Synta Provides Clinical Updates and Reports Second Quarter 2013 Financial Results

August 1, 2013

LEXINGTON, Mass.--(BUSINESS WIRE)--Aug. 1, 2013-- Synta Pharmaceuticals Corp. (NASDAQ: SNTA) today provided clinical updates and reported financial results for the second quarter ended June 30, 2013.

Clinical Updates

Our lead clinical candidate is ganetespib, a selective inhibitor of the Hsp90 chaperone protein, which is being evaluated in over 25 clinical trials that have enrolled over a thousand patients to date, including our GALAXY program in lung cancer and our ENCHANT program in breast cancer.

The GALAXY program in lung cancer

At the 2013 meeting of the American Society of Clinical Oncology (ASCO), investigators presented results from an interim analysis evaluating 252 adenocarcinoma patients treated in our ongoing GALAXY-1 Phase 2b/3 trial evaluating ganetespib in combination with docetaxel vs. docetaxel alone for the second-line treatment of advanced non-small cell lung adenocarcinoma. Results included:

- In the all-adenocarcinoma population (N=252), the ganetespib combination arm showed improved overall survival, progression-free survival, and response rate compared to the docetaxel arm.
- A statistical interaction test showed that one of the four prospectively-defined stratification factors was strongly predictive of ganetespib activity (p=0.006). Patients with "chemo-sensitive" disease (N=176; 70%) derived substantially greater benefit from ganetespib than patients with "chemo-refractory" disease (N=76; 30%).
- In the chemo-sensitive population, defined as time since diagnosis of advanced disease greater than six months, median overall survival increased from 6.4 to 10.7 months, and the Hazard ratio was 0.61 (1-sided p=0.009), corresponding to a 39% reduction in the risk of death.
- The rate of new lesion formation decreased by 50% in patients treated with ganetespib (Hazard ratio 0.50, p=0.005). This observation is consistent with preclinical and clinical results suggesting ganetespib inhibits the biological pathways that drive angiogenesis (new blood vessel formation) and metastasis (the spread of tumors) in cancer cells.
- Transient, mild-to-moderate diarrhea, manageable with OTC medication, was the most common adverse event observed with ganetespib, consistent with observations from other clinical trials. Other adverse events increased relative to control included mild to moderate anemia and fatigue, as well as an increase in the number of cases of febrile neutropenia.

Based on our current event rate projections, Synta expects the final analysis of the GALAXY-1 trial to be conducted in the fourth quarter of 2013.

The GALAXY-2 trial evaluates the same dose, schedule, and regimen as the GALAXY-1 trial, but in a larger population (N=500), with overall survival as the primary endpoint, and in chemo-sensitive patients. Trial enrollment began in the second quarter of 2013. Based on our current projections, Synta expects the first interim analysis of the GALAXY-2 trial to be conducted in the first half of 2014, and the second interim and final analyses to be conducted in the second half of 2014.

The ENCHANT program in breast cancer

Some of the strongest evidence for the role of Hsp90 in fueling cancer growth is from breast cancer: reduced expression of tumor Hsp90 is associated with significantly longer patient survival [1].

Based on the supportive scientific findings, evidence of single-agent clinical activity for ganetespib in triple-negative breast cancer, the widespread use of taxanes in this disease, and the positive results for ganetespib in combination with docetaxel in lung cancer, Synta has developed two registration programs focusing on triple-negative breast cancer. The first is in the metastatic setting, and the second is in the neo-adjuvant setting. Synta expects those programs to initiate in 2014, pending completion of certain ongoing partnership discussions.

Recently announced clinical results from the ENCHANT-1 trial have confirmed prior signals of single-agent clinical activity. Synta expects results from ENCHANT-1 will be presented at a medical conference later this year.

Other trials with ganetespib

A number of investigator and cooperative group-sponsored trials are ongoing, including trials in breast cancer in combination with fulvestrant, in multiple myeloma with bortezomib, in ALK+ NSCLC with crizotinib, in rectal cancer with chemoradiotherapy, and in AML with low-dose Ara-C. Additional trials are expected to initiate later this year or early next year including in mesothelioma with pemetrexed and cisplatin, in HER2+ breast cancer with trastuzumab and paclitaxel, in ovarian cancer with paclitaxel and carboplatin, in pancreatic cancer in combination with nab-paclitaxel and gemcitabine, and in prostate cancer with radiotherapy.

“We have made strong progress this quarter in advancing ganetespib development in both lung cancer and breast cancer,” said Safi Bahcall, President and CEO of Synta. “We are encouraged both by the promising clinical results and the growing medical community interest in working with ganetespib. We look forward to completing our GALAXY-2 Phase 3 trial in lung cancer, entering the next stage of development in breast cancer, and bringing ganetespib to patients as quickly as possible.”

Financial results

There were no revenues recognized in the second quarters of 2013 and 2012.

