Synta Provides Clinical Updates and Reports Third Quarter 2013 Financial Results

November 4, 2013

LEXINGTON, Mass.--(BUSINESS WIRE)--Nov. 4, 2013-- Synta Pharmaceuticals Corp. (NASDAQ: SNTA) today provided clinical updates and reported financial results for the third quarter ended September 30, 2013.

Clinical updates

The GALAXY program in lung cancer

At the 2013 World Conference on Lung Cancer (WCLC) last month, investigators presented one year follow-up results from the ongoing GALAXY-1 trial, evaluating Synta's lead oncology drug candidate, ganetespib, in combination with docetaxel (G+D) vs. docetaxel (D) alone for the second-line treatment of advanced non-small cell lung cancer (NSCLC). GALAXY-1 was designed to select the patient population for evaluation in the confirmatory GALAXY-2 Phase 3 trial.

"We are very pleased by the reception at the WCLC meeting to the updated GALAXY-1 results," said Dr. Vojo Vukovic, Chief Medical Officer, Synta. "These results represent the most mature data to date from this program, with over one-year of follow-up, 65% of survival events, and a strong survival signal favoring the ganetespib arm. The results have offered a wealth of data and experience for optimizing the Phase 3 trial."

Highlights from the recently presented results include:

- Continued confirmation of clinical activity in the prospectively defined chemosensitive patient population selected last year for evaluation in the ongoing GALAXY-2 Phase 3 trial.

- Patients enrolled into the GALAXY-1 trial were prospectively stratified into refractory vs. chemosensitive populations based on the rate of their disease progression during or following first-line treatment for advanced NSCLC (time since diagnosis of advanced disease less than vs. greater than six months).
- In the chemosensitive population (N=178), median overall survival (OS) increased from 7.4 to 10.7 months in patients treated with D vs. G+D arms, respectively. The Hazard ratio was 0.75 (p=0.065) and 0.72 (p=0.04), in the Cox proportional hazards univariate (unadjusted) and multivariate (adjusted) models, respectively. Median progression-free survival (PFS) improved from 3.4 months to 5.3 months, in the D vs. G+D arms, respectively, with Hazard ratios of 0.73 (p=0.031) and 0.72 (p=0.03) in the univariate and multivariate models, respectively. All p-values are 1-sided.
- In the refractory population (N=75), which progressed rapidly on or shortly after first-line chemotherapy, no benefit was observed. These results are consistent with results from other clinical trials showing little to no benefit from second-line treatment for patients with rapidly

progressing disease, and from preclinical studies showing that the chemosensitizing mechanism of action of ganetespib may be most effective in chemosensitive cancers.

- A favorable safety profile was observed with the G plus D combination in adenocarcinoma patients. Transient, mild-to-moderate diarrhea, generally manageable with over-the-counter medication, was the most common adverse event, consistent with observations from other clinical trials evaluating ganetespib. 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.
- Analysis of data to date revealed that medical profiles from certain patients enrolled from two Eastern European countries differed from patterns typical of patients enrolled from other countries in this study, as well as patients enrolled in other clinical trials for the treatment of advanced second-line NSCLC. This observation informed the operational plan for the ongoing GALAXY-2 Phase 3 trial, including the decision to limit further enrollment from these two countries.

Synta expects final overall survival results from GALAXY-1 by early 2014.

The GALAXY-2 protocol specifies that trial size and statistical assumptions may be updated based on results from GALAXY-1. Based on the near-final results from GALAXY-1, Synta intends to review with lead investigators plans for increasing the GALAXY-2 trial size from 500 patients to 700 patients. This change is intended to decrease the risk from imbalances or statistical fluctuations.

Enrollment of GALAXY-2 began in April 2013. Assuming an increased trial size of 700 patients, Synta expects that interim analyses for GALAXY-2 would be conducted in the second half of 2014, and the final analysis would be conducted in the first half of 2015.

