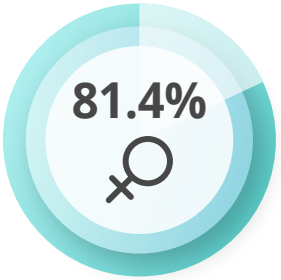
# T3MPO-1 (Phase 3)

A phase 3, randomized, placebo-controlled trial of the efficacy and safety of tenapanor for IBS-C in adults

## PATIENTS WITH IBS-C (ROME III)

Baseline characteristics




Average age
**45 years**

average weekly **COMPLETE** spontaneous bowel movements of **0.2 per week**

## PRIMARY ENDPOINT:

Combined responders were patients with ≥30% reduction in average weekly worst abdominal pain and an increase of ≥1 weekly complete spontaneous bowel movements from baseline within the same week for ≥6 of the first 12 weeks of the trial

**27.0%** of patients were combined responders

**18.7%** of patients were combined responders

Significantly more tenapanor-treated patients were combined responders (*P*=0.020)

Tenapanor  Placebo

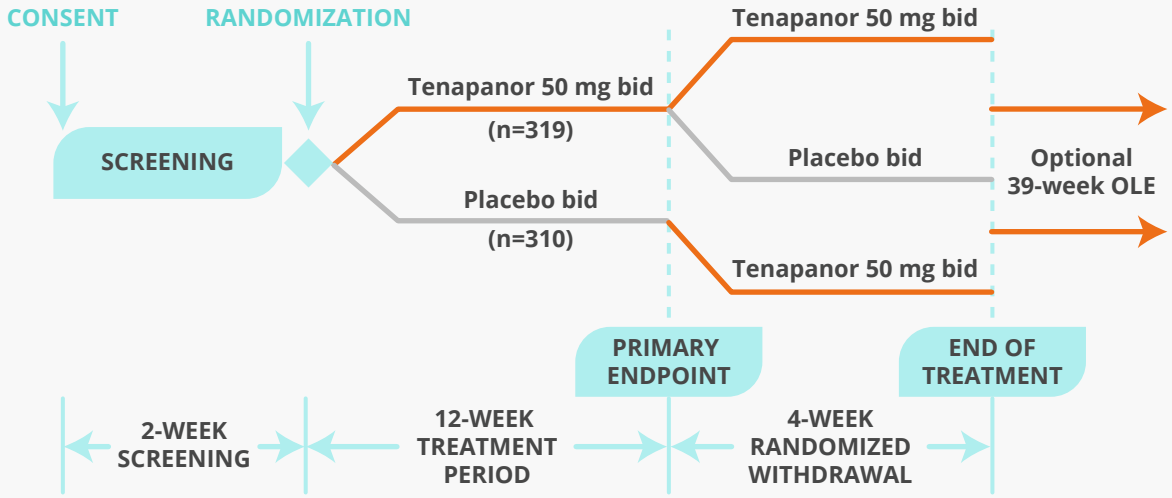
## SAFETY

Diarrhea was the most commonly reported adverse event

**45 (14.6%)**

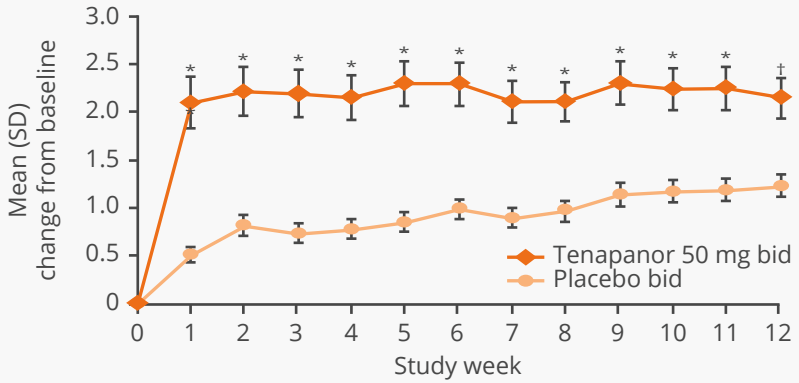
**5 (1.7%)**

## TRIAL DESIGN




## SECONDARY ENDPOINT: COMPLETE SPONTANEOUS BOWEL MOVEMENTS PER WEEK

Number of **COMPLETE** spontaneous bowel movements were **SIGNIFICANTLY IMPROVED** for patients treated with **TENAPANOR**




## STUDY LIMITATIONS

- Short-term study
- Due to the initiation date of the study, Rome III criteria were used to identify patients
- Study drug adherence was greater than what may be expected in clinical practice

*$P$<0.001, †$P$=0.001 vs placebo. Reprinted with permission from Chey WD et al. *Am J Gastroenterol*. 2020.

bid, twice a day; IBS-C, irritable bowel syndrome with constipation; OLE, open-label extension.
NCT02621892. Chey WD et al. *Am J Gastroenterol*. 2020;115:281-93.

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**IBSRELA (tenapanor) is indicated for treatment of irritable bowel syndrome with constipation (IBS-C) in adults.**

## Important Safety Information

**WARNING: RISK OF SERIOUS DEHYDRATION IN PEDIATRIC PATIENTS**

- **IBSRELA is contraindicated in patients less than 6 years of age; in nonclinical studies in young juvenile rats, administration of tenapanor caused deaths presumed to be due to dehydration. *[see PI Contraindications (4), Use in Specific Populations (8.4)]*.**
- **Avoid use of IBSRELA in patients 6 years to less than 12 years of age. *[see PI Warnings and Precautions (5.1), Use in Specific Populations (8.4)]*.**
- **The safety and effectiveness of IBSRELA have not been established in pediatric patients less than 18 years of age. *[see PI Use in Specific Populations (8.4)]*.**

### CONTRAINDICATIONS

IBSRELA is contraindicated in patients less than 6 years of age due to the risk of serious dehydration.

IBSRELA is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction.

### WARNINGS AND PRECAUTIONS

#### Risk of Serious Dehydration in Pediatric Patients

IBSRELA is contraindicated in patients below 6 years of age. The safety and effectiveness of IBSRELA in patients less than 18 years of age have not been established. In young juvenile rats (less than 1 week old; approximate human age equivalent of less than 2 years of age), decreased body weight and deaths occurred, presumed to be due to dehydration, following oral administration of tenapanor. There are no data available in older juvenile rats (human age equivalent 2 years to less than 12 years).

Avoid the use of IBSRELA in patients 6 years to less than 12 years of age. Although there are no data in older juvenile rats, given the deaths in younger rats and the lack of clinical safety and efficacy data in pediatric patients, avoid the use of IBSRELA in patients 6 years to less than 12 years of age.

#### Diarrhea

Diarrhea was the most common adverse reaction in two randomized, double-blind, placebo-controlled trials of IBS-C. Severe diarrhea was reported in 2.5% of IBSRELA-treated patients. If severe diarrhea occurs, suspend dosing and rehydrate patient.

### MOST COMMON ADVERSE REACTIONS

The most common adverse reactions in IBSRELA-treated patients (incidence ≥2% and greater than placebo) were: diarrhea (16% vs 4% placebo), abdominal distension (3% vs <1%), flatulence (3% vs 1%) and dizziness (2% vs <1%).

**For the full Prescribing Information, including Boxed Warning, click here.**


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