# Synta Provides Clinical Update and Reports Third Quarter 2012 Financial Results

November 6, 2012

*– GALAXY Phase 2b trial achieves 240-patient enrollment goal, final results expected 2013 –*

*– End-of-Phase 2 FDA meeting completed –*

*– Phase 3 ganetespib lung cancer trial initiating, final results expected 2014 –*

*– First patients treated in ENCHANT breast cancer trial and LI-1 randomized AML trial –*

LEXINGTON, Mass.--(BUSINESS WIRE)--Nov. 6, 2012-- Synta Pharmaceuticals Corp. (NASDAQ: SNTA) today reported financial results for the third quarter ended September 30, 2012 and provided clinical program updates regarding its lead oncology drug candidate, ganetespib, a potent and selective Hsp90 inhibitor.

“Clinical development of ganetespib has progressed exceptionally well this year, culminating with the recent presentation of positive interim results from the first stage of our 800-patient Phase 2b/3 randomized GALAXY program in non-small cell lung cancer,” said Safi Bahcall, Ph.D., President and CEO. “These encouraging results in combination with docetaxel, together with the previously reported promising results with ganetespib monotherapy in certain targeted patient populations, create exciting opportunities for multiple paths to registration and a unique product profile. We have been pleased with the strong support for this program in the medical oncology community, reflected in increasing rates of enrollment across all our trials and a growing number of third-party supported programs. We are looking forward to upcoming results from GALAXY and our other programs, and to realizing our goal of creating a new treatment option for cancer patients.”

Ganetespib is currently being evaluated in over 20 clinical studies. In addition to the activity observed in the GALAXY combination therapy trial, objective responses or durable anti-tumor activity have been observed with ganetespib monotherapy in patients with lung cancer, breast cancer, gastric cancer, colorectal cancer, renal cancer, and melanoma. The safety profile of ganetespib has been favorable in over 600 patients treated to date, with transient, mild or moderate diarrhea as the most common adverse event reported.

**Key accomplishments in the third quarter of 2012:**

1. At the 2012 Congress of the European Society for Medical Oncology (ESMO), investigators reported results from the second interim efficacy analysis of the Phase 2b portion of the GALAXY trial. There were 172 adenocarcinoma patients in the clinical database at the time of the September 10 cutoff for this analysis.

Highlights included:

a) An increase in overall survival was observed in adenocarcinoma patients treated with ganetespib plus docetaxel. A median overall survival of 7.4 months was observed in the docetaxel control arm, while median overall survival had not been reached in the ganetespib arm. Results for docetaxel were consistent with results from prior second line non-small cell lung cancer (NSCLC) therapy trials.

b) Objective response rate and progression-free survival in adenocarcinoma patients were also improved: from 8% to 16%, and from 2.8 months to 4.2 months, in the control arm vs. ganetespib arm, respectively. Overall response and progression-free survival rates in the control arm were consistent with results from prior trials with docetaxel in this setting.

c) Results in several GALAXY patient subpopulations, defined by pre-specified clinical and biomarker characteristics, showed a substantially improved survival difference between the control arm and ganetespib arm, as compared with the difference in the all-comer (intent-to-treat) adenocarcinoma patient population. These findings have been incorporated into the design of the Phase 3 portion of the GALAXY program, with the objective of enriching for patients likely to derive the greatest benefit from ganetespib treatment.

d) Clinical and preclinical results were presented that suggest potent ganetespib anti-angiogenic activity. Analyses of tumor samples from patients treated with ganetespib showed a reduction of levels of hypoxia induced factor (HIF) and vascular endothelial growth factor (VEGF). In addition, preclinical experiments demonstrated strong inhibition of tumor vasculature by ganetespib. These results suggest ganetespib offers a novel way to inhibit angiogenesis: reducing production of angiogenesis factors, rather than targeting those signaling factors directly with an antibody (e.g. bevacizumab) or a kinase inhibitor.

e) A favorable safety profile was observed with the ganetespib plus docetaxel combination in adenocarcinoma patients. Transient, mild-to-moderate diarrhea was the most common adverse event, consistent with observations from other clinical trials evaluating ganetespib.

2. Completion of a registered direct common stock offering with net proceeds of approximately $25.8 million.

**GALAXY Phase 2b**

The 240 adenocarcinoma patient enrollment target for the Phase 2b portion of the GALAXY trial was achieved in October. Per protocol, additional adenocarcinoma patients with elevated baseline levels of lactate dehydrogenase (LDH) or with tumors exhibiting KRAS mutations, which are pre-specified patient subpopulations with especially high medical need, may continue to be enrolled until a specified maximum number of patients with these characteristics has been achieved. We expect to enroll up to 60 additional patients in these subpopulations.

