Synta Pharmaceuticals Announces Presentation of Preliminary Results of Phase 3 SYMMETRY Trial of Elesclomol in Metastatic Melanoma at ASCO 2009

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Trend towards improvement seen in primary PFS endpoint, does not achieve significance

A significant PFS improvement was achieved for patients with normal LDH, a pre-specified exploratory analysis

Mature survival data expected by end of 2009 or early 2010

LEXINGTON, Mass.--(BUSINESS WIRE)--May 30, 2009-- Synta Pharmaceuticals Corp. (NASDAQ: SNTA), a biopharmaceutical company focused on discovering, developing, and commercializing small molecule drugs to treat severe medical conditions, today announced the preliminary results of the Phase 3 SYMMETRY^{SM} trial of elesclomol in combination with paclitaxel in metastatic melanoma. The results are the subject of an oral presentation by Steven O'Day, M.D., Chief of Research and Director of the Melanoma Program, The Angeles Clinic and Research Institute, at the Annual Meeting of the American Society of Clinical Oncology. The SYMMETRY trial and other trials for elesclomol were suspended in February 2009 after a meeting of an independent Data Monitoring Committee for the SYMMETRY trial observed an imbalance in deaths in favor of the control (paclitaxel alone) arm.

"There is an enormous unmet need and lack of treatment options for patients with metastatic melanoma. It is disappointing to all of us that the primary endpoint of the SYMMETRY trial, progression free survival (PFS), while showing a trend towards benefit, did not achieve statistical significance in the full patient population, particularly given the positive results from the prior, double-blind, randomized, controlled Phase 2b trial," said Dr. O'Day. "A statistically significant PFS improvement was achieved, however, in the normal LDH population, which constituted just over 2/3 of total evaluable patients in this trial. The preliminary safety analysis shows that both the combination and control arms were well tolerated with generally comparable adverse event profiles. The imbalance in deaths observed between the two arms to date cannot be explained by organ-specific toxicities attributable to elesclomol. More mature survival data will be needed to understand the safety profile more fully."

SYMMETRY Primary Endpoint Preliminary Results

Database lock and final analysis for the primary endpoint of the trial, PFS, are expected in Q3 2009. Preliminary results for PFS, in the full intent-to-treat (ITT) population, consisting of the 621 patients who were evaluable by April 2009 out of 651 total enrolled patients, were presented today:

PFS, ITT population	**Elesclomol + Paclitaxel**	**Paclitaxel**

	(N=309)	**(N=312)**
Events	170	192
Median (months; 95% C.I.)	3.4 (2.6 – 3.6)	1.9 (1.9 - 2.9)
Hazard ratio (95% C.I., p-value)	0.84 (0.64 – 1.04), p=0.111	

These results show a trend towards improvement in PFS, which did not achieve statistical significance (p=0.111; stratified log-rank test).

Patients in the SYMMETRY trial were stratified prospectively for level of LDH (lactate dehydrogenase), a known prognostic factor in melanoma; M-grade (degree of disease metastasis); and prior treatment history. Results of pre-specified exploratory analyses with respect to these variables showed a correlation between activity of elesclomol and level of LDH:

PFS, ITT population, normal LDH	**Elesclomol + Paclitaxel (N=209, 68%)**	**Paclitaxel (N=215, 69%)**
Events	99	124
Median (months; 95% C.I.)	3.7 (3.5 – 5.4)	2.1 (1.9 – 3.5)
Hazard ratio (95% C.I., p-value)	0.72 (0.55 – 0.94), p=0.015	

PFS, ITT population, elevated LDH	**Elesclomol + Paclitaxel (N=100, 32%)**	**Paclitaxel (N=97, 31%)**
Events	71	68
Median (months; 95% C.I.)	1.8 (1.7 – 2.0)	1.9 (1.8 - 2.5)
Hazard ratio (95% C.I., p-value)	1.11 (0.78 – 1.59), p=0.556	

Medians are calculated using Kaplan-Meier methodology. Cox proportional hazards modeling was used to generate hazard ratios. Normal LDH was defined as less than 1x ULN (the upper limit of normal, 234 U/L); elevated LDH was defined as greater than or equal to 1x ULN and less than 2x ULN. Patients with LDH greater than 2x ULN were excluded from the trial.

“We were disappointed that the primary endpoint in the Phase 3 SYMMETRY trial was not achieved,” said Eric Jacobson, M.D., Chief Medical Officer of Synta Pharmaceuticals. “The observation, however, that the combination of elesclomol plus paclitaxel improved PFS in a large subpopulation of patients with this difficult to treat disease is encouraging. The experience and insights that we have gained and will continue to gain from the SYMMETRY trial will be very important as we evaluate potential paths forward for this first-in-class program.”

“I want to thank the patients, their families, and all the healthcare professionals around the world who worked so closely with us to conduct this trial with such a high level of quality, efficiency, and attention to detail,” said Safi R. Bahcall, Ph.D., Chief Executive Officer of Synta. “While we wish

results from this study would have rapidly led to a new option for patients with metastatic melanoma, that is not the case. We are encouraged by the signs of clinical activity, and are strongly committed to more fully understanding the underlying science, which could inform the selection of patients for future trials.”

Additional Preliminary Results

Adverse events of all NCI CTC Grades 1-4 occurring in >10% of patients were, in the ELPAC vs PAC alone arm respectively, alopecia (40% vs 40%), fatigue (39% vs 38%), nausea (31% vs 25%), diarrhea (25% vs 22%) and constipation (18% vs 18%), cough (15% vs 13%), headache (14% vs 14%), asthenia (13% vs 9%), rash (13% vs 11%), peripheral neuropathy (13% vs 12%), vomiting (12% vs 9%), and pyrexia (10% vs 7%).

Moderate to severe adverse events, those of NCI CTC Grade 3-4, were, in the ELPAC vs PAC alone arm respectively, fatigue (3.6% vs