

# Treatment Satisfaction With Tenapanor (IBSREL): Real-World Survey of Patients With Irritable Bowel Syndrome With Constipation

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## Introduction

- Irritable bowel syndrome with constipation (IBS-C) is a common disorder of gut-brain interaction, characterized by abdominal pain, bloating, and constipation, that negatively affects patients' quality of life (QoL).<sup>1-3</sup>
- Tenapanor (IBSREL) is a first-in-class, minimally systemic inhibitor of intestinal sodium/hydrogen exchanger 3 indicated for treatment of IBS-C in adults.<sup>4</sup>
- Real-world data on tenapanor regarding treatment satisfaction, IBS-C symptom resolution, and improvement in QoL are lacking. Herein, we report results from a survey of patients receiving tenapanor for the treatment of IBS-C, which was conducted to help address these gaps.

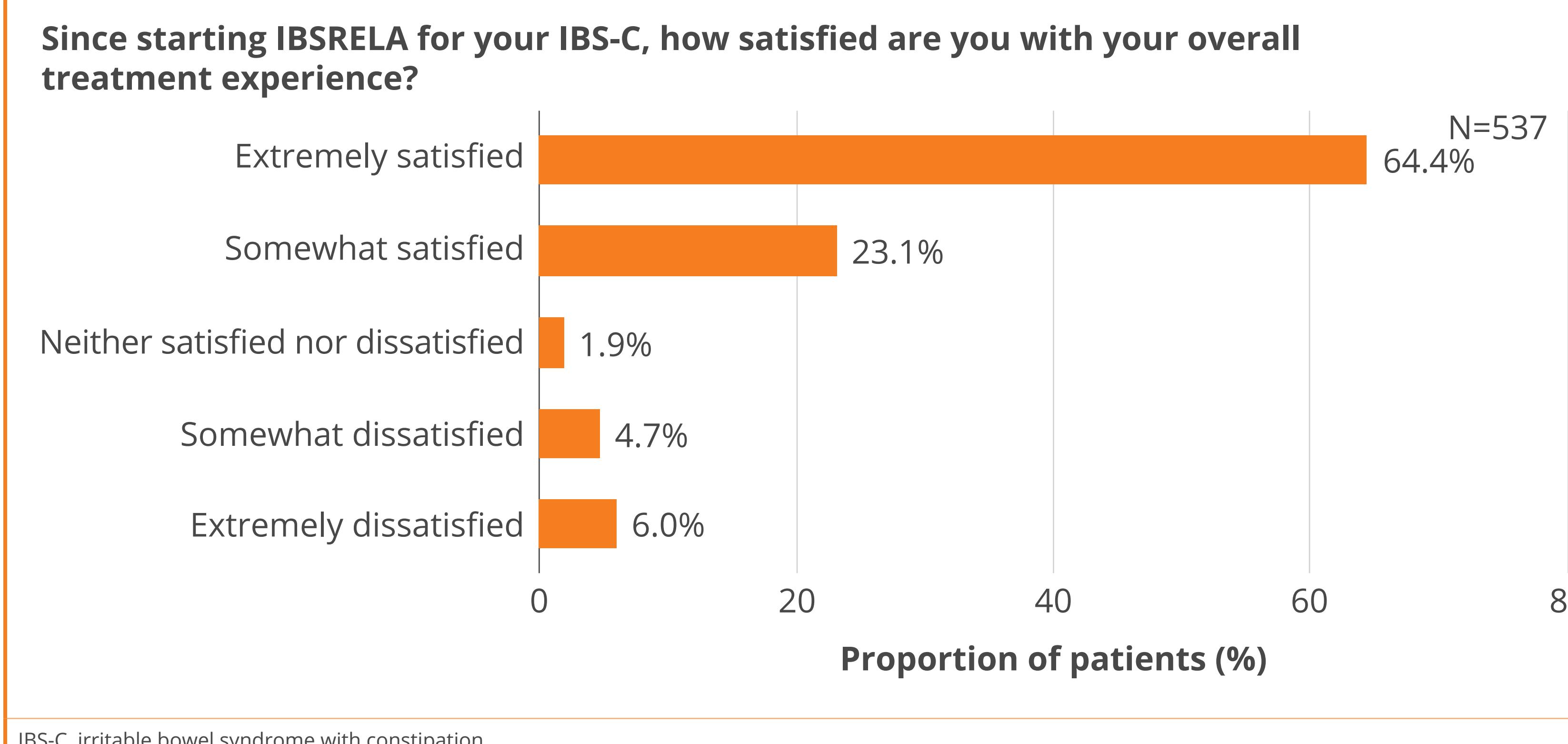