Based on our current projections, Synta anticipates final progression free survival (PFS) and updated overall survival data from the Phase 2b portion of GALAXY in the first half of 2013, and final overall survival data in the second half of 2013.

**GALAXY Phase 3**

Synta recently completed an End-of-Phase 2 (EOP2) meeting with the Food and Drug Administration (FDA) to review plans for the Phase 3 portion of the GALAXY program. Synta has

incorporated comments from the EOP2 meeting into the Phase 3 protocol and is currently initiating this trial. Enrollment is expected to begin early next year.

The Phase 3 trial has the same design as the Phase 2b trial. Adenocarcinoma patients with advanced NSCLC who have received one prior chemotherapy regimen will be randomized 1:1 to treatment with either docetaxel plus ganetespib or docetaxel alone. The same dose and schedule used in the Phase 2b trial will be used in the Phase 3 trial. Patients on both arms will receive docetaxel generally for four to six 21-day cycles, as per standard practice at their treatment center. After completion of docetaxel treatment, patients on the ganetespib arm are eligible to continue to receive ganetespib monotherapy as maintenance treatment. The trial will be conducted in many of the 60 centers across Europe and North America that participated in the Phase 2b trial, together with up to 60 additional centers.

The Phase 3 trial will enroll approximately 500 adenocarcinoma patients and overall survival will be the primary endpoint. Based on results from the Phase 2b trial, the Phase 3 trial will exclude patients who experienced rapidly progressing disease, an estimated 30 to 40% of the total eligible population. The resulting population, which excludes rapidly progressing patients, showed a substantially enhanced survival difference between the ganetespib arm and the control arm in the Phase 2b trial as compared to the survival difference observed in the total population.

Two event-driven interim analyses for the Phase 3 trial have been specified. Based on current projections and statistical assumptions, the Company expects these analyses, together with the final analysis, to occur in 2014. Additional elements of the Phase 3 trial design will be announced following the start of enrollment.

**Additional clinical updates**

- A pre-specified interim analysis of the first 20 patients in the CHIARA trial, which evaluates ganetespib monotherapy in ALK+ NSCLC patients previously untreated with a direct ALK inhibitor, is expected to occur in the first half of 2013.
- An investigator-sponsored trial evaluating the combination of ganetespib plus crizotinib in patients with ALK+ NSCLC that have not been previously treated with an ALK inhibitor continues enrolling and treating patients at Memorial Sloan-Kettering Cancer Center.
- The first patient was treated in the ENCHANT trial, evaluating ganetespib monotherapy for the treatment of HER2 positive and triple negative metastatic breast cancer. The Company expects to report preliminary data from this trial in the first half of 2013.
- The first patient was treated with ganetespib in a randomized Phase 2/3 cooperative group study evaluating ganetespib plus low dose ara-C (LDAC) vs. LDAC alone for the treatment of elderly patients with acute myeloid leukemia (AML) who are unable to tolerate intensive chemotherapy. This “Less Intensive 1” (LI-1) study evaluates a number of treatments in this randomized setting. Additional information is available at http://www.controlled-trials.com/ISRCTN40571019.
- A European cooperative group plans to initiate a randomized trial comparing paclitaxel with and without ganetespib in patients with advanced ovarian cancer in 2013

**Financial Results**

There were no revenues in the third quarter of 2012 as compared to $1.7 million dollars of revenues in the same period of 2011 which consisted of amortization of an upfront payment under the Roche

agreement that was terminated at the end of 2011, and grant revenues.

In the third quarter of 2012 research and development expenses were $11.7 million dollars as compared to $10.8 million dollars for the same period of 2011. Third quarter general and administrative expenses were $2.8 million dollars as compared to $3.1 million dollars for the comparable period in 2011.

In the third quarter of 2012 the Company's net loss was $15.0 million dollars or $0.25 cents per basic and diluted share as compared to a net loss of $12.7 million dollars or $0.26 cents per basic and diluted share in the same period of 2011.

As of September 30, 2012 the Company had approximately $55.1 million dollars of cash resources on hand. This includes net proceeds from the registered direct common stock offering to certain members of the Board of Directors in July 2012.

**Guidance**

The Company expects to end 2012 with $38-$40 million in cash, cash equivalents and marketable securities. Based on our current operating levels we expect these cash resources will be sufficient to fund operations into the second half of 2013. These estimates assume no additional funding from new partnership agreements or equity financing events, and that the timing and nature of activities contemplated for 2013 will be conducted subject to the availability of sufficient financial resources.

