

# Synta Reports First Quarter 2014 Financial Results and Provides Corporate Update

May 8, 2014

Encouraging Final Results from GALAXY-1 Trial Validate Selection of Chemosensitive Patient Population for Ongoing Phase 3 GALAXY-2 Trial

Ganetespib Included in Six Large, Randomized Clinical Trials

\$32.3 Million in Net Proceeds Raised through Common Stock Sales in 2014; Company Announces New At the Market Issuance Sales Agreement

Webcast and Conference Call Today, May 8, at 10:00 AM ET

LEXINGTON, Mass.--(BUSINESS WIRE)--May 8, 2014-- Synta Pharmaceuticals Corp. (NASDAQ: SNTA) today reported financial results for the first quarter ended March 31, 2014 and provided an update on recent corporate events.

"The final results from the GALAXY-1 study in non-small cell lung adenocarcinoma represent a significant addition to the collection of encouraging data that our ganetespib development program has generated in multiple cancer indications and confirms the choice of the chemo-sensitive patient population for the GALAXY-2 Phase 3 trial," said Keith Gollust, Chairman of the Executive Committee of Synta. "Our primary focus for the balance of 2014 will be to maximize the value of our development assets in a cost effective manner."

#### **First Quarter and Recent Updates**

- Results From Final Analysis of GALAXY-1 Study. Synta announced today final results from the global, randomized, multi-center Phase 2b GALAXY-1 study comparing the combination of ganetespib and docetaxel to docetaxel alone for the second-line treatment of advanced non-small cell adenocarcinoma. The final results from this trial, in particular the encouraging overall survival results and tolerability profile in chemosensitive patients, validate the selection of the chemosensitive population for the pivotal Phase 3 GALAXY-2 trial.
- GALAXY-2 Clinical Trial on Track to Meet Data Readout Timelines. Synta announced today that the Company's pivotal, Phase 3 GALAXY-2 trial of ganetespib and docetaxel vs. docetaxel alone for the second-line treatment of patients with advanced non-small cell adenocarcinoma remains on track to meet previously guided data readout timelines. With a target enrollment of approximately 850 patients, and based on current projections and statistical assumptions, Synta expects the two interim efficacy analyses of GALAXY-2 to be conducted by the independent Data Monitoring Committee (DMC) in the second half of 2015 and the final analysis to be conducted in the first half of 2016.

In March 2014, the Company announced that GALAXY-2 is being amended to require prospective testing to exclude patients with ALK translocations and EGFR mutations. The Company also announced in March 2014 that the independent DMC for the GALAXY-2 trial recommended continuing the trial with no change to study conduct following recent completion of its first planned safety analysis.

• ENCHANT-1 Trial Meets Study Objectives; Shifting of Resources to I-SPY 2 Breast Cancer Trial. In March 2014, Synta announced interim results from the ENCHANT-1 trial, a single-arm multi-center Phase 2 proof-of-concept study designed to evaluate ganetespib administered as monotherapy for the treatment of metastatic breast cancer, at the European Breast Cancer Conference (EBCC). These results have confirmed early signals of activity of ganetespib in breast cancer patients, as well as positive results reported with other Hsp90 inhibitors in this tumor type. The strength of the scientific rationale and evidence of clinical activity have led to the selection of ganetespib into the I-SPY 2 program. In this randomized Phase 2 trial, safety and efficacy of ganetespib will be evaluated in combination with standard chemotherapy in patients with triple-negative breast cancer, and if positive, results from this trial will provide a robust proof of concept for ganetespib in this indication. In light of the inclusion of ganetespib in the I-SPY2 program, Synta is closing the ENCHANT-1 trial and directing its resources in breast cancer towards the I-SPY 2 trial.

In March 2014, Synta and QuantumLeap Healthcare Collaborative announced that ganetespib has been selected for study in the I-SPY 2 TRIAL. I-SPY 2 is a standing Phase 2 randomized, controlled, multicenter trial for women with newly diagnosed, locally advanced breast cancer (Stage 2 or higher) that is designed to test whether adding investigational drugs to standard chemotherapy is better than standard chemotherapy alone in the neo-adjuvant setting (prior to surgery). Enrollment in the ganetespib arm of I-SPY 2 is expected to begin in 2014. Ganetespib will initially be available to patients with HER2 negative disease, with the intent to expand its eligibility to all biomarker subtypes after safety testing with trastuzumab is completed.