## Methods

- Survey invites were distributed via text messaging through the ArdelyxAssist patient assistance program (PAP).
- Patients were aged  $\geq 18$  years, consented to join ArdelyxAssist and receive text messages, and were prescribed tenapanor for the treatment of IBS-C.
  - Tenapanor was first dispensed  $\geq 6.5$  weeks before the survey started and was last dispensed within 90 days before survey start.
- Open-ended questions were analyzed by two researchers (AS and LS) using:
  - Sentiment analysis, in which the overall sentiment of each patient entry was assigned manually on a scale from -2 (negative sentiment) to 2 (positive sentiment).
  - Thematic analysis, in which key patterns across patient entries were manually identified and quantified.<sup>5,6</sup>

## Results

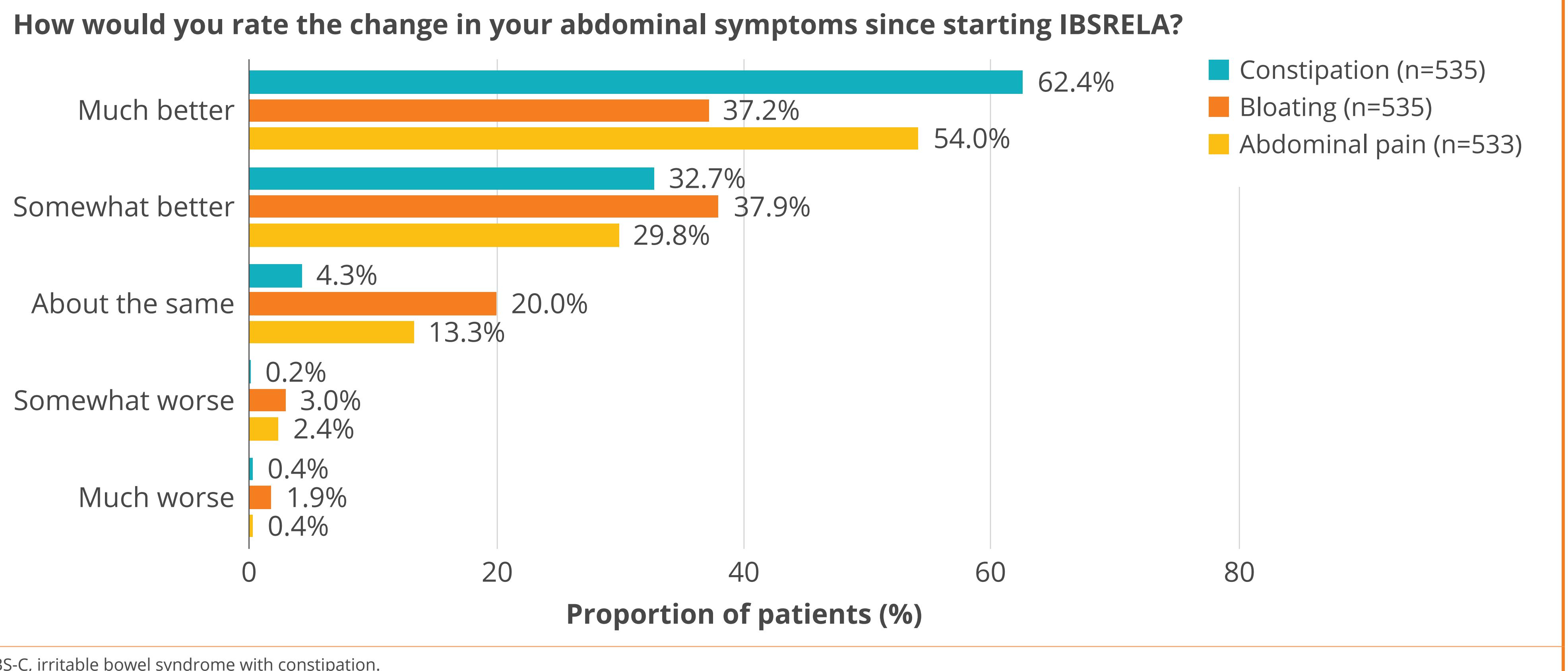
- Of the 4252 invites sent, 537 patients completed the survey.
- Overall, 87.5% of patients reported that they were somewhat or extremely satisfied with tenapanor (Figure 1).

