IBgard®, a novel targeted delivery system of peppermint oil, results in significant improvement in the Total IBS Symptom Score and individual IBS symptoms. Results from the US based, 4-week, randomized, placebo controlled, multi-center IBREST™ trial.

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Introduction

Peppermint oil (PO) has been shown to significantly reduce global symptoms as well as the abdominal pain of irritable bowel syndrome (IBS).1 It is approved by the European Medicines Agency (EMEA) and used as a first line IBS therapy outside the US. However, patients receiving single-unit, enteric-coated PO may experience adverse events, such as heartburn, abdominal pain, or an altering. IBgard® is a medical food containing a novel PO formulation consisting of ultra-purified, solid-state PO microspheres that are triple-coated to facilitate PO delivery to the small intestine. The Irritable Bowel Syndrome Reduction Evaluation and Safety Trial (IBREST) compared the efficacy and tolerability of IBgard® with placebo over a 4-week period.

IBREST® Trial Objectives

Evaluate the effectiveness and safety of IBgard® for the management of IBS

- Confirm results of previous European clinical trials of PO in a U.S. population
- Determine if PO with Site Specific Targeting (SST) technology results in rapid action and improved tolerability of PO in adult patients with IBS-M and IBS-D

Methods

- Subjects met Rome III criteria for IBS-M or IBS-D, had average daily IBS-related abdominal pain of a 4 (0-10 scale), a Total IBS Symptom Score (TISS) of 2 (0-4 scale), and were 18-60 years of age
- Exclusion criteria: diagnosis of IBS-C or IBS-U, organic gastrointestinal disease, refusal to discontinue any prohibited medications prior to study
- 3-week observation period for symptom severity assessment and prohibited medication washout
- Randomized to receive IBgard® 180 mg TID or placebo for 4 weeks
- Primary analysis based on TISS score1
  - FDA-guidance for patient-reported IBS outcome measures suggests the use of total symptom score in addition to abdominal pain intensity and stool consistency/frequency as primary endpoints
- Additional assessments included change from baseline in frequency and intensity of individual IBS symptoms and daily B-M/D symptoms
- Safety assessment included treatment-emergent adverse events (TEAE)

Total IBS Symptom Score (TISS)

- Scale used previously by Cappello et al.2 and based on the intensity and frequency (0-4) of 8 IBS symptoms: 1) abdominal pain or discomfort, 2) bloating or distention, 3) pain at evacuation, 4) urgency, 5) constipation, 6) mucus or gas, 7) sense of incomplete evacuation (IB), and 8) means of the intensity + frequency scores for each symptom are summarised and divided by 8 to obtain the TISS2

Results

- IBgard® was well tolerated and safe
- IBgard® was effective at improving the composite IBS symptom score (TISS) and all 8 individual IBS symptoms (average of frequency and intensity) over 4 weeks
- Improvement from baseline in TISS and 4 individual IBS symptoms (abdominal pain, bloating, pain at evacuation, and urgency) was significantly greater with IBgard® than placebo
- IBgard was well tolerated and safe

Conclusions

-IBgard was effective at improving the composite IBS symptom score (TISS) and all 8 individual IBS symptoms (average of frequency and intensity) over 4 weeks
- Improvement from baseline in TISS and 4 individual IBS symptoms (abdominal pain, bloating, pain at evacuation, and urgency) was significantly greater with IBgard® than placebo
- IBgard was well tolerated and safe

References


Figure 1. Reduction from Baseline in IBS Symptom Scores at 4 Weeks

Table 1. Subject Characteristics

Table 2. TISS and Individual IBS Symptom Scores at Baseline (mITT Population)

Table 3. Treatment Emergent Adverse Events