Synta Announces Presentation of Additional Ganetespib Results at ASCO

June 6, 2011

LEXINGTON, Mass., Jun 06, 2011 (BUSINESS WIRE) -- Synta Pharmaceuticals Corp. (NASDAQ: SNTA) today presented results at the Annual Meeting of the American Society for Clinical Oncology (ASCO) from a Phase 2 single agent clinical trial of ganetespib in gastrointestinal stromal tumors (GIST) and a Phase 1 trial of ganetespib in solid tumors evaluating a twice-weekly administration schedule. Ganetespib is a potent inhibitor of heat shock protein 90 (Hsp90) currently being studied in a broad range of clinical trials with approximately 400 patients treated to date. Ganetespib is structurally unrelated to earlier Hsp90 inhibitors such as 17-AAG.

"Ganetespib results presented this week at ASCO support a strategy of parallel approach to development - both single agent in targeted, biomarker-defined subpopulations, as well as more broadly, in combination with certain other anti-cancer agents," said Safi Bahcall, Ph.D., President and Chief Executive Officer, Synta Pharmaceuticals. "The results reported Saturday demonstrated compelling proof of clinical activity in lung cancer patients with ALK+ tumors. The results reported today show that ganetespib has broad potential, with activity seen in breast cancer, melanoma, as well as GIST. These results support our program of working closely with leading investigators to evaluate the potential of ganetespib in a broad range of tumor types."

Ganetespib has been studied in 15 trials across multiple cancer types. Announcements regarding additional trials and data presentations are expected later this month and the second half of this year.

Phase 2 Results of Ganetespib in GIST

"Few therapeutic options are available to patients with advanced gastrointestinal tumors following treatment with the standard of care tyrosine-kinase inhibitor drugs, imatinib and sunitinib. Ganetespib showed activity in approximately half of GIST patients evaluated with PET imaging in this Phase 2 trial, including a 20% decrease in tumor metabolic activity," said George Demetri, M.D., Principal Investigator of the trial from the Dana-Farber Cancer Institute. "Analysis of tumor biopsies and PET imaging data suggest that optimizing the administration schedule of ganetespib could potentially increase KIT suppression and improve the clinical activity of ganetespib in GIST patients. Ganetespib was well-tolerated in this patient population, with the most common adverse events being Grade 1 and 2 diarrhea which was generally manageable with supportive care."

At the time of the analysis, 23 patients out of 26 patients in the intent to treat (ITT) population were evaluable. Patients enrolled in the ITT population had experienced a median of five prior treatments.

58% of patients (7 of 12 patients evaluated) reported a greater than 20% decrease in Standardized Uptake Value (SUV) as measured by positron emission tomography (PET) imaging. 22% of evaluable patients experienced a clinical benefit at 16 weeks (Partial Response + Complete Response + Stable Disease). There were no objective responses. One patient was non-evaluable.

The most common adverse events reported in more than 5% of patients were blood alkaline phosphatase increase (11.5%), anaemia (7.7%), and diarrhea (7.7%). The most frequent reported adverse events occurring in more than 40% of patients were diarrhea (84.6%), fatigue (53.8%) and nausea (46.2%).

About the Phase 2 GIST Trial

The non-randomized, open-label, multi-center Phase 2 study was designed to characterize the efficacy and safety of ganetespib in patients with metastatic or unresectable GIST following failure of systemic treatment with imatinib (Gleevec$^{(R)}$) and sunitinib (Sutent$^{(R)}$). Patients were stratified according to whether or not they have been exposed to other Hsp90 inhibitors, and ganetespib was administered as a single agent on a once-weekly intravenous dosing schedule. Patients tolerating ganetespib could continue on treatment until disease progression. Patients were assessed for clinical benefit rate per RECIST. The impact of treatment with ganetespib on certain biomarkers was also evaluated.

About GIST

A gastrointestinal stromal tumor (GIST) is a type of cancer that occurs in the gastrointestinal (GI or digestive) tract, including the esophagus, stomach, gallbladder, liver, small intestine, colon, and rectum. The American Cancer Society estimates 4,500 to 6,000 GIST cases are diagnosed each year in the United States.

Phase 1 Results of Ganetespib - Twice-Weekly Administration

"The Phase 1 twice-weekly schedule trial results demonstrate that ganetespib is well-tolerated and has promising clinical activity at dose levels up to 144 mg/m^2," said Vojo Vukovic, M.D., Ph.D., Senior Vice President and Chief Medical Officer, Synta Pharmaceuticals. "Encouragingly, objective tumor responses were seen in a patient with triple negative breast cancer and a patient with melanoma. In addition, 15 patients out of 41 patients who were assessable for response achieved stable disease. These results suggest that twice weekly treatment with ganetespib could provide a potential single agent strategy for treating cancers driven by oncoproteins and pathways which require more frequent Hsp90 inhibition in order to show anti-cancer activity. The trial is ongoing and the maximum tolerated dose has not yet been identified."

Triple negative breast cancer is any breast cancer that does not express the genes for estrogen receptor (ER), progesterone receptor (PR) or Her2/neu. This form of breast cancer is characterized as more aggressive and less responsive to standard treatment and is generally associated with a poor prognosis.

Results

A total of 54 patients have been enrolled in the trial; 36 at doses ranging from 2-50 mg/m^2, 11 at 100-120 mg/m^2 and 7 at 144 mg/m^2.

The most frequent Grade 3 or greater adverse events occurring in more than 5% of patients were diarrhea (13%), alkaline phosphatase increase (7%), AST increase (6%) and hypophosphatemia (6%). The most common adverse events occurring in greater than 20% of patients were diarrhea (50%), fatigue (50%), nausea (39%), anemia (32%), headache (26%), constipation (24%), vomiting

(22%), abdominal pain (20%) and decreased appetite (20%).

Three adverse events with an outcome of death were reported, one at the 10 mg/m^2 dose (dyspnea and rales, possibly drug related), and two at 25 mg/m^2 (pulmonary embolism and progressive disease, neither drug related).

41 of the 54 patients were assessable for response as of March 25, 2011. Two partial responses were reported (melanoma, triple negative breast cancer). 15 patients achieved stable disease. 13 patient discontinued treatment prior to the week 8 response assessment.

Pharmacokinetics; ganetespib exposures are directly proportional to dose with no drug accumulation observed upon multiple dosing. Ganetespib exhibits biphasic pharmacokinetics and the concentrations rise rapidly during infusion and decline by a factor of 10 fold within 1 hour of infusion termination and 100 fold within 8-10 hours.

About Ganetespib

Ganetespib (formerly STA-9090) is a potent, synthetic, small-molecule inhibitor of heat shock protein 90 (Hsp90). Hsp90 is a molecular chaperone required for the proper folding and activation of many cancer-promoting proteins, and is recognized as a key facilitator of cancer cell growth and survival. In preclinical experiments, ganetespib has shown activity in multiple tumor models both as a single agent and in combination with certain widely used cancer agents. Ganetespib is currently being evaluated in a broad range of cancer clinical trials. In these trials, ganetespib has shown clinical activity in heavily pretreated patients and has been well tolerated to date with no evidence of severe liver or common ocular toxicities seen with other Hsp90 inhibitors. The most common adverse event seen to date has been diarrhea, which has been manageable with standard supportive care. Information on clinical trials with ganetespib can be found at www.clinicaltrials.gov.

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.

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