Synta Presents Results for STA-4783 in Metastatic Melanoma Showing Improvement in Overall Survival

June 5, 2007

Patients treated with STA-4783 experienced median overall survival of 12 months

Benefit appears to extend to those patients who failed treatment with initial chemotherapy and crossed over to receive STA-4783

LEXINGTON, Mass.--(BUSINESS WIRE)--June 5, 2007--Synta Pharmaceuticals Corp., (NASDAQ: SNTA) a biopharmaceutical company focused on discovering, developing, and commercializing small molecule drugs to treat severe medical conditions, today announced encouraging results from the analysis of overall survival (OS) time for patients in the Company’s double-blind, randomized, controlled, multi-center Phase 2b clinical trial in metastatic melanoma for its lead compound, STA-4783.

The analysis of overall survival showed that patients randomized to receive STA-4783 plus paclitaxel (N=53) experienced a median survival of 12 months, compared to 7.8 months for all patients who initially received paclitaxel alone (N=28). The Phase 2b trial included a crossover design that allowed patients who initially received paclitaxel alone to receive STA-4783 plus paclitaxel following evidence of a worsening of their disease. Of the 28 patients who initially received paclitaxel alone, 19 elected to subsequently receive STA-4783. The median overall survival for this group was 14.3 months. By contrast, the group of patients initially treated with paclitaxel alone who did not subsequently receive STA-4783 experienced a median survival of 5.6 months. Other randomized trial results in metastatic melanoma have consistently shown a median survival time of between six and nine months regardless of treatment (1).

"The new overall survival results reinforce the previously-reported positive results from this trial, including meeting the primary endpoint of progression free survival (PFS) and showing substantial improvement in tumor response rate," said Safi Bahcall, Ph.D., President and Chief Executive Officer of Synta. "The collective results on the anti-cancer activity of STA-4783 in metastatic melanoma, together with the favorable safety profile, are very encouraging and suggest that this novel mechanism compound has potential as an important, new therapeutic option for patients suffering from this devastating disease - both as first-line therapy and for patients who have failed chemotherapy. We are actively moving forward with a worldwide Phase 3 clinical trial in metastatic melanoma to confirm these results."

"The overall survival data from this randomized trial are impressive, particularly given the advanced stage of disease of these patients and the considerable improvement relative to what has previously been seen in this patient population. The apparent benefit to those patients who have progressed on chemotherapy is also impressive. These data, together with the previously reported results,
represent the first positive blinded, randomized, controlled clinical trial for a new agent for metastatic melanoma in three decades, and provide a strong scientific basis for initiating the pivotal Phase 3 study," said Dr. Steven O'Day, Chief of Research and Director of the Melanoma Program at The Angeles Clinic and Research Institute in Los Angeles and principal investigator of the study. "There are few effective treatment options for patients and their physicians today and these exciting results for a novel drug candidate are welcome in the melanoma treatment community."

Based on the results of the Phase 2b trial and the significant unmet medical need for new treatment options for metastatic melanoma, the Food and Drug Administration (FDA) granted STA-4783 Fast Track designation in November, 2006. Synta plans to initiate a Phase 3 clinical trial to investigate STA-4783 as a first-line therapy for patients with metastatic melanoma in mid-2007. The trial will replicate the design of the Phase 2b trial, including the same primary endpoint, progression free survival, and the same treatment comparison, STA-4783 plus paclitaxel vs. paclitaxel alone.

"The incidence of melanoma has increased more rapidly than any other cancer during the past ten years and approximately 8,200 Americans will die of the disease this year," said Karen Graham, Chairman and President of the William S. Graham Foundation for Melanoma Research, Inc. ("The Billy Foundation"). "The five year survival rate for patients diagnosed with stage IV or metastatic disease can be less than 7 percent. We are very encouraged by the Phase 2b clinical trial results for STA-4783 and look forward to Synta initiating the Phase 3 trial in the coming months for first-line treatment of patients with metastatic melanoma."

Additional Survival Results from the Phase 2b Trial

A total of 81 patients were enrolled in the trial, which compared the effects of treatment with STA-4783 plus paclitaxel (N=53) to treatment with paclitaxel alone (N=28). Patients receiving paclitaxel alone were allowed to cross over to the experimental arm upon evidence of disease progression. Of the 28 patients initially treated with paclitaxel alone, 19 patients crossed over after their disease progressed, while 9 patients did not cross over.

