



## **Synta Provides Clinical Update and Reports Second Quarter 2012 Financial Results**

August 2, 2012

LEXINGTON, Mass.--(BUSINESS WIRE)--Aug. 2, 2012-- Synta Pharmaceuticals Corp. (NASDAQ: SNTA) today reported financial results for the quarter ended June 30, 2012 and provided clinical program updates.

“We continue to make strong progress in advancing our ganetespib program along two parallel paths to registration: as a monotherapy in certain targeted cancer patient populations, and in combination with chemotherapy in a broader patient population,” said Safi Bahcall, Ph.D., President and CEO. “We expect important clinical results over the next 12 months from trials evaluating both approaches, including interim results from our monotherapy trials and final results from the 240-patient Phase 2b portion of our Phase 2b/3 GALAXY trial in lung cancer.”

Ganetespib is currently being evaluated in over 20 clinical studies, including trials enrolling genetically-defined targeted patient populations – such as ALK+ lung cancer, HER2+ breast cancer, and triple-negative breast cancer – and trials in combination with other anti-cancer agents, such as the GALAXY trial, which evaluates ganetespib plus docetaxel vs. docetaxel alone for the second-line treatment of advanced non-small cell lung cancer.

The safety profile of ganetespib has been favorable in over 600 patients treated to date. The most common adverse event reported with ganetespib has been transient, mild or moderate diarrhea, which can be prevented or effectively managed with standard supportive care. There has been no evidence of the neurotoxicity, bone marrow toxicities, and alopecia characteristic of many chemotherapies.

Preclinical studies have shown monotherapy administration of ganetespib can potentially inhibit some well-known cancer-promoting oncogenes, such as ALK or HER2. In clinical trials as a monotherapy, ganetespib has demonstrated objective responses or anti-tumor activity in patients with ALK+ lung cancer, mutant BRAF lung cancer, mutant KRAS lung cancer, mutant KRAS gastric cancer, HER2+ breast cancer, triple-negative breast cancer, renal cancer, colorectal cancer, and melanoma.

Ganetespib also potentially inhibits certain well-known mechanisms that drive drug-resistance, such as HIF-1alpha and cell-cycle and DNA-repair genes. In preclinical models, ganetespib has been shown to enhance the activity of commonly used anti-cancer agents including chemotherapies (docetaxel, paclitaxel, vincristine, pemetrexed, gemcitabine, cytarabine, carboplatin, cisplatin), hormone therapies (tamoxifen, fulvestrant), kinase inhibitors (temsirolimus, lapatinib, crizotinib, vemurafenib, selumetinib), and others (bortezomib, bevacizumab).

A recently announced interim analysis of the GALAXY lung cancer trial, evaluating the combination of docetaxel and ganetespib vs. docetaxel alone, showed encouraging improvements in PFS, ORR, and OS in the combination arm vs. the control arm. Trials of ganetespib in combination with a

number of other agents have recently been initiated or are planned for later this year.

“We are excited by the potential benefit ganetespib may bring to patients,” continued Dr. Bahcall. “Our recently announced financing creates a strong financial foundation for supporting our plans for ganetespib.”

### **Key accomplishments in the second quarter 2012:**

1. Completion of an interim analysis for the Phase 2b portion of the company’s Phase 2b/3 GALAXY trial in NSCLC.

Highlights included:

a. A 2.5-3x increase in PFS in patients with elevated baseline serum LDH and PFS in patients with mutant KRAS, the co-primary endpoints of the study.

b. An overall survival improvement in patients with adenocarcinoma, a key secondary endpoint.

c. A favorable safety profile, consistent with previous findings.

d. Differential activity in patients with adenocarcinoma and squamous cell histologies, as has also been seen with anti-angiogenic agents such as VEGF inhibitors. This pattern is consistent with preclinical results demonstrating anti-angiogenic properties of ganetespib, including inhibition of VEGF production in cancer cells and reduction in tumor vascularization. The trial has been amended to enroll adenocarcinoma patients only.

2. Initiation of the Phase 2 CHIARA trial evaluating ganetespib monotherapy for the treatment of ALK+ NSCLC patients not previously treated with a direct ALK inhibitor such as crizotinib.

Design of this study was based on results of a Phase 2 lung cancer trial, initially reported at ASCO 2011, which demonstrated durable objective responses in 4 of 8 patients (50%) identified as ALK+, and who were not previously treated with a direct ALK inhibitor. In preclinical models, treatment with ganetespib led to the degradation of the ALK protein and was effective in killing a broad panel of ALK+ cell lines resistant to treatment with crizotinib and other direct ALK inhibitors.

