Synta Announces Phase 2b/3 Trial for Ganetespib (STA-9090) in Advanced 2nd-line Non-small Cell Lung Cancer

February 26, 2011

- Combination trial with docetaxel in up to 800 patients to start in Q2 2011 -
- Builds on encouraging results seen in Phase 2 NSCLC trial with ganetespib -
- Initial data from first stage of trial expected by early 2012 -

LEXINGTON, Mass., Feb 26, 2011 (BUSINESS WIRE) -- Synta Pharmaceuticals Corp. (NASDAQ: SNTA), a biopharmaceutical company focused on discovering, developing, and commercializing small molecule drugs to treat severe medical conditions, today announced that a Phase 2b/3 clinical trial of ganetespib (STA-9090) in combination with docetaxel in non-small cell lung cancer (NSCLC) will be initiated in the second quarter of 2011.

Ganetespib is a potent inhibitor of heat shock protein 90 (Hsp90) that is structurally unrelated to earlier Hsp90 inhibitors such as 17-AAG, and has shown superior activity to these agents in preclinical studies. Ganetespib is currently being studied in broad range of Phase 2 trials, including NSCLC, with over 350 patients treated to date. Results from a Phase 2 NSCLC trial presented today at the International Association for the Study of Lung Cancer (IASLC) 11th Annual Targeted Therapies for the Treatment of Lung Cancer Meeting demonstrated that ganetespib has a favorable safety profile, and is clinically active in patients with advanced relapsed/refractory NSCLC. Durable tumor responses and sustained tumor shrinkage were observed in patients following single-agent administration of ganetespib.

"Hsp90 inhibition is a promising strategy for treating patients with advanced NSCLC, as demonstrated by the results presented today for ganetespib," said Suresh Ramalingam, MD, Associate Professor, Chief of Thoracic Oncology and Director of Medical Oncology, Emory University. Dr. Ramalingam is a principal investigator for both the upcoming Phase 2b/3 NSCLC trial and the Phase 1 trial assessing safety of ganetespib in combination with docetaxel. "Hsp90 inhibition is known to enhance the efficacy of taxanes by increasing cytotoxicity and preventing resistance. Preclinical models show potent synergistic activity between ganetespib and docetaxel. The safety results from the single-agent trials for ganetespib and the ongoing combination study with docetaxel have both suggested good tolerability of the regimens. Taken together, the preclinical and clinical evidence to date strongly support the initiation of this Phase 2b/3 program."

The Phase 2b/3 trial will evaluate treatment with ganetespib and docetaxel vs. docetaxel alone, with1:1 randomization, in patients with Stage IIIB or IV NSCLC who have completed one prior systemic therapy for advanced disease. The first stage, Phase 2b portion will assess efficacy as measured by progression-free survival in approximately 240 patients. Results from this stage will also be used to inform the choice of patient subpopulation, by histology or biomarker, for the second stage, Phase 3 portion. The second stage will assess efficacy as measured by overall survival, and will enroll between 400 and 600 patients. This trial is expected to start in Q2 2011 with interim results

from the first-stage portion of the trial expected by end of 2011 or early 2012.

The Phase 2b/3 program is designed to mitigate risk in the Phase 3 portion by evaluating biomarkers and other patient characteristics in the Phase 2b portion that identify patients most likely to benefit from treatment with ganetespib.

"Combining ganetespib and docetaxel is a two-punch strategy for improving efficacy of single-agent docetaxel," said Vojo Vukovic, M.D., PhD., Senior Vice President and Chief Medical Officer, Synta Pharmaceuticals. "First, ganetespib has clinical activity in NSCLC patients on its own, as was observed in our Phase 2 single-agent trial. Second, ganetespib has potent chemo-sensitizing effects, including inhibition of mechanisms of resistance to taxanes."

"We have been very encouraged by the results seen with ganetespib, and are hopeful that launching this program will bring us one step closer to unlocking the true potential of Hsp90 inhibition to benefit cancer patients," concluded Dr. Vukovic.

The Phase 1 trial of ganetespib in combination with docetaxel being conducted at Emory University established the recommended Phase 2 dose and schedule, which will be used in the Phase 2b/3 NSCLC trial. Detailed results from this trial are expected to be presented later this year.

"Synta is very well positioned today, with two late-stage, unpartnered oncology drug candidates, each with broad, pan-tumor potential," said Safi Bahcall, Ph.D., President and CEO, Synta Pharmaceuticals. "We have been encouraged by the partnership interest in these and other, earlier-stage programs at the company and are confident we will conclude one or more partnership agreements this year. We anticipate partnerships contributing substantial resources and complementary activities to our programs."

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 including trials in non-small cell lung, breast, prostrate, pancreatic, colorectal, gastric, small cell lung, ocular melanoma, liver, GIST and hematologic cancers. Ganetespib has shown evidence of clinical and biological activity and has been well tolerated to date with no evidence of severe liver, ocular, cardiac or renal toxicity seen with other Hsp90 inhibitors. The most common adverse events seen to date have been diarrhea and fatigue, which have been manageable and reversible. Information on clinical trials with ganetespib can be found at www.clinicaltrials.gov.

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 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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Synta Pharmaceuticals Corp.
Rob Kloppenburg, 781-541-7125