Overall survival rates at one year were as follows:

-- STA-4783 + paclitaxel patients 49%
-- Cross-over STA-4783 + paclitaxel patients 53%
-- Patients who did not receive STA-4783 22%

The one-year survival rate for patients treated with STA-4783 compares favorably with results from the only approved chemotherapy for metastatic melanoma, dacarbazine (DTIC). In four recently published randomized, controlled trials, the one-year survival rates for patients treated with DTIC were 15%, 22%, 27%, and 30%, respectively (2).

The median overall survival times, measured in months from time of initial randomization into the trial, were:

-- STA-4783 + paclitaxel patients 12.0
-- Cross-over STA-4783 + paclitaxel patients 14.3
The median overall survival times also compare favorably with results from prior trials. Median overall survival times in the recent randomized, controlled trials for DTIC were 5.6, 6.4, 6.3, and 7.8 months respectively (2). A meta-analysis of over 1,300 patients with metastatic melanoma who received a variety of treatments showed a median overall survival time of 6.4 months (3). Other randomized trials have consistently shown a median survival time between six and nine months regardless of treatment (1).

STA-4783 was generally well-tolerated in this study; side effects were predictable and were generally comparable to treatment with paclitaxel alone. Neutropenia occurred more commonly in the STA-4783 plus paclitaxel group compared to the paclitaxel alone group, but this was manageable and reversible. Although paresthesias occurred more commonly in the STA-4783 plus paclitaxel group, the incidence of severe events of this type was low and comparable between groups. The most common adverse events in the STA-4783 plus paclitaxel group included fatigue, alopecia, constipation, nausea, hypoaesthesia, arthralgia, insomnia, diarrhea, and anemia.

About the Phase 2b Trial

The blinded, randomized Phase 2b clinical trial was conducted in 21 centers in the United States and compared patients treated with STA-4783 plus paclitaxel (N=53) vs. patients treated with paclitaxel alone (N=28). In the Phase 2b trial, patients who received STA-4783 plus paclitaxel showed a doubling of median progression free survival (PFS), the primary endpoint of the study, compared to those patients who received paclitaxel alone (3.68 months vs. 1.84 months, p=0.035). In addition, the PFS at six months, considered a useful predictor of overall survival, more than doubled (35% vs. 15%), and the response rate more than tripled (15% vs. 4%).

About STA-4783

STA-4783 is a novel, injectable, small molecule investigational drug candidate that induces a potent oxidative stress response in cancer cells, driving programmed cell death and enhancing the activity of anti-cancer agents that act through the mitochondrial apoptosis pathway, including paclitaxel. In September 2006, Synta reported positive Phase 2b results for STA-4783 in combination with paclitaxel in a double-blind, randomized, multi-center clinical trial in patients with stage IV metastatic melanoma. In November 2006, Synta received Fast Track designation from the FDA for the development of STA-4783 in metastatic melanoma. Synta plans to initiate a pivotal Phase 3 clinical trial for STA-4783 in metastatic melanoma in mid-2007.

Based on the broad-acting potential of its novel mechanism of action, and the activity seen in laboratory experiments in other cancer types, Synta plans to investigate the use of STA-4783 in additional cancers and in combination with other agents, including initiating one or more Phase 2 studies in other cancer indications later in the year.

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 discovered and developed internally. For more information, please see www.syntapharma.com

Conference Call and Webcast

Synta will hold a conference call at 2:30 p.m. (ET) today to discuss the positive overall survival and sub-population data from the Phase 2b clinical trial of STA-4783. This data will also be presented at the annual meeting of the American Society of Clinical Oncology (ASCO) in Chicago, Illinois this morning.

The conference call will be webcast live over the Internet. The webcast can be accessed by logging on to the "Investors" section of Synta Pharmaceuticals' website, www.syntapharma.com, 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. Following the call, the webcast will be archived on the Company's website.

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 clinical trials of STA-4783, 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 that the results of completed clinical trials may not necessarily be predictive of results in larger, later-stage clinical trials and the other risk and uncertainties described under "Risk Factors" in our Form 10-K for the year ended December 31, 2006 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. Tarhini and Agarwala, Dermatologic Therapy 2006, 19:19-25
2. Recently published randomized, controlled studies with DTIC as control:


CONTACT: Synta Pharmaceuticals Corp.
    Rob Kloppenburg, 781-541-7125
or
    MacDougall Biomedical Communications
    Doug MacDougall, 508-647-0209

SOURCE: Synta Pharmaceuticals Corp.