The ENCHANT program in breast cancer

In July 2013, Synta announced that preliminary results of the ENCHANT-1 Phase 2 trial, evaluating ganetespib monotherapy for treatment of newly diagnosed HER2-positive or triple-negative metastatic breast cancer, support advancement into the second stage of the trial. Of the initial five HER2-positive patients enrolled in the study, two achieved objective tumor response and two achieved stable disease (SD) within the three cycles of treatment on study (12 weeks). Of the initial ten triple-negative breast cancer (TNBC) patients enrolled and evaluable for response, two achieved objective tumor response and three achieved SD following treatment with ganetespib monotherapy. One of the TNBC patients enrolled in the study who was diagnosed with inoperable disease at the time of enrollment achieved a clinical complete response at week 12 and was restaged to operable disease. This patient recently underwent surgery with curative intent.

Based on the encouraging results in HER2-positive and triple-negative breast cancer patients, the trial was expanded to add a third cohort, evaluating ganetespib monotherapy for the treatment of patients with hormone receptor-positive disease.

Synta expects initial results from ENCHANT-1 will be presented at the San Antonio Breast Cancer Symposium in December of this year.

Other clinical trials with ganetespib

A number of investigator and cooperative group-sponsored trials with ganetespib recently initiated

or are expected to initiate by end of this year, including a trial evaluating ganetespib in combination with pemetrexed and cisplatin in patients with malignant pleural mesothelioma, being sponsored by Cancer Research UK; a trial evaluating ganetespib in combination with paclitaxel in patients with recurrent, platinum-resistant ovarian, fallopian tube, or primary peritoneal cancer being sponsored at the Fox Chase Cancer Center; a trial evaluating ganetespib in combination with paclitaxel and Herceptin in HER2+ breast cancer being conducted at Memorial Sloan-Kettering Cancer Center (MSKCC) and New York University; and trials designed to evaluate ganetespib in combination with a variety of different therapeutic modalities for treatment of head and neck cancer and neuronal tumors. Ongoing investigator and cooperative group-sponsored trials include a trial in combination with crizotinib in ALK+ lung cancer; a trial in combination with fulvestrant in hormone-receptor positive breast cancer; a trial in combination with chemotherapy and radiotherapy in rectal cancer; a trial in combination with bortezemib in multiple myeloma; and a trial evaluating the combination of ganetespib and low dose ara-C chemotherapy in elderly patients with acute myeloid leukemia (AML). Initiation of additional combination trials with ganetespib in other cancer indications are planned for 2014.

Other updates

HDC platform

In September 2013, Synta announced the launch of its Hsp90-inhibitor drug conjugate (HDC) platform technology designed to improve the delivery of small-molecule anti-cancer therapies to tumors. In October 2013, the Company announced the publication of the first key patent application covering this technology, including composition of matter claims covering over 400 HDC compounds synthesized by Synta to date, methods for identifying therapeutically effective compounds, and methods of use against a wide range of diseases and conditions.

HDCs are drug candiates consisting of an Hsp90 inhibitor (targeting moiety) joined to an anti-cancer agent (payload) via a cleavable chemical linker optimized for controlled release of payload drug inside cancer cells. Because HDCs are small molecules, they diffuse into the cell passively, avoiding reliance on cell surface antigens or transporters, as is required by other delivery mechanisms such as antibody-drug conjugates (ADCs).

The longer retention of Hsp90 inhibitors in tumors results in higher concentration and longer duration of active payload drug inside cancer cells than occurs with standard administration of unconjugated chemotherapy or other payloads. This enhanced delivery creates the potential for greater cancer cell killing and reduced side effects.

Synta has developed over 400 HD-Conjugated chemotherapeutics, kinase inhibitors, hormone therapies, immunomodulators, and epigenetic modifiers, creating the potential for next-generation compounds in each of these categories. Examples include HD-Conjugated bendamustine, temozolomide, doxorubicin, 5-FU, pemetrexed, SN-38, topotecan, vorinostat, panobinostat, fulvestrant, abiraterone, lenalidomide, pomalidomide, docetaxel, carboplatin, bortezomib, sunitinib, and sorafenib.