**Conference call**

Management will conduct a conference call at 10:00 AM (EST) today to discuss clinical updates and third 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, 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 PM (EST) on November 6 through midnight (EST) on November 13. To access the replay, dial (877) 660-6853 or (201) 612-7415 and refer to conference ID 401666. The webcast will also 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 1) the GALAXY Phase 2b/3 trial evaluating ganetespib in combination with docetaxel as second-line treatment of non-small cell lung cancer (NSCLC), 2) the CHIARA Phase 2 trial evaluating ganetespib monotherapy in ALK positive NSCLC, and 3) the ENCHANT Phase 2 trial evaluating ganetespib as first-line treatment for HER2 positive 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 ocular melanoma, acute myeloid leukemia and multiple myeloma. Information on these trials can be found at www.clinicaltrials.gov.

**About the GALAXY Trial™**

The GALAXY (**G**anetespib **A**ssessment in **L**ung c**A**ncer 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 (NCT01348126).

**About Hsp90**

Hsp90 is a molecular chaperone required for the proper folding and activation of many cancer-promoting proteins, and is recognized as a key facilitator of cancer cell growth and survival. Many of the “client proteins” of Hsp90 – such as ALK, AKT, BCR-ABL, BRAF, KIT, MET, EGFR, FLT3, HER2, HIF-1alpha, PDGFRA, VEGFR are the targets of clinically validated cancer drugs. In preclinical studies, inhibiting Hsp90 causes the degradation of multiple client proteins and leads to cancer cell death.

**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 contains 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, developments and progress of our GALAXY trial, our clinical development plans for ganetespib, the expected timing for the release of data from clinical trials of ganetespib, our expected cash, cash equivalents and marketable securities as of the end of 2012, the sufficiency of our cash resources to fund operations into the second half of 2013, and the anticipated design of the Phase 3 portion of the GALAXY 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. Those risks and uncertainties include whether the results from the interim analysis of the Phase 2b portion of the GALAXY trial will be consistent with future data from the Phase 2b portion and the Phase 3 stage of the trial; whether the results at the conclusion of the Phase 2b portion of the trial will demonstrate safety and statistically significant efficacy; challenges with respect to patient enrollment or other delays in our clinical development plans; as well as other risks and uncertainties described in the "Risk Factors" section of our Form 10-K for the year ended December 31, 2011, as filed with the Securities and Exchange Commission, including those under the heading “Risks Related to the Development and Regulatory Approval of our Drug Candidates.” 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, | |
|---|---|---|---|---|
| | **2012** | **2011** | **2012** | **2011** |
| Revenues: | | | | |
| Collaboration revenues: | | | | |
| License and milestone revenue | $ — | $ 1,143 | $ — | $ 3,429 |
| Total collaboration revenues | — | 1,143 | — | 3,429 |
| Grant revenues | — | 521 | 147 | 732 |
| Total revenues | — | 1,664 | 147 | 4,161 |
| Operating expenses: | | | | |
| Research and development | 11,743 | 10,751 | 35,061 | 30,605 |
| General and administrative | 2,796 | 3,131 | 8,324 | 8,749 |
| Total operating expenses | 14,539 | 13,882 | 43,385 | 39,354 |
| Loss from operations | (14,539) | (12,218) | (43,238) | (35,193) |
| Interest expense, net | (457) | (516) | (1,429) | (1,444) |
| Net loss | $ (14,996) | $ (12,734) | $ (44,667) | $ (36,637) |
| Basic and diluted net loss per common share | $ (0.25) | $ (0.26) | $ (0.77) | $ (0.79) |
| Basic and diluted weighted average number of common shares outstanding | 60,661,720 | 49,403,589 | 58,235,263 | 46,446,328 |

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

| | **September 30, 2012** | **December 31, 2011** |
|---|---|---|
| **Assets** | | |
| Cash, cash equivalents and marketable securities | $ 55,139 | $ 39,725 |

| | | |
|---|---|---|
| Other current assets | 803 | 561 |
| Property, plant and equipment, net | 1,205 | 1,407 |
| Other non-current assets | 466 | 631 |
| Total assets | $ 57,613 | $ 42,324 |
| | | |
| **Liabilities and Equity** | | |
| Current liabilities | $ 18,965 | $ 15,148 |
| Long-term liabilities | 6,458 | 12,402 |
| Stockholders' equity | 32,190 | 14,774 |
| | | |
| Total liabilities and Stockholders' equity | $ 57,613 | $ 42,324 |

Source: Synta Pharmaceuticals Corp.

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