Synta Announces Elesclomol Clinical Development to Resume

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LEXINGTON, Mass., Mar 02, 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 reported that the U.S. Food and Drug Administration (FDA) has approved resuming clinical development of elesclomol, the Company's first-in-class oxidative stress inducer.

"The collected clinical and preclinical data presented to the FDA and to our external scientific advisory board provided compelling evidence for resuming clinical development with elesclomol," said Vojo Vukovic, M.D., Ph.D., Chief Medical Officer, Synta. "The action by the FDA will allow us to further evaluate the potential of elesclomol in treating patients with cancer, incorporating the clinical experience and scientific understanding gained through a full analysis of the most recent data. Based on these results, we expect to initiate one or more clinical trials for elesclomol in the second half of this year. Further details will be announced over the coming months."

The Phase 3 SYMMETRY(SM) trial of elesclomol in metastatic melanoma was suspended in February 2009 based on an interim analysis that identified possible safety concerns. Preliminary results from the trial were presented at ASCO in May 2009 and Perspectives in Melanoma XIII in October 2009. These results showed a differential response to treatment with elesclomol based on level of baseline lactate dehydrogenase (LDH), an established prognostic biomarker in melanoma and a pre-specified stratification variable in the trial. The primary endpoint of progression-free survival was achieved in the normal LDH population, 68% of enrolled patients, with an acceptable safety profile. In the elevated LDH population, 32% of patients, no difference was observed between the two arms of the trial for the primary endpoint, and a negative impact was observed for the survival endpoint.

Results presented at the NCI-AACR-EORTC meeting in November 2009 demonstrated that elesclomol binds copper in plasma, facilitating its uptake into cells and enabling a transition between copper oxidation states inside the cell. Additional research by Synta and by external collaborators has shown that this reaction disrupts the metabolic properties of cancer cell mitochondria and generates the oxidative stress that triggers programmed cell death. Under normal oxygen conditions elesclomol exhibits potent anti-cancer activity. Under hypoxic (low oxygen) conditions, which are often associated with elevated LDH levels, cancer cell metabolism shifts away from the mitochondria and elesclomol anti-cancer activity is reduced. These results, together with the results observed in the SYMMETRY trial, suggest excluding patients with elevated LDH from future trials with elesclomol.

The application to the FDA to resume development focused on a specific clinical trial protocol that excluded patients with elevated LDH. Additional clinical trial protocols will require additional review by the FDA.

About Elesclomol

Elesclomol is a first-in-class oxidative stress inducer that triggers apoptosis (programmed cell death) in cancer cells. In preclinical models elesclomol showed potent anti-cancer activity against a broad range of cancer cell types, as well as an ability to enhance the efficacy of certain chemotherapy agents with minimal additional toxicity. In a 21-center, double-blind, randomized, controlled Phase 2b clinical trial in 81 patients with metastatic melanoma, elesclomol in combination with paclitaxel achieved the primary endpoint of improvement in progression-free survival compared to paclitaxel alone. The subsequent Phase 3 trial in melanoma showed that level of baseline lactate dehydrogenase (LDH) was an important predictive factor for treatment outcomes with elesclomol.

In December 2009, results presented at the American Society for Hematology showed that elesclomol was highly active against acute myeloid leukemia (AML) cell lines and primary blast cells from AML patients.

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

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SOURCE: Synta Pharmaceuticals Corp.

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