Synta and QuantumLeap Healthcare Collaborative Announce Selection of Ganetespib for I-SPY 2 TRIAL in Breast Cancer

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LEXINGTON, Mass. & SAN FRANCISCO--(BUSINESS WIRE)--Mar. 11, 2014-- Synta Pharmaceuticals Corp. (NASDAQ:SNTA) and QuantumLeap Healthcare Collaborative today announced that Synta's lead drug candidate, the Hsp90 inhibitor ganetespib, has been selected for study in the I-SPY 2 TRIAL (**I**nvestigation of **S**erial Studies to **P**redict **Y**our **T**herapeutic **R**esponse with **I**maging **A**nd mo**L**ecular 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).

The I-SPY 2 TRIAL employs a unique adaptive trial design to match experimental therapies with patients. Genetic or biological markers ("biomarkers") from individual patients' tumors are used to screen promising new treatments, identifying which treatments are most effective in specific patient subgroups. Regimens that have a high Bayesian predictive probability of showing superiority in a 300 patient phase 3 confirmatory trial in at least one of 10 predefined signatures may "graduate" from I-SPY 2. A regimen can graduate early and at any time after having 60 patients assigned to it, and exits the trial after a maximum of 120 patients. This high efficacy bar and rapid turnaround time allows the trial to identify the right drug for the right patient in the most expeditious fashion.

I-SPY 2 is sponsored by QuantumLeap Healthcare Collaborative, a non-profit 501(3)C dedicated to accelerating healthcare solutions, and shares a unique partnership with the Foundation for the National Institutes of Health Biomarkers Consortium, who manages Intellectual Property that emerges from the trial. The trial was developed by principal investigators Laura J. Esserman, M.D., M.B.A., Professor of Surgery and Radiology and Director of the Carol Frank Buck Breast Care Center at UCSF Helen Diller Family Comprehensive Cancer Center in San Francisco, and Donald A. Berry, Ph.D., Professor in the Department of Biostatistics at The University of Texas MD Anderson Cancer Center, and founder of Berry Consultants. I-SPY 2 was initiated as a pre-competitive consortium that brings together the Food and Drug Administration (FDA), National Cancer Institute (NCI), pharmaceutical companies, leading academic medical centers, and patient advocacy groups under its umbrella.

"I-SPY 2 is an innovative study designed to accelerate the testing of promising investigational agents," said Dr. Esserman, "Ganetespib has several important advantages that led to its selection for the I-SPY program: demonstrated single agent clinical activity, favorable safety profile, strong scientific rationale for use in breast cancer, and results in lung cancer showing improvement in outcomes when added to a taxane. The latter is particularly relevant for neo-adjuvant breast cancer, where taxane use is standard of care. The entire I-SPY TRIAL team is excited to participate in the evaluation of this agent and determine whether this agent will improve upon our current neoadjuvant therapy for women with aggressive breast cancer."

Synta recently presented positive results from a single-arm multi-center Phase 2 proof-of-concept study, the ENCHANT-1 trial. ENCHANT-1 was designed to evaluate the clinical activity of single-agent ganetespib preceding standard first line treatment. Of four patients in the study's HER2+ cohort evaluable for response by RECIST, three patients achieved an objective response, including one complete radiological response, and one patient achieved stable disease. Of 11 evaluable patients in the study's TNBC cohort, two patients achieved a partial response and five patients achieved stable disease. Of these, one responding patient was adjudicated a clinical complete response, was restaged to operable and underwent a total mastectomy with curative intent.

"The selection of ganetespib for the I-SPY 2 program is important validation of the potential for ganetespib in breast cancer," said Dr. Iman El-Hariry, Vice President of Clinical Research at Synta. "This study represents a new standard for efficient, cutting edge collaborative research, and has already yielded promising new findings, such as those announced for investigational agents veliparib and neratinib. We look forward to participating in the trial."

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 breast cancer subtypes, including HER2 positive after safety testing with trastuzumab is completed.

In addition to I-SPY 2, ganetespib is being studied in over 25 clinical trials, including an ongoing Phase 3 trial in advanced non-small cell lung cancer and several large, investigator-led randomized studies in AML (the LI-1, AML-18, and AML-19 trials) and ovarian cancer (the GANNET53 trial).

Information regarding the I-SPY 2 TRIAL can be found at www.ispy2trial.org. ENCHANT-1 medical conference presentations 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 our compound library and discovery capabilities. For more information, please visit www.syntapharma.com.

About QuantumLeap Healthcare Collaborative

QuantumLeap Healthcare Collaborative was established in 2005 as a collaboration between medical researchers at University of California at San Francisco, and Silicon Valley entrepreneurs. QuantumLeap's mission is to accelerate transfer of high-impact research in clinical processes and systems technology into widespread adoption so that patients and physicians can benefit from the research as soon as practicable. QuantumLeap provides operational, financial and regulatory oversight to I-SPY 2 and is also the sponsor of its companion phase 3 confirmatory trial, I-SPY 3. For more information, visit: http://www.quantumleaphealth.org.

About the FNIH Biomarkers Consortium

The Biomarkers Consortium is a public-private biomedical research partnership managed by the Foundation for the National Institutes of Health (FNIH) that endeavors to develop, validate, and/or qualify biological markers (biomarkers) to speed the development of medicines and therapies for detection, prevention, diagnosis and treatment of disease and improve patient care. For additional information about the Biomarkers Consortium, please visit www.biomarkersconsortium.org.

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Source: Synta Pharmaceuticals Corp.

Synta:
Synta
Steven Bernitz, 781-541-7979
Senior Vice President, Corporate Development
sbernitz@syntapharma.com
or
Argot Partners
Andrea Rabney, 212-600-1494
andrea@argotpartners.com
or
Media:
Argot Partners
Eliza Schleifstein, 917-763-8106
eliza@argotpartners.com
or
I-SPY 2 TRIAL and QuantumLeap:
Bethany Hornthal, 415-999-7121
Bethany@hornthal.com
or
Media:
King + Company
Caren Browning, 212-561-7464
917-334-6397
caren.browning@kingcompr.com