Synta Announces First Patients Treated in Two ALK Positive Lung Cancer Trials

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LEXINGTON, Mass.--(BUSINESS WIRE)--Aug. 2, 2012-- Synta Pharmaceuticals Corp. (NASDAQ: SNTA) today announced that the first patients have been treated in two trials evaluating the company's lead drug candidate, ganetespib, a selective and potent Hsp90 inhibitor, in patients with non-small cell lung cancer (NSCLC) whose tumors show rearrangement of the anaplastic lymphoma kinase gene (ALK+). The company-sponsored CHIARA trial (**CH**aperone **I**nhibition in **A**lk **R**earranged lung c**A**ncer) is evaluating ganetespib monotherapy administration in up to 110 patients from centers in the U.S., Canada, Europe, and Asia. A trial sponsored by and conducted at the Memorial Sloan-Kettering Cancer Center in New York City is evaluating the combination of ganetespib and crizotinib (Xalkori®) in up to 55 patients. Both trials are enrolling patients who have not been previously treated with a direct ALK inhibitor, such as crizotinib.

Hsp90 is a molecular chaperone protein that was recently identified as essential for the proper expression and function of the ALK protein. In preclinical models, treatment with ganetespib led to the degradation of the ALK protein and was effective in killing a broad panel of ALK+ cell lines that were resistant to treatment with crizotinib and other direct ALK inhibitors. In addition to the potent single-agent activity seen with ganetespib, the combination of ganetespib and crizotinib has been shown to have greater activity in preclinical models of ALK+ lung cancer than either agent alone.

In clinical trials, substantial clinical activity has been observed in patients with ALK+ NSCLC treated with Hsp90 inhibitors. In a Phase 2 trial of ganetespib in NSCLC reported at the 2011 ASCO conference, four out of eight (50%) advanced ALK+ NSCLC patients, who had not received prior ALK inhibitor therapy, experienced objective responses while receiving treatment with ganetespib monotherapy. These responses were durable, lasting an average of approximately one year, with one patient who remains on therapy for 21 months. Seven patients (88%) experienced disease control.

The CHIARA trial is a single arm, Phase 2 study evaluating ganetespib monotherapy in up to 110 patients with Stage IIIB/IV non-small-cell lung cancer harboring an ALK gene rearrangement and who have not been previously treated with a direct ALK inhibitor. Patients will receive ganetespib administered at 200mg/m^2 on days 1, 8, and 15 of a 28-day cycle until disease progression per RECIST. The primary endpoint of the study is objective response rate. More information about the CHIARA trial can be found at www.clinicaltrials.gov.

"The CHIARA trial is our first trial to examine the effect of an Hsp90 inhibitor as monotherapy in a large group of patients with a specific biomarker predictive of clinical outcome," said Vojo Vukovic, M.D., Ph.D., Chief Medical Officer of Synta. "The clinical and preclinical rationale for use of Hsp90 inhibition in this setting is strong, and we are hopeful that this targeted development approach can lead to a new treatment option for these lung cancer patients."

“While crizotinib, a direct ALK inhibitor, has been shown to have strong anti-cancer activity in ALK+ lung cancer tumors, we would like to extend those benefits,” said Greg Riely, M.D., Ph.D. and Principal Investigator of the Phase 1/2 clinical trial at Memorial Sloan-Kettering Cancer Center. “The average time until patients progress on therapy is less than one year. Combination treatment with an Hsp90 inhibitor, such as ganetespib, which has demonstrated activity against ALK+ lung cancer both in preclinical models and in clinical trials, may provide a complimentary approach to targeting the underlying drivers of this disease. Combination therapy has potential to improve clinical outcomes for these patients.”

About Ganetespib

Ganetespib is a potent inhibitor of heat shock protein 90 (Hsp90) that is structurally unrelated to first-generation, ansamycin-related Hsp90 inhibitors. 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. Company-sponsored clinical trials with ganetespib include the Phase 2b/3 GALAXY Trial(TM) evaluating ganetespib in combination with docetaxel for second-line treatment of non-small cell lung cancer (NSCLC); the CHIARA(TM) trial, evaluating ganetespib monotherapy in ALK+ NSCLC; and the ENCHANT(TM) trial evaluating ganetespib monotherapy as first-line treatment for HER2+ and triple-negative metastatic breast cancer. In addition, ganetespib is being evaluated in investigator-sponsored trials including lung, breast, prostate, gastric, pancreatic, and colorectal cancers as well as melanoma, ocular melanoma, acute myeloid leukemia and multiple myeloma. The most common adverse event seen to date has been transient, mild or moderate diarrhea, which has been manageable with standard supportive care. Information on clinical trials with ganetespib can be found at www.clinicaltrials.gov.

About ALK+ 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%. There are an estimated 40,000-70,000 new cases of ALK+ lung cancer diagnosed worldwide each year.

About 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. Many of the “client proteins” of Hsp90 – such as ALK, HIF-1alpha, AKT, BCR-ABL, BRAF, KIT, MET, EGFR, FLT3, HER2, PDGFRA, VEGFR – 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.

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.

Safe Harbor Statement

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 clinical and preclinical programs, 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, 2011 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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