

# Synta Suspends Elesclomol SYMMETRYSM Trial in Metastatic Melanoma

February 26, 2009

# Analysis by independent DMC identifies safety concerns

### Investor Conference Call Scheduled for 5:30 p.m. ET Today

LEXINGTON, Mass.--(BUSINESS WIRE)--Feb. 26, 2009-- Synta Pharmaceuticals Corp. (NASDAQ: SNTA), today announced that based on an analysis by an independent Data Monitoring Committee (DMC), it has suspended the SYMMETRY<sup>SM</sup> trial, the Phase 3 clinical study comparing elesclomol in combination with paclitaxel to paclitaxel alone in chemo-naïve patients with stage IV metastatic melanoma. The decision to suspend the SYMMETRY trial was based on the results of an analysis by the independent DMC which identified safety concerns, including an imbalance in overall survival (OS), with a greater number of deaths occurring in the combination arm (elesclomol with paclitaxel) compared to the control arm (paclitaxel alone). The final analysis of the primary endpoint (PFS) as assessed by independent reviewers has not been carried out yet.

Based on these findings, Synta also announced that additional ongoing studies with elesclomol, including a study of elesclomol in combination with docetaxel in hormone-refractory metastatic prostate cancer and a monotherapy dose escalation study, will be suspended pending further analysis of the results of the SYMMETRY trial. Synta is contacting investigators regarding appropriate patient notification and care.

"Our first concern is for the safety of patients, and therefore we acted promptly to halt the SYMMETRY trial once it was evident that there were serious safety concerns," said Eric Jacobson, M.D., Chief Medical Officer. "We are enormously disappointed for melanoma patients, particularly because there are so few treatment options available. We will be working hard over the next several weeks to analyze and better understand the results from this trial."

"I would like to thank the patients who participated in this trial and the many investigators, healthcare professionals and Synta employees who have worked so hard on the development of elesclomol for whom this result is also very disappointing," said Safi Bahcall, Ph.D., President and Chief Executive Officer of Synta Pharmaceuticals. "We will present detailed results in an appropriate scientific venue as soon as a full analysis has been completed. In the interim, we will be in discussions with our collaborator, GSK, about the future development of elesclomol."

"While this is a considerable setback, Synta has both the resources and a diverse pipeline of novel drug candidates that will allow us to continue to develop our oncology and anti-inflammatory programs," said Dr. Bahcall. "We remain committed to bringing new treatment options to patients in these two major disease categories."

On its third quarter 2008 earnings call, Synta said that it expected to end the year with between \$65 million and \$70 million in cash and receivables. Synta recently concluded an agreement with Roche

for the development of the Synta CRACM (Calcium Release-Activated Calcium Modulator) program for the treatment of inflammatory and autoimmune diseases, and which provided an upfront payment of \$16 million in cash as well as committed research funding of \$9 million over the next two years and full preclinical and clinical cost reimbursement. Synta also recently announced that had achieved a milestone related to the development of elesclomol, earning an additional \$10 million payment from GSK.

Synta has a strong pipeline of products, including STA-9090, a novel Hsp90 inhibitor that is currently in two Phase 1 dose escalation studies in solid tumors; apilimod, an oral IL-12/IL-23 inhibitor currently in a Phase 2a study in rheumatoid arthritis; STA-9584, a vascular disrupting agent for cancer in pre-clinical development; and additional programs in the research and preclinical development stages.

#### **Conference Call and Webcast Information**

Synta will conduct a conference call to discuss this announcement today at 5:30 p.m. (ET). The conference call will be webcast live over the Internet and can be accessed by logging on to the "Investors" section of the Synta Pharmaceuticals website, <a href="www.syntapharma.com">www.syntapharma.com</a>, prior to the event.

The call also can be accessed by dialing (877) 407-8035 or (201) 689-8035 prior to the start of the call. For those unable to join the live conference call, a replay will be available from 10:00 p.m. (ET) today through midnight (ET) on March 5. To access the replay, dial (877) 660-6853 or (201) 612-7415 and refer to both account number 286 and conference ID 315337. The webcast also will be archived on the Company's website.

# **SYMMETRY Trial Design**

The SYMMETRY trial enrolled patients with stage IV metastatic melanoma who had not received prior chemotherapy but who may have already been treated with non-chemotherapeutic agents such as biologics. The blinded, randomized, controlled study, conducted at approximately 150 centers in 15 countries. Patients were 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 continued until disease progression. Patients were stratified according to LDH levels, M-grade status and prior treatment history. Responses were assessed using standard RECIST criteria at baseline and at a minimum every other cycle, with radiology scans being assessed by independent, blinded, reviewers at a central site. The primary endpoint of the study was progression-free survival; overall survival and tumor response rate were secondary endpoints. The trial achieved its enrollment target of 630 patients earlier this month.

# **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, developments, progress and plans 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.

Source: Synta Pharmaceuticals Corp.

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