14 CLINICAL STUDIES

14.3 IBS-D

A randomized, double-blind, placebo-controlled, single site study in which subjects with irritable bowel syndrome diarrhea-predominant (IBS-D) were treated for 6 weeks with either SBI (10 g/day), SBI (5 g/day), or placebo (10 g/day soy protein isolate). Subjects in the 5 g/day SBI group also received 5 g/day placebo so that all 3 groups received an equivalent amount of protein. Demographic characteristics of subjects included in the study were not significantly different. Subjects entered the study at Baseline, underwent a 2-week run-in period and a 6-week therapy period. Assessments included a modified IBS-36 questionnaire, daily symptoms scores, and hematology and clinical chemistry laboratory tests. A total of 66 subjects were enrolled in this study: 22 in the placebo group, 25 in the 10 g/day SBI group, and 19 in the 5 g/day SBI group. Four subjects withdrew from the study due to nausea: 1 subject in the placebo group, 2 subjects in the 10 g/day SBI group, and 1 subject in 5 g/day SBI group. A total of 51 subjects completed the study: 16 subjects in the placebo group, 17 subjects in the 10 g/day SBI group, and 18 subjects in the 5 g/day SBI group. The rate of withdrawal was similar across groups. In group comparison for subjects in the 10 g/day SBI cohort had statistically significant reductions in the number of days with symptoms from week 2 to week 6 for loose stools (-2.1 days; $p = 0.011$), abdominal pain (-2.0 days; $p = 0.008$), flatulence (-2.3 days; $p = 0.003$), bloating (-1.3 days; $p = 0.044$), urgency (-1.5 days; $p=0.050$), and any symptom (-1.6 days; $p=0.009$). In group comparison for subjects in the 5 g/day SBI cohort had statistically significant reductions from week 2 to week 6 in the number of days with flatulence (-1.7 days; $p = 0.018$), incomplete evacuation (-1.1 days; $p = 0.020$), and any symptom (-1.7 days; $p = 0.010$). Subjects in both the 10 g/day and placebo groups showed a statistically significant ($p = 0.008$) improvement in the sleep/fatigue domain as compared to those in the 5 g/day SBI group from an IBS-36 questionnaire. The study was not powered to compare differences between groups. There were no statistically significant differences between groups with respect to hematology and clinical chemistry laboratory results. No serious AEs were reported. Administration of SBI at a dose of 10 g/day for 6 weeks significantly decreased from baseline to end of treatment, the number of symptom days for loose stools, abdominal pain, flatulence, bloating, urgency and any symptom. Greater improvements in hard stools, and incomplete evacuation were also achieved with SBI. Results also demonstrate the safety and tolerability of SBI when supplemented daily for 6 weeks in subjects affected by the diarrhea predominant form of IBS.