

# Synta Provides Clinical Update and Reports Fourth Quarter and Year End 2011 Financial Results

February 22, 2012

LEXINGTON, Mass.--(BUSINESS WIRE)--Feb. 22, 2012-- Synta Pharmaceuticals Corp. (NASDAQ: SNTA) today provided an update on recent progress with its clinical programs and reported financial results for the quarter and year ended December 31, 2011.

"This past year Synta made substantial progress in developing ganetespib – including demonstrating clinical activity in certain types of lung and breast cancer; reinforcing the differentiated, favorable safety profile; and initiating a comprehensive development plan that allows for multiple paths to registration with important data readouts in 2012," said Safi Bahcall, Ph.D., President and CEO. "The clinical activity together with the favorable safety profile have established ganetespib as the leading Hsp90 inhibitor in the industry and have helped generate the broad support for our company-sponsored trials in lung and breast cancer – as well as for the over 15 investigator- or third-party-sponsored trials in lung, breast, and other cancers."

Over 500 patients have been treated to date in clinical trials with ganetespib. The most common adverse event seen with ganetespib has been mild to moderate diarrhea, which has been transient and manageable with standard supportive care. There has been no evidence of the common ocular toxicities and serious liver toxicities reported with some other Hsp90 inhibitors; or the neurotoxicity, bone marrow toxicities, or alopecia characteristic of many chemotherapies.

"We are particularly excited that ganetespib has the potential to be the first compound to realize the therapeutic potential of chaperone inhibition," continued Dr. Bahcall. "This is an entirely distinct approach to interrupting cancer cell signaling than either directly inhibiting a kinase with a small molecule, or directly binding a growth factor with a monoclonal antibody. We are hopeful that ganetespib can provide a new approach to treating cancer, which is different than, and potentially complementary to kinase inhibitors, monoclonal antibodies, and chemotherapy."

Synta is currently initiating a global clinical trial in patients with advanced non-small cell lung cancer whose tumors show an ALK gene rearrangement (ALK+ NSCLC), and a global clinical trial in patients with breast cancer whose tumors show either a HER2+ or triple-negative genetic profile. The GALAXY trial – a Phase 2b/3 trial evaluating ganetespib in combination with docetaxel vs. docetaxel alone in patients with advanced lung cancer who have progressed following one prior treatment – was initiated in 2011 and is currently enrolling patients in the U.S. and Europe.

Ganetespib is a potent inhibitor of heat shock protein 90 (Hsp90) that is structurally unrelated to first-generation, ansamycin-family Hsp90 inhibitors such as 17-AAG, 17-DMAG and IPI-504.

#### **Ganetespib Clinical Update**

Highlights of Recent Ganetespib Results and 2011 Achievements

#### • Activity in ALK+ NSCLC

- Results presented at ASCO in 2011 showed a 50% (4/8) objective response rate and 88% (7/8) disease control rate following treatment with ganetespib monotherapy (singleagent) in patients with advanced ALK+ NSCLC. These patients had previously failed to respond to, or progressed following treatment with, multiple prior treatments for advanced NSCLC, including combination chemotherapy. Responses were durable, with patients remaining on treatment an average of approximately one year.
- Preclinical results demonstrated that ganetespib activity is complementary to direct ALK inhibition (e.g. crizotinib) – suggesting promising potential for combination treatment in ALK+ NSCLC patients.

### · Activity in breast cancer

Ganetespib is the first Hsp90 inhibitor to show single-agent activity in breast cancer.
 Results presented at the San Antonio Breast Cancer Symposium in 2011 showed encouraging anti-tumor activity in both HER2+ and triple-negative breast cancer.

#### Favorable safety

Over 500 patients have been treated to date in trials with ganetespib. Results from ongoing safety reviews are consistent with previously reported findings: absence of the common ocular toxicities and serious liver toxicities seen with other Hsp90 inhibitors; and an absence of the neurotoxicity, bone marrow toxicities, or alopecia characteristic of chemotherapy. The most common adverse event seen with ganetespib has been transient, mild to moderate diarrhea, which has been manageable with standard supportive care.

#### Physicochemical properties

o Synta scientists published preclinical results of physicochemical properties of ganetespib believed to contribute to the improved safety and activity profile seen relative to other Hsp90 inhibitors. These include smaller molecular weight, greater potency, greater lipophilicity, ability of ganetespib to enter the ATP binding pocket of Hsp90 in either the open- or closed-pocket lid conformation, ability of ganetespib to penetrate deep into tumor tissues, absence of the benzoquinone moiety in ganetespib's molecular structure, and reduced accumulation in the retina.

#### Synergy with other anti-cancer agents

 Hsp90 is believed to be critical for cancer cells' abilities to recover or resist a range of stresses – including those induced by certain chemotherapeutic and targeted agents. Synta scientists and collaborators published preclinical results showing synergistic activity of ganetespib with paclitaxel, docetaxel, cisplatin, carboplatin, PI3K/mTOR inhibitors, MEK inhibitors, HER2 inhibitors, and other widely used agents.