Proof-of-concept has been established in preclinical models of cancer. HDC improved delivery of SN-38 anti-cancer payload, achieving over thirty times the concentration of this cytotoxic agent in tumor as compared to the concentration in plasma and other tissues. Strongly enhanced anti-tumor activity was seen with the HD-Conjugate as compared to the commonly used SN-38 prodrug,

irinotecan, in a broad range of animal models of cancer, including breast cancer, colon cancer, ovarian cancer, small cell lung cancer, bladder cancer, and melanoma.

“We are excited by the progress we have made this past quarter both with our ganetespib program and with our HDC program,” said Dr. Safi Bahcall, CEO, Synta. “Our top priority is to bring ganetespib to a positive outcome in Phase 3. We are doing this by conducting the GALAXY-2 Phase 3 trial to high standards of operational excellence, and being data-driven in our approach. I am proud of our team and collaborators for their work in achieving this, including the selection of the Phase 3 patient population and identifying means to reduce the operational risks that often confound large, global registration programs.”

Financial results

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

Research and development expenses were $17.6 million for the third quarter in 2013, compared to $11.7 million for the same period in 2012. General and administrative expenses were $4.2 million for the third quarter in 2013, compared to $2.8 million for the same period in 2012.

The Company reported a net loss of $22.5 million, or $0.33 per basic and diluted share, in the third quarter of 2013, compared to a net loss of $15.0 million, or $0.25 per basic and diluted share, for the same period in 2012.

As of September 30, 2013, the Company had $53.4 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 November 4, 2013.

Guidance

Based on our current operating levels the Company expects its cash resources of approximately $53.4 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 the remainder of 2013 and 2014 will be conducted subject to the availability of sufficient financial resources.

Conference call

Management will host a conference call and webcast at 10:00 a.m. ET today to discuss the third quarter 2013 financial results and provide clinical updates.

The conference call can be accessed by dialing (877) 407-8035 (U.S.) or (201) 689-8035 (International). For those unable to join the live call, a replay will be available from 2:00 p.m. ET on November 4 through 11:59 p.m. ET on November 11. To access the replay, please dial (877) 660-6853 (U.S.) or (201) 612-7415 (International) and refer to conference ID 100513.

The live webcast can be accessed by visiting the Investor Relations section of the Synta

Pharmaceuticals website, www.syntapharma.com. The webcast will also be archived under Webcasts and Events within the Investor Relations section of 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. 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 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 Phase 2b/3 trial (GALAXY-1) to determine the patient population most likely to derive benefit from ganetespib, and a 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 trial designed to evaluate single-agent ganetespib safety and clinical activity in patients with locally advanced or metastatic 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 potential for increasing the GALAXY-2 trial size from 500 patients to 700 patients, the timing of interim and final analyses of the GALAXY-2 trial, the timing of results from the ENCHANT-1 trial, and plans with respect to investigator and cooperative group-sponsored trials with ganetespib and to initiate additional combination trials with ganetespib in specific cancer indications in 2013 and 2014, 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2013	**2012**	**2013**	**2012**
Revenues:				

Grant revenues	$ —	$ —	$ —	$147
Operating expenses:				
Research and development	17,623	11,743	51,879	35,061
General and administrative	4,171	2,796	12,236	8,324
Total operating expenses	21,794	14,539	64,115	43,385
Loss from operations	(21,794)	(14,539)	(64,115)	(43,238)
Interest expense, net	(721)	(457)	(1,915)	(1,429)
Net loss	$(22,515)	$(14,996)	$(66,030)	$(44,667)
Basic and diluted net loss per common share	$(0.33)	$(0.25)	$(0.96)	$(0.77)
Basic and diluted weighted average number of common shares outstanding	69,047,161	60,661,720	69,024,656	58,235,263

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

	September 30, 2013	December 31, 2012
Assets		
Cash, cash equivalents and marketable securities	$ 53,384	$ 100,599
Other current assets	1,358	786
Property, plant and equipment, net	1,488	1,174
Other non-current assets	433	458
Total assets	$ 56,663	$ 103,017

Liabilities and Equity		
Current liabilities	$ 25,931	$ 23,486
Long-term liabilities	16,120	4,465
Stockholders' equity	14,612	75,066
Total liabilities and Stockholders' equity	$ 56,663	$ 103,017

Source: Synta Pharmaceuticals Corp.

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