



Synta Announces Presentation of Ganetespib Results at the 2013 European Cancer Congress

September 28, 2013

– *Final analysis for GALAXY-1 expected Q4 2013* –

AMSTERDAM--(BUSINESS WIRE)--Sep. 28, 2013-- Synta Pharmaceuticals Corp. (NASDAQ: SNTA) today announced presentation of results from the GALAXY-1 trial, a global, randomized, multi-center Phase 2b/3 study designed to identify the patients with advanced non-small cell lung adenocarcinoma most likely to benefit from second-line treatment with the Company's lead drug candidate, the Hsp90 inhibitor ganetespib. The results, from a planned interim analysis conducted in May, will be presented at the 2013 ECCO/ESMO/ESTRO conference and include a review of interim findings previously presented at ASCO 2013 as well as additional results for two of the study's prespecified primary patient populations.

"We are encouraged by the improvements in PFS and OS in patients treated with ganetespib in the GALAXY-1 study," said Dr. Vojo Vukovic, Chief Medical Officer, Synta. "We look forward to the GALAXY-1 final analysis, expected to be conducted later this year, and to results from GALAXY-2, expected in 2014."

GALAXY program trial design

Drugs targeting the Hsp90 chaperone protein silence a broad network of cancer-promoting proteins, creating a wide range of potential biomarkers for selecting patients. The GALAXY-1 trial was designed to enroll a substantially larger number of patients than conventional Phase 2b trials, in order to allow sufficient statistical power to detect signals in one or more patient populations identified by Hsp90-related clinical markers.

Patients with non-small cell lung adenocarcinoma who had received one prior regimen for advanced disease were randomized 1:1 to treatment with either ganetespib plus docetaxel or docetaxel alone. Key patient populations evaluated include:

1. Patients with elevated LDH. LDH-A is a marker of HIF-1alpha activity, a strong Hsp90 client and a key driver of tumor invasiveness and metastasis. Ganetespib has been shown to inhibit HIF-1alpha in tumors in both preclinical models of cancer and in translational studies in patients.

Patients with elevated LDH have poor prognosis and limited treatment options, representing a population with high unmet medical need.

2. Patients with KRAS mutations. A number of RAS signaling pathway proteins are Hsp90 clients and have been shown to be inhibited by ganetespib in preclinical models.

3. Chemo-sensitive patients. Patients who do not respond to first-line chemotherapy may not

benefit from the chemo-sensitizing effects of Hsp90 inhibition. To evaluate this hypothesis, enrollment was stratified for patients with first-line chemotherapy-sensitive (vs. chemo-refractory) disease, defined as having been diagnosed with advanced adenocarcinoma greater than (vs. less than) six months prior to study entry.

Activity in patients with elevated LDH and mutant KRAS are co-primary endpoints in GALAXY-1. Of the three GALAXY-1 stratification factors in addition to eLDH, Dg>6 months showed high predictive significance for ganetespib activity (p=0.006); ECOG PS and smoking status showed no predictive significance.

GALAXY-1 updates in detail

Results that will be presented at the 2013 ECCO/ESMO/ESTRO conference are based on the May 2013 data cutoff for all patients in the primary, all-adenocarcinoma enrollment phase of the trial, which completed enrollment in November 2012 (N=252). Results for the chemo-sensitive (Dg > 6 months) and ITT populations were previously presented.

		Elevated LDH	mKRAS	Chemo-sensitive (Dg>6m)	ITT
		n=76	n=63	N=176	N=252
PFS	Median	3.4 vs. 1.9	4.1 vs. 3.0	5.4 vs. 3.4	4.5 vs. 3.2
	Events	61 (80%)	46 (73%)	122 (69%)	180 (71%)
	HR	0.88	0.83	0.61	0.84
	(90% CI)	(0.57, 1.36)	(0.51, 1.37)	(0.45, 0.83)	(0.65, 1.07)
	Unadjusted	p=0.309	p=0.271	p=0.004	p=0.038
	HR	0.60	0.96	0.62	0.83
	(90% CI)	(0.37, 0.96)	(0.57, 1.59)	(0.45, 0.86)	(0.64, 1.06)
	Adjusted	p=0.038	p=0.442	p=0.007	p=0.108
OS	Median	6.1 vs. 4.3	9.8 vs. 6.3	10.7 vs. 6.4	9.8 vs. 7.4
	Events	56 (74%)	35 (56%)	92 (52%)	134 (53%)
	HR	0.63	0.85	0.61	0.82
	(90% CI)	(0.40, 0.99)	(0.48, 1.50)	(0.43, 0.87)	(0.62, 1.09)
	Unadjusted	p=0.046	p=0.313	p=0.009	p=0.082

HR	0.45	0.97	0.55	0.73
(90% CI)				
	(0.27, 0.73)	(0.53, 1.77)	(0.38, 0.79)	(0.55, 0.98)
Adjusted	p=0.004	p=0.461	p=0.004	p=0.041

**Population
selected for
Phase 3**

In the table above for G+D vs. D, all p-values are one-sided; Hazard ratios are calculated using the Cox Proportional Hazards model either with treatment effect as sole variable (unadjusted) or adjusting for the effects of other variables in the study, as prospectively specified in the statistical analysis plan (gender, smoking status, LDH, ECOG performance status, interval since diagnosis advanced disease, age, total baseline target lesion size, and geographic region).

