Synta Announces First Patients Treated in Pivotal GALAXY-2 Trial Evaluating Ganetespib in Advanced Non-Small Cell Lung Cancer

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LEXINGTON, Mass.--(BUSINESS WIRE)--Apr. 22, 2013-- Synta Pharmaceuticals Corp. (NASDAQ: SNTA) announced today that the first patients have been treated in the randomized GALAXY-2 Phase 3 trial designed to evaluate docetaxel plus ganetespib, its investigational Hsp90 inhibitor, versus docetaxel alone for the second-line treatment of non-small cell lung adenocarcinoma. The study will enroll approximately 500 patients from about 140 cancer treatment centers worldwide.

“The clinical results presented from the GALAXY-1 trial so far have been encouraging,” said Vojo Vukovic, M.D., Chief Medical Officer of Synta. “The confirmatory GALAXY-2 trial is critical for delivering on our regulatory strategy in non-small cell lung cancer and achieving our goal of bringing ganetespib to patients with this devastating disease.”

The GALAXY program is based on a two-stage, operationally adaptive trial design, with the first Phase 2b/3 stage (GALAXY-1) intended to identify the optimal patient population to be evaluated in a confirmatory Phase 3 trial (GALAXY-2). An interim analysis of adenocarcinoma patients in GALAXY-1 presented last September supported potential activity in the second-line treatment setting. The prespecified patient population in GALAXY-1 with a diagnosis of advanced disease more than six months prior to study entry, i.e., those patients who generally received a normal course of first-line chemotherapy before experiencing disease progression (approximately two-thirds of enrolled patients), was chosen for further evaluation in GALAXY-2.

GALAXY-2 Trial Design

GALAXY-2 will enroll approximately 500 patients with Stage IIIB/IV non-small cell lung adenocarcinoma who were diagnosed with advanced disease at least six months prior to study entry and received one prior chemotherapy-based regimen for metastatic disease. All patients must have documented disease progression and ECOG performance status of 0 or 1. Enrollment will be stratified to ensure the balance of key prognostic factors including ECOG performance status (0 versus 1), baseline level of LDH (greater versus less than upper limit of normal), and best response to first-line therapy (complete response or partial response versus stable disease or progressive disease). Patients will be randomized 1:1 to receive ganetespib plus docetaxel, or docetaxel alone, at the same dose and schedule as in the GALAXY-1 trial. Docetaxel will be administered at 75 mg/m2 on day 1 of a 21-day treatment cycle in both arms. Patients in the combination arm will also receive ganetespib 150 mg/m2 on days 1 and 15. In the combination arm, following the completion of docetaxel therapy, treatment with ganetespib alone may be continued until disease progression or treatment intolerance.

The primary endpoint of the GALAXY-2 trial is overall survival. Two event-driven interim analyses are planned, which will be reviewed by an independent data monitoring committee. Key secondary

endpoints include progression-free survival and overall response rate, as well as overall survival in certain prespecified biomarker-defined subpopulations. Based on current projections, Synta expects the interim and final analyses of the GALAXY-2 trial to be conducted in 2014.

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, or become “addicted” to, Hsp90 client proteins including AKT, ALK, BCR-ABL, BRCA1, CDK1, CHK1, EGFR, FAK, HER2, HIF1-alpha, IGF-1R, MEK, MET, PDGFR, VEGFR, and WEE1. In preclinical models, inhibition of Hsp90 by ganetespib results in the inactivation, destabilization, and eventual degradation of many of these cancer-promoting proteins. A number of Hsp90 client proteins are also involved in the resistance of cancer cells to other anti-cancer treatments including chemotherapy, targeted therapy, and radiotherapy, supporting potential for ganetespib use in combination therapy. Ganetespib is being evaluated in over 20 clinical trials including trials in lung, breast, colorectal, and hematologic malignancies. Information on these trials can be found at www.clinicaltrials.gov

About the GALAXY Program

The GALAXY (Ganetespib Assessment in Lung cAncer with docetaXel) program consists of two randomized trials comparing the combination of ganetespib and docetaxel versus docetaxel alone in patients with Stage IIIB/IV non-small cell lung cancer (NSCLC) who have received one prior systemic therapy: a 300-patient Phase 2b/3 trial (GALAXY-1) to determine the patient population most likely to derive benefit from ganetespib, and a 500-patient confirmatory Phase 3 trial (GALAXY-2). More information about the GALAXY trials can be found at www.clinicaltrials.gov (NCT01348126 and NCT01798485).

About Lung Cancer

Lung cancer is the leading cause of cancer-related death in the world, accounting for nearly 1.4 million deaths in 2008, according to the World Health Organization. The five-year survival rate for this disease is about 16%, and over half of people with lung cancer die within one year of being diagnosed. In the U.S., the American Cancer Society estimates that 228,000 cases of lung cancer will be diagnosed in 2013. Non-small cell adenocarcinoma comprises about 40% of all lung cancer.

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.

Safe Harbor Statement

This media release may contain forward-looking statements about Synta Pharmaceuticals Corp.

Such forward-looking statements can be identified by the use of forward-looking terminology such as "will", "would", "should", "expects", "anticipates", "intends", "plans", "believes", "may", "estimates", "predicts", "projects", or similar expressions intended to identify forward-looking statements. Such statements, including statements relating to the developments and progress of our clinical and preclinical programs, including the timing of two interim and the final analyses of the GALAXY-2 trial, reflect our current views with respect to future events and are based on assumptions and subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such forward-looking statements, including those described in "Risk Factors" of our Form 10-K for the year ended December 31, 2012 as filed with the Securities and Exchange Commission. Synta undertakes no obligation to publicly update forward-looking statements, whether because of new information, future events or otherwise, except as required by law.

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