# Synta Announces Results From Final Analysis of the GALAXY-1 Trial of Ganetespib in NSCLC

May 8, 2014

***Encouraging Improvement in Survival Shown in Chemosensitive Patients;***
***Confirms Choice of Population for GALAXY-2 Phase 3 Trial***

LEXINGTON, Mass.--(BUSINESS WIRE)--May 8, 2014-- Synta Pharmaceuticals Corp. (NASDAQ: SNTA) today announced final results from the GALAXY-1 trial, a global, randomized, multi-center study designed to identify the patients with advanced non-small cell lung cancer (NSCLC) with adenocarcinoma histology most likely to benefit from second-line treatment with the Company's lead drug candidate, the Hsp90 inhibitor ganetespib, in combination with docetaxel versus docetaxel alone. Ganetespib is a next-generation inhibitor of the chaperone protein Hsp90, which is critical for the activation and stability of numerous proteins that drive cancer growth and proliferation. Ganetespib has been studied in over 1000 patients to date.

GALAXY-1 was designed to identify patient populations that are most responsive to treatment with the combination of ganetespib and docetaxel. Co-primary endpoints of the study were progression free survival (PFS) in patients with elevated LDH (eLDH) and PFS in patients with mutant KRAS (mKRAS). Key secondary endpoints were overall survival (OS) and PFS in adenocarcinoma patients. Prespecified stratification factor analysis has shown that the chemosensitive patient population (defined as patients diagnosed with advanced NSCLC more than 6 months prior to study entry) derived the most benefit with combination treatment. This chemosensitive population was selected for the ongoing Phase 3 GALAXY-2 trial. Key efficacy results are presented in the table below:

| | **Hazard Ratio G+D vs. D** | **eLDH** N=87 | **mKRAS** N=89 | **Chemosensitive*** N=177 | **Adenocarcinoma** N=253 |
|---|---|---|---|---|---|
| **OS** | Unadjusted | 0.88 | 1.18 | **0.71** | 0.87 |
| | | p=0.300 | p=0.755 | **p=0.023** | p=0.150 |
| | Adjusted | 0.75 | 1.23 | **0.69** | 0.84 |
| | | p=0.118 | p=0.204 | **p=0.019** | p=0.114 |
| **PFS** | Unadjusted | 1.06 | 0.93 | **0.75** | 0.85 |
| | | p=0.595 | p=0.387 | **p=0.040** | p=0.112 |
| | Adjusted | 0.88 | 1.11 | **0.74** | 0.82 |
| | | p=0.295 | p=0.338 | **p=0.042** | p=0.078 |

* Population selected for Phase 3 GALAXY-2 trial

P-values are 1-sided

Hazard ratios were calculated using Cox proportional hazards model

Unadjusted: univariate analysis

Adjusted: pre-specified analysis adjusting for multiple prognostic variables such as gender, smoking status, LDH, ECOG performance status, interval since diagnosis of advanced disease, age, total baseline target lesion size, and geographic region

The safety profile of adenocarcinoma patients treated with the combination of ganetespib (G) and docetaxel (D) was favorable, consistent with previously reported results. The most common adverse events (AEs), all grades, were neutropenia (46% vs. 45%), diarrhea (50% vs. 17%) and fatigue (35% vs. 24%), for G+D (N=123) vs. D (N=126), respectively. Diarrhea was effectively prevented or managed with standard supportive care; the incidence of grade 3 or 4 diarrhea was 4% (G+D) vs. 0 (D). Fatigue was predominantly grade 1 and grade 2; grade 3 or 4 fatigue was 6% (G+D) vs. 4% (D). The most common grade 3 or 4 AEs were neutropenia (41% vs. 42%), febrile neutropenia (9% vs. 5%), and leukopenia (10% vs. 6%). Only one case of visual impairment was reported in this study, which was mild (Grade 1) and transient. The safety profile of patients in the chemosensitive population being evaluated in Phase 3 was comparable to the profile in the adenocarcinoma population.

"Results from the final analysis of GALAXY-1 support our selection of the chemosensitive patient population for study in the pivotal Phase 3 GALAXY-2 trial," said Dr. Vojo Vukovic, Chief Medical Officer, Synta. "This mature data set confirms that the improvements in progression-free survival and overall survival with ganetespib and docetaxel in chemosensitive patients are very encouraging."

Publication of the final data from GALAXY-1 is expected in the second half of 2014. A slide set summarizing these results can be found on the Synta website. These slides will be referred to during the Company's first quarter 2014 results conference call at 10:00 AM (ET) this morning.

**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 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 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 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 expected timing for the publication of the final data from GALAXY-1 in the second half of 2014, 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.

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