Synta Announces FDA's Oncologic Drugs Advisory Committee to Discuss Pediatric Uses for Ganetespib

November 5, 2014

LEXINGTON, Mass.--(BUSINESS WIRE)--Nov. 5, 2014-- Synta Pharmaceuticals Corp. (NASDAQ:SNTA) today announced that the Company has been invited by the U.S. Food and Drug Administration (FDA) to participate in a meeting of the Oncologic Drugs Advisory Committee's (ODAC) Pediatric Subcommittee on December 11, 2014. The purpose of the meeting is to inform the FDA as to whether there is sufficient interest in the pediatric investigator community to warrant the FDA issuing a Pediatric Written Request to Synta. If the FDA issues a Pediatric Written Request and Synta fulfills its requirements, an additional six months of exclusivity will be granted to ganetespib. At the meeting, the subcommittee will review the SARC 023 study, investigating ganetespib in patients with malignant peripheral nerve sheath tumors (MPNSTs) and other sarcomas. Ganetespib is a next-generation inhibitor of the chaperone protein Hsp90, which is critical for the activation and stability of numerous proteins that control malignant tumor growth. Ganetespib has been studied in over 1,200 adult patients to date.

SARC 023, sponsored by the Sarcoma Alliance for Research through Collaboration (SARC), is an open label Phase 1/2 trial of ganetespib in combination with the mTOR inhibitor sirolimus in patients with refractory sarcoma, including MPNST. The Principal and Co-Principal Investigators are AeRang Kim, MD, PhD, of the Children's National Medical Center and Brigitte Widemann, MD, Section Head, National Cancer Institute Pediatric Oncology Branch. The Pediatric Subcommittee of ODAC will review the design of SARC 023, as well as pre-clinical data demonstrating the scientific rationale for studying this combination in a clinical trial.

The Phase 1 portion of the study, which is currently ongoing, is designed to assess the safety, tolerability, and maximum tolerated/recommended dose of the combination in patients ≥ 18 years of age (to be amended to ≥ 16 years of age) with refractory sarcomas or unresectable or metastatic sporadic or neurofibromatosis type-1 associated MPNST. Upon determination of the recommended dosing, the primary objective of the phase 2 portion will be to determine the clinical benefit rate (CR, PR, or stable disease ≥ 4 months using WHO criteria) of the combination in patients with refractory MPNST. Secondary objectives include determination of the pharmacokinetic profile of these agents in combination and pharmacodynamic markers in tumor tissue and peripheral blood mononuclear cells, patient reported pain outcomes, and volumetric MRI analysis of tumor measurement. For additional information, click here.

"Outcomes for unresectable, recurrent, or metastatic MPNST are very poor, underscoring an urgent need for new therapeutic options," said Dr. Vojo Vukovic, Chief Medical Officer, Synta. "Drugs that target Hsp90 and mTOR have shown synergistic activity in MPNST animal models. If the combination proves safe and effective in patients, it may provide an important new therapeutic strategy for this disease. We look forward to discussing the current clinical experience with ganetespib as well as the ongoing SARC 023 study with the FDA and Pediatric Subcommittee."

Background material for this meeting will be available on the FDA website 1-2 days prior to the meeting.

About Ganetespib

Ganetespib, an investigational drug candidate, is a selective inhibitor of heat shock protein 90 (Hsp90), a molecular chaperone which controls the folding and activation of a number of client proteins that drive tumor development and progression. Many solid and hematologic tumors are dependent on Hsp90 client proteins including proteins involved in "oncogene addiction" (ALK, HER2, mutant BRAF and EGFR, androgen receptor, estrogen receptor, and JAK2); proteins involved in resistance to chemotherapy and radiation therapy (ATR, BCL2, BRCA1/2, CDK1/4, CHK1, survivin, and WEE1); proteins involved in angiogenesis (HIF-1alpha, VEGFR, PDFGR, and VEGF); and proteins involved in metastasis (MET, RAF, AKT, MMPs, HIF-1alpha, and IGF-1R). In preclinical models, inhibition of Hsp90 by ganetespib results in the inactivation, destabilization, and eventual degradation of these cancer-promoting proteins. Ganetespib is being evaluated in trials in lung cancer, breast cancer, and other tumor types. 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 these trials can be found at www.clinicaltrials.gov. Ganetespib has received Fast Track designation from FDA for second-line treatment of non-small cell lung adenocarcinoma in combination with docetaxel.

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 its compound library and discovery capabilities. For more information, please visit www.syntapharma.com.

Safe Harbor Statement

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