Research and development expenses were $17.9 million for the second quarter in 2013, compared to $11.3 million for the same period in 2012. General and administrative expenses were $4.2 million for the second quarter in 2013, compared to $2.9 million for the same period in 2012.

The Company reported a net loss of $22.8 million, or $0.33 per basic and diluted share, in the second quarter of 2013, compared to a net loss of $14.6 million, or $0.25 per basic and diluted share, for the same period in 2012.

As of June 30, 2013, the Company had $70.2 million in cash, cash equivalents and marketable securities, compared to $100.6 million in cash, cash equivalents and marketable securities as of December 31, 2012.

More detailed financial information and analysis may be found in the Company's Quarterly Report on Form 10-Q, which was filed with the Securities and Exchange Commission (SEC) on August 1, 2013.

Guidance

Based on our current operating levels the Company expects its cash resources of approximately $70.2 million will be sufficient to fund operations into the second quarter of 2014. This estimate assumes no additional funding from new partnership agreements or equity financing events, and that the timing and nature of certain activities contemplated for 2013 and 2014 will be conducted subject to the availability of sufficient financial resources.

Conference call

Management will conduct a conference call at 10:00 a.m. (EDT) today to discuss the second quarter 2013 financial results and clinical updates. The conference call will be webcast live over the Internet and can be accessed by logging on to the Investors section of the Synta Pharmaceuticals website, www.syntapharma.com, prior to the event.

The call can also be accessed by dialing (877) 407-8035 or (201) 689-8035 prior to the start of the call. A replay will be available from 2:00 p.m. (EDT) this afternoon through midnight (EDT) on August 8. To access the replay, dial (877) 660-6853 or (201) 612-7415 and refer to conference ID 418164. The webcast will also be archived on the Company's website.

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, 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. 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 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 the ENCHANT-1 Clinical Trial

ENCHANT-1 is a proof-of-concept, ”window-of-opportunity” trial designed to evaluate single-agent ganetespib safety and clinical activity in locally advanced or first line metastatic HER2-positive and triple-negative 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 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 approximately 16%; 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 Breast Cancer

Breast cancer is the most frequent cancer in women, accounting for 458,000 deaths worldwide in 2008, according to the World Health Organization. In the U.S., the American Cancer Society estimates that about 297,000 cases of breast cancer will be diagnosed in 2013. Breast cancer is often characterized in the context of three biomarkers: ER/PR positive, HER2-positive, or negative for all three (triple-negative). Standard treatment for the first two categories includes therapies targeting hormonal or HER2 signaling pathways. There are no established targeted therapies for patients with triple-negative disease, which accounts for approximately 15% of all breast cancer and is associated with poor patient prognosis.

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 sufficiency of our cash resources, the developments and progress of our clinical and preclinical programs, including the timing of the final analysis of the GALAXY-1 trial, the timing of interim and final analyses of the GALAXY-2 trial, and the timing of results from the ENCHANT-1 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.

1. Q. Cheng et al, “Amplification and high-level expression of heat shock protein 90 marks aggressive phenotypes of human epidermal growth factor receptor 2 negative breast cancer”, Breast Cancer Res. 2012 Apr 17;14(2):R62.

Synta Pharmaceuticals Corp.
Condensed Consolidated Statements of Operations
(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2013	**2012**	**2013**	**2012**
Revenues:				
Grant revenues	$ —	$ —	$ —	$147
Operating expenses:				
Research and development	17,876	11,252	34,256	23,318
General and administrative	4,187	2,882	8,065	5,528
Total operating expenses	22,063	14,134	42,321	28,846
Loss from operations	(22,063)	(14,134)	(42,321)	(28,699)
Interest expense, net	(724)	(486)	(1,194)	(972)
Net loss	$(22,787)	$(14,620)	$(43,515)	$(29,671)
Basic and diluted net loss per common share	$(0.33)	$(0.25)	$(0.63)	$(0.52)
Basic and diluted weighted average number of common shares outstanding	69,034,823	57,650,412	69,013,217	57,008,702

Synta Pharmaceuticals Corp.
Condensed Consolidated Balance Sheets Data
(in thousands)
(unaudited)

	June 30, 2013	December 31, 2012
Assets		
Cash, cash equivalents and marketable securities	$ 70,203	$ 100,599
Other current assets	1,637	786
Property, plant and equipment, net	1,620	1,174
Other non-current assets	464	458
Total assets	$ 73,924	$ 103,017
Liabilities and Equity		
Current liabilities	$ 20,071	$ 23,486
Long-term liabilities	18,417	4,465
Stockholders' equity	35,436	75,066
Total liabilities and Stockholders' equity	$ 73,924	$ 103,017

Source: Synta Pharmaceuticals Corp.

Synta Pharmaceuticals Corp.
George Farmer, 781-541-7213
gfarmer@syntapharma.com
or
Argot Partners
Andrea Rabney, 212-600-1494
andrea@argotpartners.com