



## **Synta and GlaxoSmithKline Announce Elesclomol Granted Orphan Drug Designation by the FDA**

January 28, 2008

LEXINGTON, Mass.--(BUSINESS WIRE)--Jan. 28, 2008--Synta Pharmaceuticals Corp. (NASDAQ: SNTA) and GlaxoSmithKline (GSK) today announced that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation to elesclomol (formerly STA-4783) for the treatment of patients with metastatic melanoma. Elesclomol is being developed under a global collaboration agreement between Synta and GSK. Elesclomol is an investigational drug that is not approved for any indication in any market at this time.

Orphan drug status is designed to encourage biotechnology and pharmaceutical companies to develop drugs for rare diseases which affect fewer than 200,000 people in the United States. In November 2006 elesclomol received Fast Track designation from the FDA for development in metastatic melanoma.

"We are pleased that the FDA granted elesclomol orphan drug status for the treatment of metastatic melanoma," said Eric Jacobson, M.D., Senior Vice President and Chief Medical Officer, Synta Pharmaceuticals. "With the incidence of melanoma increasing more rapidly than any other cancer during the past ten years, there is a significant need for innovative therapies such as elesclomol."

"Orphan drug status is an acknowledgment of the significant need to develop new therapies for patients with metastatic melanoma, a disease for which there are few treatment options," said Paolo Paoletti, Senior Vice President of the Oncology Medicine Development Center at GSK. "Through the development of products like elesclomol, GSK Oncology is reaffirming its commitment to address clinical needs in cancer treatment and improve the lives of patients."

### **About Elesclomol (Formerly STA-4783)**

Elesclomol is a novel, injectable, investigational drug candidate that is believed to kill cancer cells by elevating oxidative stress levels beyond a breaking point, triggering programmed cell death. This mechanism of action, called oxidative stress induction, represents a novel way of selectively killing cancer cells.

A pivotal Phase 3 clinical trial of elesclomol in combination with paclitaxel in metastatic melanoma (the SYMMETRY(SM) trial) was initiated in October 2007 and Phase 2 trials in other indications, and in combination with other agents, are planned. Information about the SYMMETRY trial can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

In a double-blind, randomized, controlled Phase 2b clinical trial in 81 patients with 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.

### About Orphan Drug Status

The Orphan Drug Act (ODA) provides economic incentives to encourage biotechnology and pharmaceutical companies to develop drugs for rare diseases which affect fewer than 200,000 people in the United States. Orphan drug designation entitles Synta and GSK to seven years of market exclusivity for elesclomol for the treatment of patients with metastatic melanoma. Additional incentives for orphan drug development include tax credits related to development expenses, reduction in FDA user fees and FDA assistance in clinical trial design.

### About Metastatic Melanoma

The incidence of melanoma has increased more rapidly than any other cancer during the past ten years. 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. Treatments are limited and the expected survival for patients with metastatic melanoma is only six to nine months.

### 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 elesclomol. For more information, please visit [www.syntapharma.com](http://www.syntapharma.com).

### 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](http://www.gsk.com).

GSK Oncology is dedicated to producing innovations in cancer that will make profound differences in the lives of patients. Through GSK's "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 centers. GSK is developing a new generation of patient-focused cancer treatments in prevention, supportive care, chemotherapy and targeted therapies.

### Synta Pharmaceuticals 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-Q for the quarter ended September 30, 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.

#### GlaxoSmithKline cautionary statement regarding forward-looking statements

Under the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995, the company cautions investors that any forward-looking statements or projections made by the company, 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 the Group's operations are described under 'Risk Factors' in the 'Business Review' in the company's Annual Report on Form 20-F for 2006.

#### MULTIMEDIA AVAILABLE:

<http://www.businesswire.com/cgi-bin/mmg.cgi?eid=5594272>

CONTACT: Synta Pharmaceuticals Corp.  
Rob Kloppenburg, +1 781-541-7125  
MacDougall Biomedical Communications  
Doug MacDougall, +1 508-647-0209  
or  
GlaxoSmithKline  
US Media enquiries:  
Sarah Alspach, +1 919-483-2839  
Mary Anne Rhyne, +1 919-483-2839  
or  
UK Media enquiries:  
Philip Thomson, +44 20 8047 5502  
Claire Brough, +44 20 8047 5502  
Joss Mathieson, +44 20 8047 5502  
Alice Hunt, +44 20 8047 5502  
or  
European Analyst/Investor enquiries:  
David Mawdsley +44 20 8047 5564  
Sally Ferguson +44 20 8047 5543  
or  
US Analyst/ Investor enquiries:  
Frank Murdolo, +1 215-751-7002  
Tom Curry +1 215-751-5419

SOURCE: Synta Pharmaceuticals Corp.