#### Parallel paths to registration

- Designed and initiated a comprehensive clinical plan that can potentially lead to seven or more separate paths to registration, with meaningful data readouts expected in 2012.
- The GALAXY trial de-risks the path to registration in second-line lung cancer through a two-stage Phase 2b/3 design – using the biomarker and subpopulation results, as well as operational experience, gained in the first-stage, 240-patient Phase 2b portion, to de-risk the second-stage, Phase 3 portion.
- Identified targeted patient populations, such as ALK+ NSCLC, HER2+ breast cancer, and triple-negative breast cancer with encouraging single-agent activity.
- Designed and initiated a development plan in these targeted patient populations that offers complementary paths to registration to the populations being evaluated in the GALAXY trial.

- Built third-party support for additional proof-of-concept trials in lung cancer, breast cancer, colon cancer, prostate cancer, melanoma, AML, and multiple myeloma already initiated, or expected to initiate in 2012.
- Scientific and medical community awareness
  - Over 15 investigator-sponsored, foundation-sponsored, or cooperative-group sponsored trials already initiated or expected to initiate in 2012.

#### Expected 2012 Ganetespib Milestones

- GALAXY trial: Phase 2b/3 trial evaluating ganetespib in combination with docetaxel vs. docetaxel alone in patients with advanced NSCLC who have progressed following one prior treatment for metastatic disease
  - Complete enrollment of 240-patient, first-stage Phase 2b portion in Q2
  - o Interim Phase 2b results in Q2
  - Final PFS data and preliminary OS data from Phase 2b portion in 2H
  - Initiate Phase 3 portion in 2H, based on results from Phase 2b
- ALK+ trial: monotherapy ganetespib treatment in advanced NSCLC patients previously untreated with ALK inhibitor
  - Preliminary results by year-end
- Breast cancer trial: HER2+ and triple-negative breast cancer patients
  - Preliminary results by year-end
- Investigator, foundation, or cooperative group trials initiating in 2012:
  - Trial in combination with crizotinib in ALK+ NSCLC
  - Trial in combination with paclitaxel and Herceptin® in HER2+ breast cancer, and in combination with paclitaxel in triple-negative breast cancer
  - Trial in combination with Velcade® in multiple myeloma
  - Trial in combination with radiotherapy in rectal cancer
  - Randomized trial in elderly patients with acute myeloid leukemia in combination with the chemotherapy drug ara-C

"We have worked closely with investigators over the past year to develop a diversified, risk-mitigated registration plan," said Dr. Vojo Vukovic, Chief Medical Officer. "The results to date with ganetespib in lung cancer, breast cancer, and certain other tumors – together with the very strong preclinical results and supportive results seen with other Hsp90 inhibitors – form a very compelling picture. The results in ALK+ NSCLC position this program on the cutting edge of available treatment options, and we have seen this resonate strongly with leading investigators in U.S., Europe, and Asia."

#### **Additional Programs at Synta**

In addition to progress with our ganetespib program in 2011, we also made significant progress with our elesclomol and CRAC programs. For our elesclomol program we published preclinical results demonstrating that elesclomol triggers cancer cell apoptosis by disrupting mitochondrial energy metabolism, potentially establishing elesclomol as a leading compound in the emerging field of anti-cancer therapies targeting cancer cell metabolism. We also continued development of elesclomol in patients with advanced ovarian cancer, in a trial being conducted by the Gynecologic Oncology Group and supported by the National Cancer Institute; and in acute myeloid leukemia, working closely with a leading cancer center in Canada. For our CRAC program, our scientists developed a number of distinct families of preclinical stage compounds that exhibited a favorable

safety and activity profile in inflammatory disease models.

#### **Additional Updates**

Please go to www.syntapharma.com for additional details.

#### Fourth Quarter and Full Year 2011 Financial Results

In the fourth quarter of 2011, Synta recognized total revenue of \$3.4 million compared to \$4.0 million for the same period in 2010. Total revenue was \$7.6 million for the year ended December 31, 2011 compared to \$14.8 million for the same period in 2010.

Research and development expenses were \$10.9 million for the fourth quarter in 2011 compared to \$9.3 million for the same period in 2010. Research and development expenses were \$41.5 million for the year ended December 31, 2011 compared to \$40.3 million for the same period in 2010.

General and administrative expenses were \$2.8 million for the fourth quarter in 2011 compared to \$3.1 million for the same period in 2010. General and administrative expenses were \$11.5 million for year ended December 31, 2011 compared to \$11.4 million for the same period in 2010.

The Company reported a net loss of \$10.7 million or \$0.22 per basic and diluted share in the fourth quarter of 2011, compared to a net loss of \$8.8 million or \$0.21 per basic and diluted share for the same period in 2010. For the year ended December 31, 2011, the Company reported a net loss of \$47.4 million or \$1.00 per basic and diluted share, compared to a net loss of \$37.5 million or \$0.93 per basic and diluted share for the same period in 2010.

As of December 31, 2011, the Company had \$39.7 million in cash, cash equivalents and marketable securities compared to \$51.0 million as of December 31, 2010.

