Synta Announces Ganetespib Phase 2 Non-small Cell Lung Cancer Trial Results Show Encouraging Single Agent Clinical Activity

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- 75% of patients with ALK+ and 62% of patients with KRAS-mutant tumors show tumor shrinkage in target lesions -

- Overall disease control rate of 54% -

- Ganetespib well-tolerated in advanced NSCLC patients -

LEXINGTON, Mass., Jun 04, 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 advanced non-small cell lung cancer (NSCLC) that showed promising clinical activity in patients with progressive disease. 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.

"The results from this trial demonstrate encouraging single agent clinical activity in heavily pretreated advanced NSCLC patients," said Geoffrey Shapiro, M.D., Ph.D., Dana-Farber Cancer Institute, a co-principal investigator on the Phase 2 trial. "Ganetespib is a potent, differentiated Hsp90 inhibitor, having shown none of the serious hepatic or ocular toxicities seen with other Hsp90 inhibitors. Patients in this trial were particularly difficult to treat, as enrollment required progressive disease. The overall disease control rate of 54% in this broad population of advanced progressive disease is encouraging and indicates single agent clinical activity. In addition, particularly promising activity was seen in patients with certain tumor gene profiles. Six of eight patients with ALK rearrangement experienced tumor shrinkage, including four patients with durable, objective responses. Seven of eight of these patients received ganetespib for 16 weeks or more. Some tumor shrinkage also occurred in patients whose tumors have a KRAS mutation, a particularly therapeutically challenging population."

"The evidence of clear single agent activity combined with a favorable safety profile is exciting," concluded Dr. Shapiro. "These results suggest ganetespib has the potential to provide a new therapeutic option for patients with advanced NSCLC."

"The disease control and anti-tumor activity seen in this trial is encouraging, and compares favorably with disease control rates reported in similar trials, in either the broad patient population or in trials focused on subpopulations with specific gene profiles," said Vojo Vukovic, M.D., Ph.D, Senior Vice President and Chief Medical Officer, Synta Pharmaceuticals. "The favorable safety profile seen in this trial is consistent with results seen in the now over 15 trials initiated to date with ganetespib, with over 400 patients treated. Ganetespib is well tolerated and does not have the serious hepatic or common ocular toxicities reported with other Hsp90 inhibitors."

"We are excited to begin treating patients this month in our Phase 2b/3 trial in combination with

docetaxel in NSCLC," continued Dr. Vukovic. "A separate dose-escalation study, conducted at Emory University, has shown docetaxel can be combined safely with ganetespib. In addition, in this trial we have seen evidence that the two drugs together can provide added benefit, as suggested by the complementary mechanisms of action and evidence from the preclinical models. A number of patients who experienced mixed responses with single agent ganetespib - decrease of target tumor lesions, but eventual growth of new lesions - showed continued decrease of target lesions as well as decrease in new lesions when docetaxel was added."

Results

At the time of analysis, 76 patients were evaluable, having received at least one dose of ganetespib and one follow-up scan. All tumor size measurements are per RECIST criteria. Disease control is defined as CR+PR+SD at first scan (week 8).

Of the 76 evaluable patients, 14 were in cohort A (EGFR mutation), 13 were in cohort B (KRAS mutation), and 48 were in cohorts C and D (neither EGFR nor KRAS mutation). 23 of 48 evaluable patients in cohorts C and D were subsequently tested for ALK translocation or rearrangement, in up to three separate assays.

Of the 23 patients tested for ALK translocation or rearrangement (ALK+), 8 patients were ALK+ in at least one assay. Six of these eight patients (75%) showed tumor shrinkage in target lesions, one patient showed no change in tumor size, and one patient achieved stable disease (tumor growth <20%). The disease control rate in this population was 7/8 (88%), and the objective response rate (CR+PR) was 4/8 (50%).

In cohorts C and D, wild type for EGFR and KRAS, tumor shrinkage in target lesions was seen in 15/48 (31%). The stable disease rate per RECIST was 24/48 (50%), the objective response rate was 4/48 (8%), and the disease control rate was 28/48 (58%).

Of the 13 evaluable patients in cohort B, with KRAS mutation, eight patients experienced tumor shrinkage in target lesions (62%). The stable disease rate per RECIST was 5/13 (38%). The overall disease control rate was 38%.

Of the 14 evaluable patients in Cohort A, with EGFR mutation, five patients experienced tumor shrinkage (36%). The stable disease rate per RECIST was 7/14 (50%). The overall disease control rate was 50%.

In total, of the 76 evaluable patients, the overall disease control rate at 8 weeks was 54% and the overall objective response rate was 5.3%.

The most common adverse events were diarrhea, fatigue and nausea. In a total of 96 patients treated, the most common adverse events grade 3 or higher occurring in more than 5% of patients were dyspnoea in 12 patients (12.5%), fatigue in 12 patients (12.5%) , diarrhea in 9 patients (9.4%) and hyponatraemia in 5 patients (5.2%). The most common adverse events were diarrhea in 75 patients (78.1%), fatigue in 48 patients (50%), nausea in 37 patients (38.5%) and decreased appetite in 32 patients (33.3%).

About the Phase 2 NSCLC Trial

The Phase 2 NSCLC trial was designed to enroll patients with advanced, metastatic disease (Stage

IIIB and IV) who had failed prior therapy. Patients were grouped into one of three cohorts based on the genetic profile of their cancer - (A) EGFR mutation, (B) KRAS mutation, (C) neither EGFR nor KRAS mutation - and were treated with ganetespib, as a monotherapy, once-weekly at a dose of 200 mg/m^2. Based on encouraging signs of activity, an amendment announced in September 2010 expanded the trial with two additional patient cohorts, including a cohort which allowed for combination treatment with ganetespib and docetaxel.

About Non-small Cell Lung Cancer

Lung cancer is the leading cause of cancer-related mortality in the United States, with over 225,000 new cases and 157,000 deaths estimated in 2010. The five year survival rate for advanced-staged lung cancer is less than 5%. Approximately 85% of all lung cancers are classified as non-small cell.

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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