• Ganetespib Selected for the AML-LI-1, AML-18 and AML-19 Trials in AML/MDS. In January 2014, the Company announced three multicenter, randomized trials, supported by the Leukemia & Lymphoma Research Fund and Cancer Research UK, evaluating ganetespib in combination with chemotherapy in first-line treatment of patients with acute myeloid

leukemia (AML) and high risk myelodysplastic syndrome (MDS). The trials are being conducted under the auspices of the UK National Cancer Research Institute Hematological Oncology Study Group, and under the sponsorship of Cardiff University. The AML-LI (Less Intensive)-1 Phase 2/3 trial, which is currently ongoing, evaluates the combination of ganetespib with low dose cytarabine (Ara-C) vs. low dose Ara-C alone in patients who are not eligible for intensive chemotherapy and are traditionally not included in most trials. An interim analysis will be conducted after 50 patients have been enrolled to evaluate whether to proceed with full Phase 3 enrollment. This interim analysis is expected to be conducted in mid-2014. The AML-18 and AML-19 Phase 2/3 studies are expected to begin enrolling patients in the first and second half of 2014, respectively.

- Ganetespib Selected for the GANNET53 Trial in Ovarian Cancer. In January 2014, the Company announced the initiation of GANNET53, a Seventh Framework Programme (FP7) research project funded by the European Commission, which is a pan-European randomized trial designed to evaluate the combination of ganetespib and paclitaxel vs. paclitaxel alone in over 200 patients with metastatic, predominantly p53 mutant, platinum-resistant ovarian cancer. The safety lead-in Phase 1 portion of GANNET53 is expected to begin enrollment in mid-2014.
- Presented Preclinical Results for Hsp90 Inhibitor Drug Conjugates (HDC). In February and March of 2014, Synta reported on progress with lead compounds from its Hsp90-Inhibitor Drug Conjugate platform at the IASLC 14<sup>th</sup> Annual Targeted Therapies of the Treatment of Lung Cancer Meeting and the 12<sup>th</sup> International Congress on Targeted Anticancer Therapies. The new compounds, consisting of an Hsp90-inhibitor conjugated with SN-38 (HDC SN-38) and an Hsp90-inhibitor conjugated with docetaxel (HDC docetaxel), demonstrated proof of principle in multiple preclinical cancer models. Notably, complete or near complete regressions of tumors were observed in models of NSCLC, small-cell lung cancer, breast cancer, pancreatic cancer, colon cancer, and skin cancer, including models that are generally resistant or show limited response to treatment with the unconjugated therapies.

### First quarter 2014 financial results

There were no revenues recognized in the first guarters of 2014 and 2013.

Research and development expenses were \$17.6 million for the first quarter in 2014, compared to \$16.4 million for the same period in 2013. General and administrative expenses were \$5.3 million for the first quarter in 2014, compared to \$3.9 million for the same period in 2013.

The Company reported a net loss of \$23.6 million, or \$0.28 per basic and diluted share, in the first quarter of 2014, compared to a net loss of \$20.7 million, or \$0.30 per basic and diluted share, for the same period in 2013.

As of March 31, 2014, the Company had \$78.8 million in cash, cash equivalents and marketable securities, compared to \$91.5 million in cash, cash equivalents and marketable securities as of December 31, 2013.

During March and April 2014, the Company sold an aggregate of 6,588,875 shares of common stock pursuant to its at the market sales agreement with MLV & Co. LLC for an aggregate of approximately \$28.0 million in gross proceeds at an average selling price of \$4.25 per share. Net proceeds to the Company were approximately \$27.3 million after deducting commissions and other transactions costs, including approximately \$9.3 million from the sale of 2,158,360 shares in March 2014 and approximately \$18.0 million from the sale of 4,430,515 shares in April 2014.

In April 2014, the Company sold 1,250,000 shares of its common stock at a purchase price of \$4.01 per share in a registered direct offering to an affiliate of a director who is its largest stockholder. These shares were sold directly without a placement agent, underwriter, broker or dealer. The net proceeds to the Company were approximately \$5.0 million after deducting offering expenses payable by the Company.

In May 2014, the Company entered into a new at the market issuance sales agreement with MLV & Co. LLC under which the Company, at its option, may issue and sell shares of its common stock having an aggregate offering price of up to \$40 million from time to time through MLV as its sales agent. Any shares would be sold pursuant to the Company's effective shelf registration statement on Form S-3 (File No. 333-187242).