3. Initiation of the Phase 2 ENCHANT trial evaluating ganetespib monotherapy for the first-line treatment of metastatic HER2+ and triple-negative breast cancer.

Design of this study was based on positive results seen in earlier studies with ganetespib monotherapy in both HER2+ and triple-negative breast cancer patients. Evidence of anti-cancer activity in HER2+ disease has also been seen in preclinical and clinical studies with the first-generation Hsp90 inhibitor, 17-AAG.

4. Initiation of enrollment in several investigator-sponsored trials including:

a. A Phase 1/2 trial of ganetespib in combination with crizotinib for treatment of ALK+ NSCLC being conducted at Memorial Sloan Kettering Cancer Center in New York.

b. A randomized Phase 2 trial of ganetespib in combination with fulvestrant for treatment of hormone positive breast cancer being conducted at the Dana-Farber Cancer Institute in Boston.

c. A Phase 1 trial of ganetespib in combination with radiotherapy and capecitabine for treatment of rectal cancer being conducted at the Winship Cancer Institute at Emory University.

d. A Phase 1/2 trial of ganetespib both as a single agent and in combination with bortezomib for the treatment of multiple myeloma. This is a multi-center trial being conducted in collaboration with the Multiple Myeloma Research Foundation (MMRF).

5. Presentation of company sponsored studies at the 2012 meeting of the American Society of Clinical Oncologists (ASCO):

a. Preclinical activity of ganetespib in ALK, ROS, and RET driven cancers: results showed potent single-agent activity against cancer lines resistant to direct ALK inhibitors, as well as synergistic activity of ganetespib and crizotinib in ALK+ tumor models

b. Ocular toxicity profiles of Hsp90 inhibitors: certain Hsp90 inhibitors have shown a high incidence of ocular toxicity in clinical trials; ganetespib and 17-AAG have not. Results showed that these other Hsp90 inhibitors accumulated in the retina and led to pronounced retinal damage in *in vivo* models, whereas ganetespib and 17-AAG did not.

c. Final results from the Phase 1b trial evaluating the ganetespib plus docetaxel combination, as used in the GALAXY trial, which demonstrated favorable safety.

### **Upcoming milestones**

As previously announced, Synta intends to complete a second interim analysis of the Phase 2b portion of the GALAXY trial in Q3 2012. Results are planned for presentation at the September 28 – October 2 2012 meeting of the European Society for Medical Oncology (ESMO). Synta also plans to meet with regulatory agencies and transition to the Phase 3 portion of the GALAXY trial before the end of this year.

Based on current estimates, Synta expects to complete enrollment of the 240-patient Phase 2b portion of the GALAXY trial in Q4 2012 and have final data from this portion of the study in the first half of 2013. Also based on current estimates, Synta expects preliminary results from the CHIARA and ENCHANT trials by the end of this year.

### **Financial Results**

There were no revenues in the second quarter in 2012 compared to total revenue of \$1.4 million for the same period in 2011. The Company reported a net loss of \$14.6 million or \$0.25 per basic and diluted share for the second quarter in 2012, compared to a net loss of \$12.5 million, or \$0.26 per basic and diluted share for the same period in 2011.

Research and development expenses were \$11.3 million for the second quarter in 2012 compared to \$10.4 million for the same period in 2011. General and administrative expenses were \$2.9 million for the second quarter in 2012 compared to \$2.9 million for the same period in 2011.

As of June 30, 2012, the Company had \$44.7 million in cash, cash equivalents and marketable securities as compared to \$39.7 million in cash, cash equivalents and marketable securities as of December 31, 2011.

In July 2012, the Company raised approximately \$25.8 million in net proceeds from the sale of 3,976,702 shares of its common stock at a purchase price of \$6.49 per share in a registered direct offering to certain of its directors, including its largest stockholder. These shares were sold directly to these directors without a placement agent, underwriter, broker or dealer.

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 2, 2012.

## **Guidance**

Based on our current operating levels, the Company expects its cash resources of approximately \$70.5 million, which includes the \$25.8 million in net proceeds raised in the registered direct offering in July 2012, will be sufficient to fund operations into the second half of 2013. This estimate assumes no additional funding from new partnership agreements or equity financing events. Certain activities contemplated for 2012 and 2013 will be conducted subject to the availability of sufficient financial resources.

## **Conference Call**

Management will conduct a conference call at 10:00 a.m. (ET) today to review the Company's second-quarter financial results. 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](http://www.syntapharma.com), prior to the event.

