Synta Pharmaceuticals Announces Updated Elesclomol SYMMETRY(SM) Data Presented at Melanoma XIII

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LDH emerges as predictive factor for treatment with elesclomol in melanoma for both PFS and OS endpoints

LEXINGTON, Mass., Oct 12, 2009 (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 additional results from its Phase 3 trial (SYMMETRY(SM)) of elesclomol in combination with paclitaxel in metastatic melanoma was presented at the Perspectives in Melanoma XIII Conference by Steven O'Day, M.D., principal investigator and Chief of Research and Director of the Melanoma Program at the Angeles Clinic in Santa Monica, California.

"The data from the SYMMETRY trial presented at the Perspectives in Melanoma XIII Conference shows an important connection between patients' baseline level of LDH (lactate dehydrogenase), an established biomarker in melanoma, and treatment outcome with elesclomol," said Dr. O'Day. "Patients with low and normal baseline levels of LDH showed an improvement in progression free survival (PFS), the primary endpoint of the study. The OS (overall survival) data for these groups are still highly censored and evolving; no difference has been observed to date between the treatment and control arms. In contrast, patients with high baseline level of LDH showed no PFS benefit and a decreased survival time relative to the control arm. These results, along with the results of other recent randomized clinical trials, suggest that baseline LDH status may evolve from a prognostic factor for the disease to a potentially predictive factor for treatment. This could pave the way for a more personalized approach to treating this disease that considers markers such as LDH in determining an optimal approach to therapy."

"We believe there are three emerging findings from the SYMMETRY trial that are important for the future of the elesclomol program," said Vojo Vukovic, M.D., Ph.D., Senior Vice President and Chief Medical Officer, Synta Pharmaceuticals. "First, there are clear signs of clinical benefit in the normal LDH population. In this patient group, which represents 68% of the trial population, the PFS endpoint was achieved. Second, any potential adverse effect on survival in favor of the control arm appears to be restricted to the high LDH patient population. Finally, and importantly in considering development of elesclomol beyond melanoma, there were no substantial differences in Grade 3 or 4 toxicities between the two arms of the trial, consistent with safety findings from prior trials, indicating that elesclomol was well tolerated."

"Additional survival data, as well as a further understanding of the interaction between oxidative stress induction and LDH level, will be important for determining the future of the program," continued Dr. Vukovic. "Both the elesclomol oxidative stress mechanism and LDH relate to metabolic pathways. Together with our academic collaborators we are actively investigating the connection between the two, and expect to present initial results at scientific meetings later this

year. We expect to present SYMMETRY survival data with 12 months minimum follow-up, and announce further decisions related to the future of the elesclomol program, in the first half of 2010."

SYMMETRY Results Presented at Melanoma XIII

Updated results for PFS, OS, response rate, and safety were presented, including prespecified exploratory analyses of the effects of baseline LDH levels on treatment outcomes. The complete presentation can be found at http://www.syntapharma.com/Documents/SYMMETRYPIM13.pdf.

Progression Free Survival

Updated progression free survival data showed no substantial changes from results presented May 30 this year at the American Society for Clinical Oncology meeting. Results for the overall Intent to Treat (ITT) population presented at the Melanoma XIII meeting showed a trend in favor of elesclomol in combination with paclitaxel as compared to paclitaxel alone (3.4 vs. 1.9 months, HR=0.88, p=0.188). The normal LDH population, 68% of patients, experienced a significant improvement in median PFS (3.6 vs. 2.1 months, HR=0.76, p=0.027). In contrast, the high LDH population, 32% of patients, showed no benefit (1.8 vs. 1.9 months, HR=1.10, p=0.549).

Response Rate

The Overall Response Rate (complete response plus partial response) was measured based on RECIST objective tumor response criteria for those patients with at least one follow-up assessment. Overall Response Rates for ELPAC vs. PAC were 7.4% vs. 4.4% for all randomized patients (N=595, p=0.121); 8.4% vs. 3.9% for the normal LDH population (N=407, p=0.065); and 5.3% vs. 5.4% for the high LDH population (N=188, p=1.00). Of the responders, two were complete responses, which occurred in the ELPAC arm in the normal LDH population; all other responses were partial responses.

Overall Survival

Survival results presented represent a minimum of six months follow-up since study termination on February 26, 2009. This data set shows a 55% censoring rate, indicating that results are not yet mature and may change. The hazard ratio in the full patient population (ITT analysis) is 1.17 (95% C.I. 0.93-1.48, p=0.173). The hazard ratio in the high LDH population (LDHgreater-than or equal to 1x ULN) is 1.49 (1.05-2.11); in the normal LDH population (LDH