LDN--Treatment For Active Crohn's Disease and IBS

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Methods

Eligible subjects with histologically and endoscopically confirmed active Crohn's disease with a Crohn's Activity Index (CDAI) score of 220-450 were enrolled in a study using 4.5 mg naltrexone/day. Subjects were required to be off infliximab for at least 8-weeks, and this medication was not allowed during the trial. Other drug therapy for Crohn's disease utilized 4 or more weeks prior to enrollment was continued at the same dosages.... Drug [LDN] was administered orally each evening for a 12-week period. Laboratory tests, erythrocyte sedimentation rates, C - Reactive Protein, and CDAI scores were assessed monthly and 4 weeks after discontinuing the medication.

Results

Seventeen patients with a mean initial CDAI score of 356 ± 27 were enrolled in the study. CDAI scores decreased significantly ($p<0.01$) with LDN, and remained statistically lower than baseline 4-weeks after completing therapy.

Eighty-nine percent of patients exhibited a response to therapy (>70-point decrease in CDAI, $p<0.001$) and 67% achieved remission (CDAI score <150). Quality of Life surveys indicated marked improvement with LDN. No laboratory abnormalities were noted. One subject undergoing routine endoscopic procedures showed healing of the intestinal mucosa. In both subjects with open fistulas,

closure was noted with LDN. The most common side effect of LDN was sleep disturbances (7 patients).

Conclusions

LDN therapy offers an alternative safe, effective, and economic means of treating subjects with active Crohn's disease.

Pain Therapeutics Ends Irritable Bowel Syndrome Trials of Ultra-low Naltrexone Dosage

In December 2005, Pain Therapeutics, Inc. announced results of its Phase III study with PTI-901. Excerpt from PTI's announcement:

This randomized, double-blinded, multi-center U.S. study compared a daily dose of PTI-901 against placebo in 600 women with documented IBS over a three-month treatment period. PTI-901 showed a favorable safety profile and patients reported statistically meaningful relief of IBS symptoms in the second month of treatment ($p<0.02$), but the drug did not demonstrate a meaningful benefit in the third month of treatment, which was defined as the primary endpoint. According to current regulatory standards, an experimental drug for chronic IBS needs to show efficacy at the end of a three-month treatment period.

The Company believes this study was well designed to detect any durable benefits of PTI-901 versus placebo in a large patient population with IBS. Based on the adequacy of the study itself, coupled with today's clinical results, the Company is discontinuing all further clinical development activities with PTI-901.

[Editor's Note: PTI-901 contains only 0.5mg of naltrexone, which is well below the therapeutic dosage range for LDN—normally from 1.75mg to 4.5mg every night. LDN in the normal dosage range has been anecdotally reported quite beneficial in halting IBS.]