The call also can be accessed by dialing (877) 407-8035 or (201) 689-8035 prior to the start of the call. For those unable to join the live conference call, a replay will be available from 2:00 p.m. (ET) on August 2 through midnight (ET) on August 9. To access the replay, dial (877) 660-6853 or (201) 612-7415 and refer to both account number 286 and conference ID 397604. The webcast also will be archived on the Company's website.

## **About Ganetespib**

Ganetespib is a potent inhibitor of heat shock protein 90 (Hsp90) that is structurally unrelated to first-generation, ansamycin-related Hsp90 inhibitors. In preclinical experiments, ganetespib has shown activity in multiple tumor models both as a single agent and in combination with certain widely used cancer agents. Company-sponsored clinical trials with ganetespib include the Phase 2b/3 GALAXY Trial<sup>(TM)</sup> evaluating ganetespib in combination with docetaxel for second-line treatment of non-small cell lung cancer (NSCLC); the CHIARA<sup>(TM)</sup> trial, evaluating ganetespib monotherapy in ALK+ NSCLC; and the ENCHANT<sup>(TM)</sup> trial evaluating ganetespib monotherapy as first-line treatment for HER2+ and triple-negative metastatic breast cancer. In addition, ganetespib is being evaluated in investigator-sponsored trials including lung, breast, prostate, gastric, pancreatic, and colorectal cancers as well as melanoma, ocular melanoma, acute myeloid leukemia and multiple myeloma. 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 clinical trials with ganetespib can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

## **About the GALAXY Trial**

The GALAXY (**G**anetespib **A**ssessment in **L**ung **c**Ancer with doceta**X**el) trial is a randomized Phase 2b/3 trial comparing the combination of ganetespib and docetaxel versus docetaxel alone in patients with Stage IIIB/IV NSCLC who have received one prior systemic therapy. More information about the GALAXY trial can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (NCT01348126).

### **About the CHIARA Trial**

The CHIARA (**C**Haperone **I**nhibition in **A**lk **R**earranged lung **c**Ancer) trial is a single arm, Phase 2 study evaluating ganetespib monotherapy in patients with Stage IIIB/IV non-small-cell lung cancer harboring an ALK gene rearrangement and who have not been previously treated with a direct ALK inhibitor. The primary endpoint of the study is objective response rate. A total of 110 patients are planned for accrual. More information about the CHIARA trial can be found at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (NCT01562015).

### **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](http://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 timing, development and progress of our preclinical and clinical programs, including plans to complete a second interim analysis of the Phase 2b portion of the GALAXY trial in Q3 2012, to complete enrollment of the Phase 2b portion of the GALAXY trial in Q4 2012, to transition to the Phase 3 portion of the GALAXY trial before the end of this year, to have final data from the Phase 2b portion of the study in the first half of 2013, timing of preliminary data for the ENCHANT and CHIARA trials, and the sufficiency of our cash resources to fund operations into the second half of 2013, 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, 2011 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 June 30,		Six Months Ended June 30,	
	2012	2011	2012	2011
Revenues:				
Collaboration revenues:				
License and milestone revenue	\$ —	\$ 1,143	\$ —	\$ 2,286
Total collaboration revenues	—	1,143	—	2,286
Grant revenues	—	211	147	211
Total revenues	—	1,354	147	2,497
Operating expenses:				
Research and development	11,252	10,417	23,318	19,854
General and administrative	2,882	2,946	5,528	5,618
Total operating expenses	14,134	13,363	28,846	25,472
Loss from operations	(14,134 )	(12,009 )	(28,699 )	(22,975 )
Interest expense, net	(486 )	(493 )	(972 )	(928 )
Net loss	\$(14,620 )	\$(12,502 )	\$(29,671 )	\$(23,903 )
Basic and diluted net loss per common share	\$(0.25 )	\$(0.26 )	\$(0.52 )	\$(0.53 )
Basic and diluted weighted average number of common shares outstanding	57,650,412	47,845,315	57,008,702	44,943,190

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

	June 30, 2012	December 31, 2011
<b>Assets</b>		
Cash, cash equivalents and marketable securities	\$ 44,656	\$ 39,725
Other current assets	839	561
Property, plant and equipment, net	1,166	1,407
Other non-current assets	503	631

Total assets	\$ 47,164	\$ 42,324
<b>Liabilities and Equity</b>		
Current liabilities	\$ 18,254	\$ 15,148
Long-term liabilities	8,446	12,402
Stockholders' equity	20,464	14,774
Total liabilities and	\$ 47,164	\$ 42,324

Stockholders' equity

Source: Synta Pharmaceuticals Corp.

Synta Pharmaceuticals Corp.  
George Farmer, 781-541-7125