



## Synta Announces Presentation of Ganetespib Phase 2 Non-small Cell Lung Cancer Trial Results at IASLC 14th World Conference on Lung Cancer

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- Ganetespib shows activity in crizotinib-refractory NSCLC patient-
- Ganetespib and docetaxel combination shows activity in NSCLC-

LEXINGTON, Mass., Jul 07, 2011 (BUSINESS WIRE) -- Synta Pharmaceuticals Corp. (NASDAQ: SNTA) today presented [results](#) at the International Association for the Study of Lung Cancer (IASLC) 14<sup>th</sup> World Conference on Lung Cancer from a Phase 2 single agent clinical trial of ganetespib in advanced non-small cell lung cancer (NSCLC) that showed promising clinical activity in patients with progressive disease. Ganetespib is a potent inhibitor of heat shock protein 90 (Hsp90) currently being studied in a broad range of clinical trials with approximately 400 patients treated to date. [Ganetespib](#) is structurally unrelated to first-generation, ansamycin-family Hsp90 inhibitors such as 17-AAG or IPI-504.

"Ganetespib has shown encouraging single agent clinical activity and a good safety profile in pretreated advanced NSCLC patients," said Julie Brahmer, M.D., Sidney Kimmel Comprehensive Cancer Center, Johns Hopkins Hospital. "The case study presented today shows a patient whose ALK positive cancer had progressed on treatment with crizotinib, the most clinically advanced ALK inhibitor, who then experienced significant tumor shrinkage within the first several weeks of treatment with ganetespib. The results for ganetespib in NSCLC, particularly in patients with ALK or KRAS mutations, suggest this compound has promising potential to benefit lung cancer patients."

Of the 23 patients in the Phase 2 trial tested for ALK translocation or rearrangement (ALK+), eight patients were ALK+ in at least one assay. Six of these eight patients (75%) showed tumor shrinkage in target lesions, one patient showed no change in tumor size, and one patient achieved stable disease (tumor growth <20%). The disease control rate in this population was 7/8 (88%), and the objective response rate (CR+PR) was 4/8 (50%).

Approximately 45,000 patients each year are believed to develop advanced lung cancer with an ALK rearrangement<sup>1</sup>. In clinical trials to date, patients treated with crizotinib have experienced disease progression after a median of 10 months<sup>2</sup>. There is a clear medical need for a drug active in ALK+ NSCLC patients following crizotinib treatment failure.

At the IASLC meeting, an additional case study was presented demonstrating that the combination of ganetespib and docetaxel is active in a patient whose disease has progressed after ganetespib single agent treatment.

"Several patients in the NSCLC single agent ganetespib study had mixed responses - some of their tumor lesions responded to treatment and other secondary lesions did not," said Vojo Vukovic, M.D.,

Ph.D., Senior Vice President and Chief Medical Officer, Synta Pharmaceuticals. "Patients with mixed responses had the option of being treated with the combination of ganetespib and docetaxel at the discretion of their physician. We are very encouraged that the combination controlled the tumors better than single agent treatment. This result, along with a strong preclinical rationale and a favorable safety profile emerging from the Phase 1 ganetespib and docetaxel combination study, provides strong support for the ongoing Phase 2b/3 GALAXY trial in NSCLC."

### **Case Study - Crizotinib Refractory Patient**

- 24 year old male diagnosed with non-small cell lung cancer in January 2009.
- Initial treatment with pemetrexed plus cisplatin with pemetrexed maintenance therapy until February 2010.
- EML4-ALK positive; treated with crizotinib for approximately one year.
- Re-biopsy showed resistance mutation.
- After three weeks treatment with ganetespib (received three injections), significant tumor shrinkage observed.

Additional results from the Phase 2 NSCLC trial with ganetespib can be found at [http://www.syntapharma.com/Documents/Ganetespib\\_NSCLC\\_WCLC\\_2011\\_Presentation.pdf](http://www.syntapharma.com/Documents/Ganetespib_NSCLC_WCLC_2011_Presentation.pdf).

### **About the Phase 2 NSCLC Trial**

The Phase 2 NSCLC trial was designed to enroll patients with advanced, metastatic disease (Stage IIIB and IV) who had failed prior therapy. Patients were grouped into one of three cohorts based on the genetic profile of their cancer - (A) EGFR mutation, (B) KRAS mutation, (C) neither EGFR nor KRAS mutation - and were treated with ganetespib, as a monotherapy, once-weekly at a dose of 200 mg/m<sup>2</sup>. Based on encouraging signs of activity, an amendment announced in September 2010 expanded the trial with two additional patient cohorts, including a cohort which allowed for combination treatment with ganetespib and docetaxel.

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

According to the American Cancer Society, lung cancer is the leading cause of cancer-related mortality in the United States, with over 225,000 new cases and 157,000 deaths estimated in 2010. The five year survival rate for advanced-staged lung cancer is less than 5%. Approximately 85% of all lung cancers are classified as non-small cell.

### **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 diarrhea, which has been manageable with standard supportive care. Information on clinical trials with ganetespib can be found at

<http://www.clinicaltrials.gov>.

## **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 <http://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 timing, developments and progress of our ganetespib clinical and preclinical program, 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, 2010 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.

1. Assumes 3.5% incidence of ALK+ NSCLC pts (Palmer et al, Biochem J 2009). More recent estimates: 5-12% (Shaw, Hayes, Martins ASCO 2011; Martinez et al. ASCO 2011 Abst 7566; Kris et al ASCO 2011 Abst CRA 7506), and as high as 22% in pts selected for certain clinical features (Shaw et al, JCO 2009); estimated treatable pts top 7 markets: 30,000 - 70,000.
2. R. Camidge, ASCO 2011 Abst 2501.

SOURCE: Synta Pharmaceuticals Corp.

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