



Synta Announces Positive Interim Results from the ENCHANT-1 Trial of Ganetespib in Metastatic Breast Cancer at the 2013 San Antonio Breast Cancer Symposium

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- 3 of 4 HER2+ patients (75%) achieved objective response with ganetespib monotherapy, including one radiologic complete response –*
- 7 of 11 evaluable TNBC patients (64%) achieved disease control with ganetespib monotherapy –*
- 7 of 15 total evaluable HER2+ and TNBC patients (47%) showed rapid metabolic response by PET scan –*

SAN ANTONIO--(BUSINESS WIRE)--Dec. 12, 2013-- Synta Pharmaceuticals Corp. (NASDAQ: SNTA) today announced presentation of 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 during a poster session at the 2013 San Antonio Breast Cancer Symposium in San Antonio, Texas.

The ENCHANT-1 trial is designed to evaluate the efficacy and safety of ganetespib monotherapy for treatment of HER2+ (Cohort A) or triple-negative (Cohort B) breast cancer (TNBC) patients previously untreated for locally advanced or metastatic disease. A third cohort was recently added to evaluate ganetespib in ER/PR+, HER2- (HER2-negative) patients.

The goal of the window-of-opportunity trial design is to obtain initial evidence of the presence or absence of clinical activity for single-agent ganetespib in patients diagnosed with advanced breast cancer during a 12-week period prior to first-line treatment. Per protocol, all patients enrolled are to receive baseline PET and CT scans, a PET scan at week 3 to assess metabolic response, and subsequent CT scans every 6 weeks to measure best objective response via modified RECIST 1.1 criteria. Continuation of treatment with ganetespib, or the combination of ganetespib and standard-of-care, after the 12-week initial assessment period is at investigator discretion.

Target enrollment is 35 patients in each cohort, with an interim analysis planned at N=15. At the time of interim analysis conducted earlier this year, five patients were enrolled into the HER2+ cohort and 15 patients were enrolled into the TNBC cohort. Of these, four patients in the HER2+ cohort and 11 patients in the triple-negative cohort were evaluable by independent review for objective response, per protocol.

Of the four patients in the HER2+ cohort evaluable for objective RECIST response by independent review, three patients (75%) achieved an objective response, including one complete radiological response (CR) and two partial responses (PR). One patient (25%) in this cohort achieved stable disease (SD).

Of the 11 patients in the TNBC cohort evaluable for objective RECIST response by independent review, two patients achieved PR (18%) and five patients achieved stable disease (SD, 45%), for a total disease control rate of 64%. As previously reported, one of the responding patients was adjudicated a clinical complete response at week 12 after receiving only three cycles of ganetespib therapy. Her disease was restaged to operable and she underwent a total mastectomy with curative intent. She is now receiving adjuvant chemotherapy.

At the week 3 PET assessment for metabolic response, three of the four patients (75%) evaluable by independent review in the HER2+ cohort achieved a metabolic response. In the triple-negative cohort, four of the 11 patients (36%) evaluable by independent review achieved a week 3 metabolic response.

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.

“The central role that Hsp90 plays in fueling breast cancer growth and metastasis is evidenced by the strong single-agent activity of ganetespib in these difficult-to-treat cancers,” said Dr. Neil Spector, Co-Director of Developmental Therapeutics Program, Duke University and an investigator on the trial. “The clinical activity, which includes a complete clinical response as well as a complete radiological response, illustrates the exciting potential for ganetespib in breast cancer, and the rationale for exploring ganetespib in a broader spectrum of disease stages and combinations.”

“Results from ENCHANT-1 to date, while early, have demonstrated that ganetespib is clinically active as a single-agent in both HER2+ and triple-negative metastatic breast cancers,” said Dr. Iman El-Hariry, Vice President of Clinical Research at Synta. “The results suggest the exciting potential to realize a new category of treatment option for patients with advanced breast cancer, and we are looking forward to vigorously advancing development of ganetespib in breast cancer in order to bring this option to patients.”

A copy of the ENCHANT-1 poster presentation may be found in the [Ganetespib Presentations](#) section of the Company’s website, www.syntapharma.com.

Additional results from this trial are expected to be presented at a medical conference next year.

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, PDGFR, 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 the ENCHANT-1 Clinical Trial

ENCHANT-1 is a proof-of-concept trial designed to evaluate single-agent ganetespib safety and clinical activity in locally advanced or first-line metastatic HER2-positive, triple-negative, and hormone-refractory ER/PR+ (HER2-) breast cancer. The trial will also evaluate the combination of ganetespib with paclitaxel. More information about this trial can be found at www.clinicaltrials.gov (NCT01677455)

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 www.syntapharma.com

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