



Synta Pharmaceuticals Announces Phase 2 Trial Data Showing STA-4783 Doubles Median Progression-Free Survival in Metastatic Melanoma

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Novel Investigational Agent Achieves Primary Study Endpoint

Full Data to be Presented at Joint International Melanoma Congress, Noordwijk, The Netherlands, September 16, 2006

Lexington, MA -September 11, 2006- Synta Pharmaceuticals Corp., a biopharmaceutical company focused on discovering, developing, and commercializing small-molecule drugs to treat severe medical conditions, today announced positive data from a Phase 2b study in metastatic melanoma for STA-4783, a first-in-class heat shock protein 70 (Hsp70) inducer that activates natural killer (NK) cell-mediated tumor killing. In the double-blind, randomized, controlled trial in patients with Stage IV disease, STA-4783 plus paclitaxel doubled progression-free survival (PFS), the prospectively defined primary study endpoint, compared to paclitaxel alone.

"These positive Phase 2b results in metastatic melanoma, a devastating cancer with an extremely poor prognosis and limited treatment options, are very encouraging," said Steven O'Day, MD, Chief of Research and Director of Melanoma at The Angeles Clinic and Research Institute in Los Angeles and Principal Investigator for the study. "Metastatic melanoma has proven resistant to many therapeutic approaches and pharmaceutical agents. To my knowledge, this study is the first in metastatic melanoma to demonstrate increased progression-free survival by a small molecule in a double-blind, randomized, controlled trial."

The Phase 2b study of STA-4783 was conducted at 21 U.S. clinical sites and enrolled 81 patients with Stage IV metastatic melanoma. Study participants were randomized in a 2:1 ratio to receive STA-4783 plus paclitaxel or paclitaxel alone, respectively. Patients were dosed intravenously once-a-week for three weeks followed by one week off therapy, until disease progression. The prospectively-defined primary efficacy endpoint was PFS. Based on the intent-to-treat (ITT) analysis, median PFS for patients receiving STA-4783 plus paclitaxel was 112 days versus 56 days for those receiving paclitaxel alone, a statistically significant difference ($p=0.035$) that met the primary endpoint. STA-4783 was well-tolerated in the study, with adverse events typical of those expected for paclitaxel alone.

"We are encouraged that our first-in-class anticancer compound, STA-4783, has demonstrated clinical benefit in a robust, well-controlled study," said Safi Bahcall, Ph.D., President and CEO of Synta. "The possibility that this drug could make a difference for metastatic melanoma patients, who have very limited treatment options today, is exciting to all of us involved with the program. We look forward to collaborating closely with regulatory agencies and our medical advisors to advance development of this drug candidate expeditiously."

Full trial results will be presented by Dr. O'Day at the joint Perspectives in Melanoma X and the Third International Melanoma Research Congress, Noordwijk, The Netherlands on September 16, 2006. For more information on the Congress, visit www.imedex.com/announcements/251.asp.

Melanoma Clinical Trial Results

In a double-blind, randomized, controlled Phase 2b trial conducted at 21 study sites in the U.S., 81 patients were randomly assigned in a 2:1 ratio to receive STA-4783 in combination with paclitaxel versus paclitaxel alone. The randomized patient populations were well balanced with respect to demographic characteristics. Presence or absence of elevated lactate dehydrogenase (LDH), a known poor prognostic factor, was balanced between groups (elevated LDH for STA-4783 plus paclitaxel: 43%; paclitaxel alone: 44%). In addition, the timing of tumor progression assessments between the two groups was equivalent.

For the ITT analysis, which included all patients randomized into the trial, the results were:

Intent-to-Treat Analysis

Primary Endpoint	STA-4783+Paclitaxel (N=53)	Paclitaxel (N=28)	Statistical Significance (p-value**)
Progression-Free Survival (Days) Median (95% Confidence Interval)*	112 (75, 169)	56 (49, 105)	0.035

*Kaplan-Meier product-limit method; **2-sided log-rank test

The per-protocol (PP) population was prospectively defined as patients receiving at least one dose of study drug and having at least one post-baseline tumor assessment. For the per-protocol analysis (N=77), the results were:

Per-Protocol Analysis

Primary Endpoint	STA-4783+Paclitaxel (N=50)	Paclitaxel (N =27)	Statistical Significance (p-value**)
Progression-Free Survival (Days) Median (95% Confidence Interval)*	134 (86, 217)	56 (49, 105)	0.017

*Kaplan-Meier product-limit method; **2-sided log-rank test

The study demonstrated that the combination of STA-4783 with paclitaxel reduced the risk of disease progression by approximately 50% based on the ITT analysis (or 58% based on the PP analysis).

The secondary endpoint of objective response rate was more than three times higher in the STA-4783 plus paclitaxel group (15.1%, ITT; 16.0%, PP) than in the paclitaxel alone group (3.6%, ITT; 3.7%, PP), and trended towards but did not reach statistical significance. The PFS results observed in the paclitaxel alone arm were consistent with published efficacy results in this disease for single-agent chemotherapy, including dacarbazine (DTIC).

STA-4783 was well tolerated in this study; adverse events were typical of those expected for paclitaxel alone. The most common adverse events in the STA-4783 plus paclitaxel group included fatigue, alopecia, constipation, nausea, hypoaesthesia, arthralgia, insomnia, diarrhea, and anaemia. Certain adverse events including hypoaesthesia, neutropenia, stomatitis, arthralgia, and fatigue - all expected from paclitaxel treatment alone - occurred with higher incidence in the STA-4783 plus paclitaxel group, which may be partially attributable to the longer duration of paclitaxel treatment in this study group due to longer PFS. The incidences of adverse events (including Grade 3 and above) were generally comparable between the two groups.

About STA-4783

STA-4783 is an investigational, first-in-class new chemical entity that induces the expression of heat shock protein 70 (Hsp70) on the surface of tumor cells, which attracts natural killer (NK) immune cells and activates NK-mediated tumor cell killing. STA-4783 acts synergistically with taxanes, a commonly used chemotherapeutic class. In preclinical studies, STA-4783 combined with taxanes has shown activity against a range of cancers, including breast, lung, colon, lymphoma, and melanoma. To date, STA-4783 has been administered to a total of approximately 300 patients across multiple studies and has demonstrated an acceptable safety profile. Additional trials in melanoma and other cancers are being planned.

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 8,000 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 deeper lesions or 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 last novel, small-molecule drug to treat patients with this disease was approved by the FDA over 30 years ago.

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 internally-developed drug candidates targeting large therapeutic markets in clinical and preclinical development. For more information, please see www.syntapharma.com