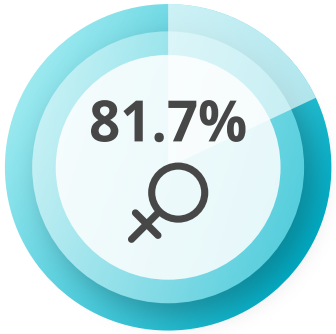
# T3MPO-3 (Phase 3)

A long-term, phase 3, open-label safety extension trial of tenapanor 50 mg bid for IBS-C in adults

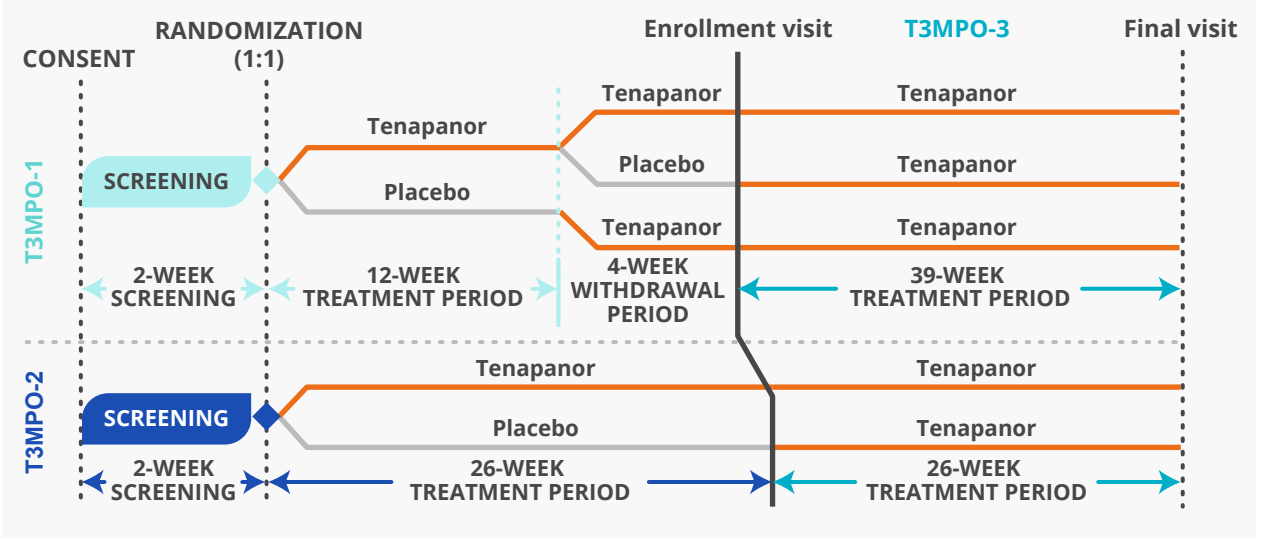
## PATIENTS WITH IBS-C (ROME III) WHO COMPLETED T3MPO-1 OR T3MPO-2

Baseline characteristics at time of enrollment in T3MPO-3




Average age
**49.5 years**

## TRIAL DESIGN




## SAFETY

TENAPANOR was generally well tolerated with DIARRHEA as the most COMMONLY REPORTED adverse event

NO DEATHS occurred during this study

### AMONG TENAPANOR-TREATED PATIENTS (N=312) DURING T3MPO-3

| Any TEAE | Treatment-related TEAEs | Serious TEAEs | TEAEs leading to discontinuation | Discontinued due to diarrhea |
|---|---|---|---|---|
| 117 (37.5%) | 48 (15.4%) | 3 (1.0%) | 13 (4.2%) | 11 (3.5%) |

**TEAEs experienced by >2% of patients by preferred term**

| Diarrhea | Headache | Flatulence | Upper respiratory tract infection |
|---|---|---|---|
| 33 (10.6%) | 11 (3.5%) | 7 (2.2%) | 7 (2.2%) |

### STUDY LIMITATIONS

Study was not specifically designed to assess efficacy and did not include a control group


bid, twice a day; IBS-C, irritable bowel syndrome with constipation; OLE, open-label extension; TEAE, treatment-emergent adverse event.
NCT02727751. Lembo AJ et al. *Neurogastroenterol Motil*. 2023;35:e14658.

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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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