



## Synta Pharmaceuticals Presents Phase 2a Data at DDW for STA-5326 in Patients with Crohn's Disease

May 18, 2005

Trial Meets Safety Endpoints and Suggests Evidence of Clinical Response and Remission

Chicago, Ill. - May 18, 2005 - Synta Pharmaceuticals today presented data from a multi-center, open-label Phase 2a clinical trial of STA-5326 in patients with Crohn's disease. STA-5326 is the first oral, small-molecule, and highly selective inhibitor of the IL-12 cytokine family, including IL-12 and IL-23, cytokines that play a central role in Crohn's disease and other chronic inflammatory diseases. At daily doses of 35 mg and above, treatment with STA-5326 showed clinically meaningful response and disease remission rates in patients with active Crohn's disease. STA-5326 was also generally well tolerated over four weeks of administration. These data were presented at Digestive Disease Week (DDW) being held in Chicago, Ill. May 14 - 19, 2005.

Synta's Phase 2a open-label study assessed 73 patients in five different dose cohorts. The highest rate of response to therapy was seen in the 35 mg, once-a-day group. Results from this dose cohort include the following:

82 percent of patients (9/11) showed a decrease of 70 points or more at Week 4 in the Crohn's Disease Activity Index (CDAI), the standard measurement of disease severity for this condition;  
64 percent of patients (7/11) achieved the more stringent criterion of a decrease of 100 points or more at Week 4 in CDAI score based on an additional analysis; and  
36 percent (4/11) of patients achieved clinical remission as determined by a CDAI score of less than 150 points at Week 4.

Meaningful clinical activity was observed at all dose levels except the lowest administered dose level of 14 mg twice-a-day. Results across the four higher dose levels, which ranged from 35 mg to 70 mg daily either as a single or twice-daily divided dose, include the following:

51 percent of patients (30/59) experienced a decrease of 70 points or more at Week 4 in CDAI score, with the onset of responses occurring within two weeks of initiation of treatment;  
44 percent of patients (26/59) experienced a decrease of 100 points or more at Week 4 in CDAI score; and  
24 percent (14/59) of patients achieved clinical remission, as determined by a CDAI score of less than 150 points at Week 4.

STA-5326 was generally well tolerated over four weeks of treatment at all dose levels. No serious adverse events related to the use of STA-5326 were reported. Seven patients discontinued treatment as a result of drug-related adverse events. The most common adverse events were dizziness, nausea, headache, and fatigue. The frequency of adverse events was not dose-related.

"These results suggest STA-5326 is generally well tolerated in Crohn's disease patients, that the higher doses tested may increase clinical rates of response and remission, and that once-a-day dosing may be effective in patients with active disease," said Matthew L. Sherman, M.D., Senior Vice President and Chief Medical Officer at Synta. "We are encouraged that the data suggest clinically meaningful response and remission rates for the treatment of active Crohn's disease and that STA-5326 has the added benefit of oral administration. Based on these preliminary data, we expect to initiate a large, randomized, double-blind, placebo-controlled Phase 2b trial by the end of the year."

### About STA-5326

STA-5326 is a novel, orally administered, small-molecule drug candidate that selectively and potently inhibits the production of the IL-12 family of proteins, including IL-12 and IL-23. Over-production of these proteins plays a central role in chronic inflammatory diseases, driving the body's immune system to infiltrate and damage tissues and organs.

### About Crohn's Disease

Crohn's disease is a chronic inflammatory bowel disease characterized by inflammation throughout the length of the gastrointestinal, or digestive, tract. Symptoms can be severe, and include abdominal pain, frequent diarrhea, and intestinal bleeding. Approximately 500,000 people in the U.S. and over a million people worldwide are affected by Crohn's disease.

### About Synta

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 chronic inflammatory disease and cancer. Synta currently has three drug candidates in human clinical trials, as well as a diverse pipeline of internally developed discovery programs. For more information, please see [www.syntapharma.com](http://www.syntapharma.com).