based pharmaceutical and healthcare companies - is committed to improving the quality of human life by enabling people to do more, feel better, and live longer. For company information, visit GlaxoSmithKline at www.gsk.com.

About Synta Pharmaceuticals Corp.

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 drug 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 III clinical trial for the treatment of metastatic melanoma. For more information, please visit www.syntapharma.com.

GlaxoSmithKline Cautionary Statement Regarding Forward-Looking Statements

Under the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Factors that may affect GSK's operations are described under 'Risk Factors' in the 'Business Review' in the company's Annual Report on Form 20-F for 2007.

Synta Pharmaceuticals Corp. 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, 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.

Notes to Editors:

To access the latest GSK Oncology media materials, visit www.gsk.com/media.

GlaxoSmithKline Inquiries:

US Media inquiries:	Sarah Alspach	1 215 287 6354
	(onsite at ASCO)	
	Mary Anne Rhyne	1 919 483 2839

UK Media inquiries:	Philip Thomson	44 20 8047 5502
	Joss Mathieson	44 20 8047 5502
	Gwenan White	44 20 8047 5502
European Analyst /Investor inquiries:	Anita Kidgell	44 20 8047 5542
	Sally Ferguson	44 20 8047 5543
	David Mawdsley	44 20 8047 5564
US Analyst/Investor inquiries:	Frank Murdolo	1 215 751 7002
	Tom Curry	1 215 751 5419

Synta Pharmaceuticals Corp. Inquiries:

US Media/Investor inquiries:	Rob Kloppenburg	1 781 541 7125
---------------------------------	-----------------	----------------

References:

- (1) Gonzalez R, Lawson D, et. Al. Final Poster for Abstract # 9036 - Phase 2 Trial of Elesclomol (Formerly STA-4783) and Paclitaxel in Stage IV Metastatic Melanoma (MM): Subgroup analysis by prior chemotherapy. To be presented at the 2008 American Society of Clinical Oncology annual meeting.
- (2) Melanoma Home Page. National Cancer Institute. <http://www.cancer.gov/cancertopics/types/melanoma> (March 18, 2008).
- (3) Melanoma Signs and Symptoms. University of California San Francisco Medical Center. http://www.ucsfhealth.org/adult/medical_services/cancer/skin/conditions/Melanoma/signs.html (March 18, 2008).
- (4) What You Need to Know About Melanoma. National Cancer Institute. September 2002. <http://www.cancer.gov/cancertopics/wyntk/melanoma> (March 18, 2008).
- (5) Why You Should Know About Melanoma. American Cancer Society. http://www.cancer.org/downloads/CRI/Why_You_Should_Know_About_Melanoma.pdf (March 18, 2008).
- (6) Cancer Facts & Figures 2008. American Cancer Society. <http://www.cancer.org/downloads/STT/2008CAFFfinalsecured.pdf> (March 18, 2008).
- (7) Melanoma FAQ. World Health Organization. <http://www.who.int/uv/faq/skincancer/en/index1.html> (April 17, 2008).
- (8) Tarhini A, Agarwala S. Cutaneous Melanoma: Available therapy for metastatic disease. *Dermatologic Therapy*. 2006; 19:19-25.
- (9) United States Securities and Exchange Commission. Synta Pharmaceuticals Corp. Form 10-K. Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Commission file number 002-33277. For the fiscal year ended December 31, 2007.
- (10) Kirshner J. Elesclomol (formerly STA-4783) induces apoptosis and enhances the anticancer activity of paclitaxel through induction of oxidative stress. Poster presented at the International Conference on Molecular Targets and Cancer Therapeutics: AACR-NCI-EORTC on October 24, 2007.

SOURCE GlaxoSmithKline; Synta Pharmaceuticals Corp.