With regard to these results, Dr. Vukovic noted: "The results show improved PFS and OS across key populations in the trial, and support the choice of including chemo-sensitive, and excluding chemo-refractory, patients for the ongoing GALAXY-2 Phase 3 trial. Results in the elevated LDH population, while early, are interesting in light of the limited treatment options and high unmet need."

Patients enrolled in the biomarker extension phase of the trial (eLDH, mKRAS), which completed enrollment in May 2013, were not included in the interim analysis that will be presented. Results from these patients will be included in the final analysis expected later this year.

Safety

As presented earlier this year, the safety profile of patients in the ITT population treated with the combination of ganetespib and docetaxel was generally similar to that of docetaxel alone and consistent with previously reported results for ganetespib. The most common adverse events (AEs), all grades, were neutropenia (42% vs. 43%), diarrhea (48% vs. 16%) and fatigue (34% vs. 24%), for G+D (N=123) vs. D (N=125), respectively. Diarrhea was effectively managed with supportive care; the incidence of grade 3 or 4 diarrhea was 3% (G+D) vs. 0% (D). Fatigue was predominantly grade 1 and grade 2; grade 3 or 4 fatigue was 6% (G+D) vs. 3% (D). The most common grade 3 or 4 AEs were neutropenia (37% vs. 38%), febrile neutropenia (11% vs. 2%), and anemia (8% vs. 2%). The proportions of patients with AEs leading to death were 12% vs. 11%, and AEs leading to treatment discontinuation were 7% vs. 5% for G+D vs. D, respectively. Consistent with prior findings with ganetespib, reports of visual impairment in this study were infrequent: 2 (2%) in the G+D arm and 0 (0%) in the D arm. Both cases of visual impairment were transient and grade 1 or 2. A high incidence of visual impairment has been reported following treatment with certain other Hsp90 inhibitors. The safety profile of patients in the Dg > 6 months population was comparable to the safety profile in the ITT population.

A copy of this poster presentation, "Ganetespib in combination with docetaxel versus docetaxel

alone in second line NSCLC adenocarcinoma patients with KRAS mutation and elevated LDH levels" by Fennel et. al (abstract #3416), can be found on [Synta's website](#).

Inhibition of tumor growth in preclinical models

Synta will also present results at the ECCO/ESMO/ESTRO conference demonstrating the anti-angiogenic and anti-metastatic properties of ganetespib in preclinical models of cancer. Results show that ganetespib treatment reduced the ability of cancer cells to promote new blood vessel formation and suppressed their ability to migrate and form tumors at distant sites. These observations are supportive of a significant decrease in the rate of new lesion formation observed in patients treated with ganetespib plus docetaxel versus docetaxel alone in the GALAXY-1 trial.

A copy of this poster presentation, "Antimetastatic activity of ganetespib: Preclinical studies and assessment of progressions due to new lesions in the GALAXY-1 NSCLC trial" by Proia et. al (abstract #3517), can be found on [Synta'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, 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, PDGFR, 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 the GALAXY Program

The GALAXY (Ganetespib Assessment in Lung cAnCer with docetaXel) program consists of two randomized trials comparing the combination of ganetespib and docetaxel versus docetaxel alone in patients with Stage IIIB/IV NSCLC who have received one prior systemic therapy: a 300-patient Phase 2b/3 trial (GALAXY-1) to determine the patient population most likely to derive benefit from ganetespib, and a 500-patient confirmatory Phase 3 trial (GALAXY-2). More information about the GALAXY trials can be found at www.clinicaltrials.gov (NCT01348126 and NCT01798485).

About Lung Cancer

Lung cancer is the leading cause of cancer-related death in the world, accounting for nearly 1.4 million deaths in 2008, according to the World Health Organization. The five-year survival rate for this disease is approximately 16%; over half of people with lung cancer die within one year of being diagnosed. In the U.S., the American Cancer Society estimates that 228,000 cases of lung cancer

will be diagnosed in 2013. Non-small cell adenocarcinoma comprises about 40% of all lung cancer.

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

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Source: Synta Pharmaceuticals Corp.

Investor Relations Contact:

Synta Pharmaceuticals Corp.
George Farmer, 781-541-7213
gfarmer@syntapharma.com

or

Argot Partners
Andrea Rabney, 212-600-1494
andrea@argotpartners.com

or

Media Contact:

Argot Partners
Eliza Schleifstein, 973-361-1546
eliza@argotpartners.com