Synta Announces Presentation of Results of Ganetespib Study in Combination with Docetaxel in Solid Tumors

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-Combination well-tolerated in heavily-pretreated patient population-

LEXINGTON, Mass., Sep 26, 2011 (BUSINESS WIRE) -- Synta Pharmaceuticals Corp. (NASDAQ: SNTA) announced that results of a Phase 1 study of ganetespib in combination with docetaxel in solid tumors were presented at the Annual Meeting of the European Society of Medical Oncology in Stockholm, Sweden. Ganetespib is a potent inhibitor of heat shock protein 90 (Hsp90) currently being studied in a broad range of clinical trials with over 400 patients treated to date. Ganetespib is structurally unrelated to first-generation, ansamycin-family Hsp90 inhibitors such as 17-AAG or IPI-504.

"The results presented today show that ganetespib is well-tolerated when combined with docetaxel, a chemotherapeutic agent used in the treatment of a number of cancers including non-small cell lung cancer," said Suresh Ramalingam, M.D., Associate Professor, Chief of Thoracic Oncology and Director of Medical Oncology, Emory University. "Over half the patients in this heavily pre-treated population received at least 4 cycles of treatment. The dose-limiting toxicity for the combination was neutropenia which is associated with single agent docetaxel use. These results support the use of ganetespib at a dose of 150 mg/m^2 in combination with docetaxel at a dose of 75 mg/m^2 in the on-going Phase 2b/3 trial (GALAXY) in non-small cell lung cancer."

A confirmed partial response, with over 50% shrinkage of target tumor lesions, was reported for a patient on the trial diagnosed with cancer of the parotid gland, the largest of the salivary glands. The patient did not respond to prior treatment regimens including carboplatin, cetuximab, and methotrexate.

"The results from this safety trial, combined with the strong preclinical results and scientific rationale supporting synergistic activity between ganetespib and docetaxel, are encouraging, providing additional support for our GALAXY Phase 2b/3 trial in lung cancer," said Vojo Vukovic, M.D., Ph.D., Chief Medical Officer, Synta. "These results also support further evaluation of this combination in other indications where docetaxel is currently used."

About the Phase 1 Trial

The trial evaluated three dose-level combinations of docetaxel and ganetespib, administered on a three-week cycle, with the primary objective of determining an optimal dose for future clinical trials. Docetaxel was administered as a one hour IV infusion on day 1 and ganetespib was administered as a one hour IV infusion on days 1 and 15. The dose level combinations evaluated were 150 mg/m^2 and 60 mg/m^2; 150 mg/m^2 and 75 mg/m^2; and 200 mg/m^2 and 75 mg/m^2 for ganetespib and docetaxel respectively. The standard of care dose level for docetaxel is 75 mg/m^2. A total of 19 patients received at least one dose of study treatment at the time of data cut-off on July 29. The

median number of cycles of treatment was 4, with a range of 1 to 11 cycles of treatment. No prophylactic treatment for neutropenia was used. The combination of ganetespib at 150 mg/m^2 and docetaxel at 75 mg/m^2 was selected as the recommended dose.

The most common adverse event was neutropenia (67%), including four patients (22%) who reported febrile neutropenia. Neutropenia, a known effect of docetaxel treatment, was commonly observed at approximately 8 days following dosing and typically resolved spontaneously within 7 days. Serious adverse events were reported in a total of nine patients (50%) including two reports of pneumonia and one report each of chest pain, chills, dyspnea, fatigue, mucosal inflammation, neutropenia, pneumothorax, pulmonary embolism, rib fracture, transient ischaemic attack, and vomiting.

Pharmacokinetic data indicate a pharmacokinetic similarity between ganetespib administered alone and ganetespib administered prior to docetaxel. There was no effect of ganetespib on docetaxel pharmacokinetics. No ganetespib accumulation was observed which is consistent with other studies with ganetespib monotherapy.

About Ganetespib

Ganetespib (formerly STA-9090) is a potent, synthetic, small-molecule inhibitor of heat shock protein 90 (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. 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. Ganetespib is currently being evaluated in a broad range of cancer clinical trials. In these trials, ganetespib has shown clinical activity in heavily pretreated patients and has been well tolerated to date with no evidence of severe liver or common ocular toxicities seen with other Hsp90 inhibitors. The most common adverse event seen to date has been diarrhea, which has been manageable with standard supportive care. Information on clinical trials with ganetespib can be found at http://www.clinicaltrials.gov.

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 http://www.syntapharma.com.

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