Synta Pharmaceuticals Announces FDA Fast Track Designation for STA-4783 in Metastatic Melanoma

November 15, 2006

Designation Follows Announcement of Positive Phase 2b Clinical Data for Novel Compound

Lexington, MA - November 15, 2006 - Synta Pharmaceuticals Corp., a biopharmaceutical company focused on discovering, developing, and commercializing small molecule drugs to treat severe medical conditions, announced today that its lead oncology drug candidate, STA-4783, has been granted Fast Track designation by the U.S. Food and Drug Administration (FDA) for the treatment of metastatic melanoma, a serious type of skin cancer. In a recently completed, Phase 2b double-blind, randomized, controlled clinical trial in patients with Stage IV metastatic malignant melanoma, treatment with STA-4783 plus paclitaxel achieved the primary endpoint of increasing progression-free survival.

"We are very pleased to have received Fast Track designation for STA-4783. This is an important milestone for the program that will help the development and regulatory process," said Safi Bahcall, President and Chief Executive Officer of Synta. "Metastatic melanoma is a disease with very limited treatment options for patients and a high mortality rate. We look forward to a productive collaboration with the FDA as we seek to realize the potential of STA-4783 to benefit these patients."

The FDA's Fast Track program is designed to facilitate the development and expedite the review of new drug candidates that are intended to treat serious or life-threatening diseases and that demonstrate the potential to address unmet medical needs. Fast Track designation allows a company to file a New Drug Application (NDA) on a rolling basis as data become available. This permits the FDA to review the filing as it is received, rather than waiting for the entire document prior to commencing the review process. Fast Track designation may facilitate more frequent interactions with the FDA and may lead to a priority review, which could decrease the typical review period. However, Fast Track designation has no impact on the standard of review or on whether the FDA ultimately approves the drug for marketing.

About STA-4783

STA-4783 is an investigational, novel, small molecule drug candidate that induces a stress response in a wide variety of cancer cell types. This stress response results in two changes that may be important to the role of STA-4783 in tumor cell killing in combination with taxanes: a dramatic increase in the production of Hsp70 and other heat shock and stress-related proteins, which can enhance immune-mediated killing of tumor cells, and the alteration of certain signal transduction pathways in tumor cells, which can affect cell proliferation and induce programmed cell death, or apoptosis. In preclinical studies, STA-4783 combined with taxanes has shown activity against a broad range of cancers, including breast, lung, colon, lymphomas, and melanoma. To date, STA-4783 has been administered to a total of approximately 300 patients across multiple studies.

STA-4783 was tested in a Phase 2b double-blind, randomized, controlled clinical trial in patients with Stage IV metastatic melanoma at 21 clinical sites in the United States. A total of 81 patients were enrolled in this trial, which compared the effects of treatment with STA-4783 plus paclitaxel to treatment with paclitaxel alone. The primary endpoint of this trial was progression-free survival, which is the time from randomization until death or objective tumor progression, as defined by the industry standard RECIST criteria (Response Evaluation Criteria in Solid Tumors). In the intent-to-treat analysis, which includes all 81 patients, treatment improved the median progression-free survival from 1.84 months for patients receiving paclitaxel alone to 3.68 months for those receiving paclitaxel plus STA-4783 (p=0.035). In this analysis, the hazard ratio, an estimate of the risk of progression in the combination arm relative to the control arm, was 0.50. In the per-protocol analysis, which includes the 77 patients who were evaluable for efficacy as specified in the protocol, treatment improved progression-free survival from 1.84 months for paclitaxel alone to 4.40 months for paclitaxel plus STA-4783 (p=0.017). The hazard ratio in this analysis was 0.42.

STA-4783 was generally 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 anemia. 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 progression-free survival. The incidences of adverse events (including Grade 3 and above) were generally comparable between the two groups.

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 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