Synta Announces Expansion of Phase 2 Trial for STA-9090 in Non-Small Cell Lung Cancer Based on Encouraging Clinical Activity

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Trial size expanded from up to 69 patients to up to 146 patients

LEXINGTON, Mass., Sep 13, 2010 (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 it was expanding its Phase 2 clinical trial of STA-9090 in patients with Stage IIIB and Stage IV non-small cell lung cancer (NSCLC) from up to 69 patients to up to 146 patients based on encouraging activity observed in the first stage of the two stage clinical trial. STA-9090 is a potent, second-generation, small-molecule Hsp90 inhibitor, with a chemical structure unrelated to the first-generation, ansamycin family of Hsp90 inhibitors (e.g., 17-AAG or IPI-504).

"This NSCLC trial is enrolling patients into cohorts defined by the mutational status of key genes in order to identify cancer types especially responsive to STA-9090," said Vojo Vukovic, M.D., Ph.D., Senior Vice President and Chief Medical Officer, Synta Pharmaceuticals. "In the first stage of this trial we have seen exactly that; patients with EGFR and KRAS wild type, representing over 70% of all NSCLC, have shown a high disease control rate, over 70%. This early signal, combined with the objective responses seen following treatment with STA-9090, is very encouraging, particularly as the patients have been heavily pretreated and are refractory to many standard of care drugs. Also encouraging is that STA-9090 continues to be well tolerated at the 200mg/m2 once-weekly schedule, without the serious hepatic or ocular toxicities observed with other Hsp90 inhibitors. Based on these findings, we worked closely with investigators, modified the protocol, and expanded the trial in order to confirm and further characterize the observed activity in this group of patients. We expect to report on additional results from this trial, as well as plans for future trials in lung cancer, later this year or early next year."

Synta also announced that the Phase 2 trial will allow for the first focused evaluation of STA-9090 combination therapy in NSCLC. An additional cohort was created to allow certain patients to receive treatment with both STA-9090 and docetaxel. Clinical and preclinical results provide a strong rationale for combining taxanes and Hsp90 inhibitors, with the potential for synergistic activity.

About the Phase 2 Trial

The Phase 2 trial was initially designed to enroll up to 23 patients (14 in Stage 1, 9 in Stage 2) in each of three cohorts specified by cancer genetic profile. The cohorts are: EGFR mutation, KRAS mutation, and absence of EGFR and KRAS mutations ("wild type"). The recent amendment allows for two new cohorts. The first is an expansion cohort of up to 35 patients with EGFR and KRAS wild type. An additional up to 14 patients is allowed in this cohort for each of three additional disease subtypes hypothesized to have enhanced sensitivity to Hsp90 inhibition. The second is a combination therapy cohort that allows certain patients from this trial to receive both docetaxel and

STA-9090.

Disease Control Rate in NSCLC

Disease control rate (DCR) consists of complete response (CR) plus partial response (PR) and stable disease (SD). According to recent studies, DCR at week 8 is a more powerful predictor of subsequent survival than is the traditional tumor response rate in advanced NSCLC, and provides an early assessment of subsequent outcome.[1]

About STA-9090

STA-9090 is a potent, second-generation, small-molecule Hsp90 inhibitor, with a chemical structure unrelated to the first-generation, ansamycin family of Hsp90 inhibitors (e.g., 17-AAG or IPI-504). In preclinical studies, STA-9090 has shown potency up to 100 times greater than the first-generation Hsp90 inhibitors as well as activity against a wider range of kinases. In *in vitro* and *in vivo* models, STA-9090 has shown potent activity against a wide range of cancer types, including lung, prostate, colon, breast, gastric, pancreatic, melanoma and certain hematologic cancers - as well as potent activity against cancers resistant to imatinib (Gleevec(R)), sunitinib (Sutent(R)), erlotinib (Tarceva(R)), and dasatinib (Sprycel(R)).

STA-9090 is currently being evaluated in eleven clinical trials: seven Phase 2 trials in solid tumor cancers - non-small cell lung cancer, gastrointestinal stromal tumors, colon cancer, gastric cancer, and small cell lung cancer; and five Phase 1 and Phase 1/2 trials in hematologic and solid tumor cancers. Trials in colon cancer, gastric cancer, small cell lung cancer and hepatocellular carcinoma are investigator-sponsored. The most common adverse events observed to date have been fatigue and diarrhea, which were manageable and reversible. Information on clinical trials with STA-9090 can be found at www.clinicaltrials.gov.

About Hsp90

Hsp90 is a chaperone protein required for the proper folding and activation of other cellular proteins, particularly kinases. Many of these "client proteins" of Hsp90 - such as AKT, BCR-ABL, BRAF, KIT, MET, EGFR, FLT3, HER2, PDGFRA, VEGFR - have been shown to be critical to cancer cell growth, proliferation, and survival and are the targets of clinically validated cancer drugs. In preclinical studies, inhibiting Hsp90 causes the degradation of multiple client proteins and leads to cancer cell death. Because mutated kinases which no longer respond to treatment with kinase inhibitors remain dependent on Hsp90 for their activity, inhibiting Hsp90 offers the potential for treating cancers that have become resistant to targeted therapies such as kinase inhibitors.

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%.[2] Approximately 85% of all lung cancers are classified as non-small cell. Of those, 70-75% are estimated to be EGFR and KRAS wild type.[3]

References

1. Lara, P. N. Jr. et al, Disease Control Rate at 8 Weeks Predicts Clinical Benefit in Advanced

Non-Small-Cell Lung Cancer: Results from Southwest Oncology Group Randomized Trials, J Clin Oncol, Vol 26, No. 3, Jan. 20, 2008, pp 463-467.

2. American Cancer Society.

3. Socinski, M., Biomarkers in Advanced NSCLC, Clinical Lung Cancer, Vol 11, No. 3, May 2010, pp 49-159.

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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This media release may contain forward-looking statements about Synta Pharmaceuticals Corp. Such forward-looking statements can be identified by the use of forward-looking terminology such as "will", "would", "should", "expects", "anticipates", "intends", "plans", "believes", "may", "estimates", "predicts", "projects", or similar expressions intended to identify forward-looking statements. Such statements, including statements relating to the timing, developments and progress of our STA-9090 program in NSCLC and other cancer indications, reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such forward-looking statements, including those described in "Risk Factors" of our Form 10-K for the year ended December 31, 2009 as filed with the Securities and Exchange Commission. Synta undertakes no obligation to publicly update forward-looking statements, whether because of new information, future events or otherwise, except as required by law.

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