This press release shall not constitute an offer to sell or the solicitation of an offer to buy the securities discussed herein, nor shall there be any offer, solicitation, or sale of the securities in any state in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state.

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 May 8, 2014.

#### Guidance

Based on our current operating levels the Company expects its cash resources of approximately \$78.8 million at March 31, 2014, plus the \$23.0 million in net proceeds from common stock sales during April 2014, will be sufficient to fund operations at least into the first half of 2015. 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 2014 and 2015 will be conducted subject to the availability of sufficient financial resources.

#### Conference call

Synta will host a conference call at 10:00 AM (ET) today to discuss corporate updates and first quarter 2014 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>.

A slide set summarizing the GALAXY-1 results announced this morning can be found on the <u>Synta website</u>. These slides will be referred to during the Company's first quarter 2014 results conference call this morning.

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 May 8 through 11:59 p.m. ET on May 15. To access the replay, please dial (877) 660-6853 (U.S.) or (201) 612-7415 (International) and refer to conference ID 13580529.

The live <u>webcast</u> can be accessed by visiting the <u>Investor Relations</u> section of the Synta Pharmaceuticals website, <u>www.syntapharma.com</u>. The webcast will also be archived under <u>Webcasts and Events</u> 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, and 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 <a href="https://www.clinicaltrials.gov">www.clinicaltrials.gov</a>. Ganetespib has received Fast Track designation from FDA for second-line treatment of non-small cell lung adenocarcinoma in combination with docetaxel.

### About Hsp90 inhibitor Drug Conjugates (HDC)

HDCs are small-molecule drugs 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. They exploit the preferential retention of Hsp90 inhibitors in tumors to selectively deliver anti-cancer payloads. HDCs represent a promising new therapeutic class with the potential to enhance the safety and efficacy of a wide range of small molecule anti-cancer drugs.

Synta has established proof of concept for HDC lead candidates in preclinical studies and has developed HDCs using a range of Hsp90 inhibitor moieties, cleavable linkers, and anti-cancer payloads. The latter include cytotoxic chemotherapeutics, kinase inhibitors, hormone therapies, immunomodulators, and epigenetic modifiers, creating the potential for next-generation compounds in each of these categories. Synta has filed worldwide patent applications that include comprehensive claims covering the HDC platform, compositions of matter, methods for identifying therapeutically effective compounds, and methods of use of such compounds against a wide range of diseases and conditions.

### **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 its compound library and discovery capabilities. For more information, please visit <a href="https://www.syntapharma.com">www.syntapharma.com</a>.

### Safe Harbor Statement

Synta Pharmaceuticals Corp.

Operating expenses:

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 anticipated timing for the interim and final analyses from the GALAXY-2 trial, the start of enrollment in the ganetespib arm of the I-SPY 2 trial, the interim analysis from the AML-LI (Less Intensive)-1 trial, the start of enrollment in the AML-18 and AML-19 trials, and the start of enrollment of the safety lead-in Phase 1 portion of GANNET53, as well as the expectation that Synta's current cash resources will be sufficient to fund operations into the first half of 2015, reflect Synta's 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, 2013 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.

Three Months Ended March 31,	
2014	2013
\$ —	\$ —
	March 31, 2014

Research and development	17,583		16,380	
General and administrative	5,324		3,878	
Total operating expenses	22,907		20,258	
Loss from operations	(22,907	)	(20,258	)
Interest expense, net	(650	)	(470	)
Net loss	\$ (23,557	)	\$ (20,728	)
Basic and diluted net loss per common share	\$ (0.28	)	\$ (0.30	)
Basic and diluted weighted average number of common shares outstanding	85,438,127 68,991,371			

# Synta Pharmaceuticals Corp.

# **Condensed Consolidated Balance Sheets Data**

(in thousands)

(unaudited)

	March 31,	December 31,
	2014	2013
Assets		
Cash, cash equivalents and marketable securities	\$ 78,787	\$ 91,476
Other current assets	1,605	765
Property, plant and equipment, net	1,408	1,553
Other non-current assets	384	1,409
Total assets	\$ 82,184	\$ 95,203
Liabilities and Equity		
Current liabilities	\$ 32,365	\$ 32,207
Long-term liabilities	11,595	13,905
Stockholders' equity	38,224	49,091
Total liabilities and		
Stockholders' equity	\$ 82,184	\$ 95,203

Source: Synta Pharmaceuticals Corp.

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