In January and February 2012, the Company raised approximately \$33.0 million in net proceeds from the sale of an aggregate of 8,050,000 shares of its common stock in a public offering at a public offering price of \$4.40 per share, including 7,000,000 shares in the initial closing in January 2012 and 1,050,000 shares in a second closing in February 2012 following the full exercise of the over-allotment option granted to the underwriters.

More detailed financial information and analysis may be found in the Company's Annual Report on Form 10-K, which was filed with the Securities and Exchange Commission on February 22, 2012.

#### Guidance

Based on our current operating levels, the Company expects its cash resources, including the \$33.0 million in net proceeds raised in the January and February 2012 public offering, will be sufficient to fund operations into the first half of 2013. This estimate assumes no additional funds from new partnership agreements or equity financing events. Certain activities contemplated for 2012 would be conducted subject to the availability of additional financial resources.

#### **Conference Call**

Management will conduct a conference call at 10:00 a.m. (ET) this morning to review the Company's fourth-quarter and year-end 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, <a href="https://www.syntapharma.com">www.syntapharma.com</a>, 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 February 22 through midnight (ET) on February 29. To access the replay, dial (877) 660-6853 or (201) 612-7415 and refer to both account number 286 and conference ID 388181. The webcast also will be archived on the Company's website.

#### **About Ganetespib**

Ganetespib (formerly STA-9090) is a potent, synthetic, small-molecule inhibitor of heat shock protein 90 (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. 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. Ganetespib is currently being evaluated in a broad range of cancer clinical trials. In these trials, ganetespib has shown clinical activity in heavily pretreated patients and has been well tolerated to date with no evidence of severe liver or common ocular toxicities seen with other Hsp90 inhibitors. 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 <a href="https://www.clinicaltrials.gov">www.clinicaltrials.gov</a>.

### About the Phase 2b/3 GALAXY Trial<sup>TM</sup> in NSCLC

The Phase 2b/3 trial will evaluate treatment with ganetespib and docetaxel vs. docetaxel alone, with 1:1 randomization, in patients with Stage IIIB or IV NSCLC who have completed one prior systemic therapy for advanced disease. The first stage, Phase 2b portion, will assess efficacy as measured by progression-free survival in approximately 240 patients. Results from this stage will also be used to inform the choice of patient subpopulation, by histology or biomarker, or other disease characteristic for the second stage, Phase 3 portion. The second stage will enroll between 400 and 600 patients. Interim results from the first-stage portion of the trial are expected in Q2 2012. More information on the trial can be found at www.clinicaltrials.gov.

#### **About Non-small Cell Lung Cancer**

Lung cancer is the leading cause of cancer-related mortality in the United States, with over 226,000 new cases and 160,000 deaths estimated in 2012 according to the American Cancer Society. The five year survival rate for advanced-staged lung cancer is approximately 4%. Approximately 85% of all lung cancers are classified as non-small cell. Estimates for the global incidence of ALK+ NSCLC range from 40,000 to 70,000 new cases per year.

#### **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 <a href="https://www.syntapharma.com">www.syntapharma.com</a>.

#### **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 clinical and preclinical programs, including the generation of significant data readouts in 2012 for ganetespib; the information set forth above under the heading "Expected 2012 Ganetespib Milestones"; and the sufficiency of our cash resources to fund operations into the first 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 December 31,		Twelve Months Ended December 31,		
	2011	2010	2011	2010	
Collaboration revenues:					
License and milestone revenue	\$3,302	\$1,143	\$6,731	\$4,572	
Cost sharing reimbursements, net		1,916	_	9,253	
Total collaboration revenues	3,302	3,059	6,731	13,825	
Grant revenue	121	978	853	978	
Total revenues	3,423	4,037	7,584	14,803	
Operating expenses:					
Research and development	10,859	9,347	41,464	40,252	
General and administrative	2,803	3,055	11,552	11,449	
Total operating expenses	13,662	12,402	53,016	51,701	

Loss from operations	(10,239	) (8,365	) (45,432	) (36,898	)
Interest expense, net	(504	) (458	) (1,948	) (569	)
Net loss	\$(10,743	) \$(8,823	) \$(47,380	) \$(37,467	)
Basic and diluted net loss per common share	\$(0.22	) \$(0.21	) \$(1.00	) \$(0.93	)
Basic and diluted weighted average number of					
common shares outstanding	49,426,80	6 41,263,62	8 47,197,57	2 40,365,21	5

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

## December 31, 2011 December 31, 2010

#### **Assets**

Cash, cash equivalents and marketable securities	\$	39,725	\$	50,973				
Other current assets Property and equipment, net		561 1,407		547 2,181				
Other non-current assets		631		366				
Total assets	\$	42,324	\$	54,067				
Liabilities and Equity								
Current liabilities Long-term liabilities	\$	15,148 12,402	\$	16,736 13,852				
Stockholders' equity		14,774		23,479				
Total liabilities and Stockholders' equity	\$	42,324	\$	54,067				

Source: Synta Pharmaceuticals Corp.

Synta Pharmaceuticals Corp. Rob Kloppenburg, 781-541-7125