Synta Announces Positive Interim Results from the ENCHANT-1 Trial of Ganetespib in Metastatic Breast Cancer at the 9th European Breast Cancer Conference

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LEXINGTON, Mass.--(BUSINESS WIRE)--Mar. 20, 2014-- Synta Pharmaceuticals Corp. (NASDAQ: SNTA) today announced presentation of interim results from the ENCHANT-1 trial, a single-arm multi-center Phase 2 proof-of-concept study designed to evaluate ganetespib, the Company's lead drug candidate, administered as monotherapy for the treatment of metastatic breast cancer. The results are being presented today in an oral session at the 9th European Breast Cancer Conference (EBCC) in Glasgow, Scotland at 9:45 AM local time.

The ENCHANT-1 trial was designed to evaluate ganetespib single agent activity in metastatic breast cancer and identify potential predictive biomarkers. Target enrollment is 35 patients in three cohorts, which include HER2+ breast cancer, triple-negative breast cancer (TNBC), and, recently added and now recruiting, ER/PR-positive patients previously untreated for locally advanced or metastatic disease. The goal of the trial design is to obtain initial evidence of a clinical activity signal with single-agent ganetespib administered for up to 12 weeks. Continuation of ganetespib as a single agent or in combination with paclitaxel after the initial assessment is at investigator discretion.

"Hsp90 has emerged as an important chaperone in cancer cells due to its key role in a wide range of signaling pathways, including tumor growth, angiogenesis, and metastasis," said Professor David Cameron, Professor of Oncology and Director of Cancer Services, NHS Lothian, the principal investigator on the trial. "Ganetespib appears to not only overcome the challenges of earlier-generation Hsp90 inhibitors, with a good tolerability profile, but demonstrates highly encouraging single-agent activity in both HER2+ and triple-negative disease. These results warrant expanded study of ganetespib in this metastatic disease setting."

To date, 10 patients were enrolled into the HER2+ cohort and 38 patients were enrolled into the TNBC cohort. Of the patients evaluable for metabolic response based on having reached the week 3 PET assessment, 6 of 7 achieved a metabolic response in the HER2+ cohort and 18 of 31 achieved a metabolic response in the TNBC cohort. Of the 6 HER2+ and 26 TNBC patients that reached the 6 week assessment and therefore evaluable for objective RECIST response, 4 achieved an objective response (CR+PR) and two achieved stable disease (SD) in the HER2+ cohort, while 2 achieved an objective response, 11 achieved stable disease, and 13 had progressive disease in the TNBC cohort. All objective responses were confirmed by independent radiological review. Of note, one HER2+ patient achieved a complete objective response and has remained on treatment for over 10 months.

Consistent with previously reported results, diarrhea, fatigue, and nausea were the most common adverse events associated with ganetespib treatment, and were mostly Grade 1 or 2 in severity.

"Like the I-SPY 2 breast cancer trial, ENCHANT-1 gives us the opportunity to rapidly evaluate the clinical activity of ganetespib in an early treatment setting, providing a new paradigm for screening novel agents in the treatment of breast cancer," said Dr. Iman El-Hariry, Vice President of Clinical Research at Synta. "These results continue to provide exciting preliminary evidence of ganetespib's clinical activity, which we look forward to elucidating further in the ENCHANT-1 and I-SPY 2 trials."

Synta recently announced that ganetespib has been selected for study in the I-SPY 2 TRIAL (Investigation of Serial Studies to Predict Your Therapeutic Response with Imaging And moLecular Analysis 2). I-SPY 2 is a standing Phase 2 randomized, controlled, multicenter trial for women with newly diagnosed, locally advanced breast cancer (Stage 2 or higher) that is designed to test whether adding investigational drugs to standard chemotherapy is better than standard chemotherapy alone in the neo-adjuvant setting (prior to surgery). Enrollment in the ganetespib arm of I-SPY 2 is expected to begin in 2014. Ganetespib will initially be available to patients with HER2 negative disease, with the intent to expand its eligibility to all biomarker subtypes after safety testing with trastuzumab is completed.

A copy of the ENCHANT-1 presentation may be found in the Ganetespib Presentations section of the Company's website, www.syntapharma.com.

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.

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