### Figure 1: Treatment Satisfaction With Tenapanor



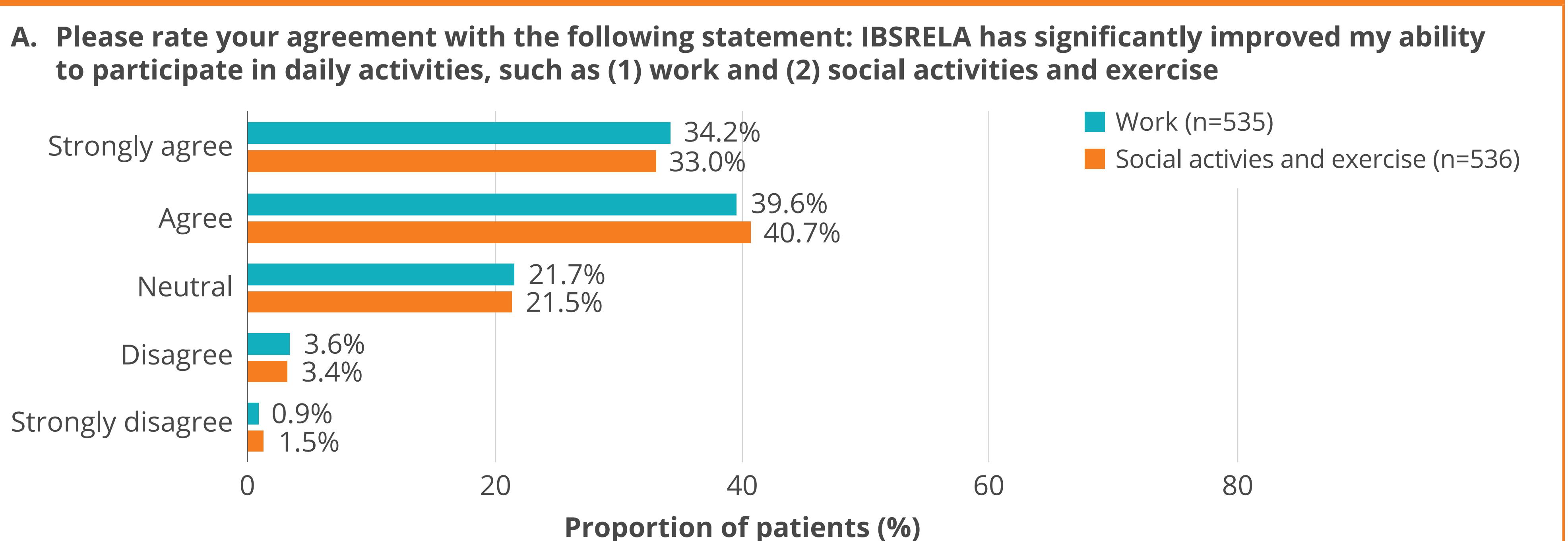
- Additionally, most patients reported somewhat or much better improvement in constipation (95.1%), bloating (75.1%), and abdominal pain (83.9%) with tenapanor (Figure 2).
  - All 3 symptoms improved in 69.1% of patients.

### Figure 2: Improvement in IBS-C Symptoms With Tenapanor



- QoL also improved with tenapanor, with most patients reporting that tenapanor enhanced their ability to participate in daily activities, including work (74%) and social activities and exercise (74%; Figure 3A).
  - QoL improvements related to **either** work **or** social activities/exercise were reported for 77.2% of patients.
  - QoL improvements related to **both** work **and** social activities/exercise were reported for 70.5% of patients.
- Improvements in constipation, bloating, and abdominal pain were each predictive of improved QoL (Figure 3B).
- Improvement in constipation was predictive of treatment satisfaction (Figure 3C).

### Figure 3: (A) Improvement in QoL With Tenapanor, (B) Predictors of QoL Improvements, and (C) Predictors of Treatment Satisfaction



#### B. Predictors of QoL improvement

Factors <sup>a</sup>	OR	95% CI	P
Improvement in constipation	2.80	1.10 to 7.18	0.03
Improvement in bloating	3.05	1.94 to 4.79	<0.001
Improvement in abdominal pain	4.02	2.33 to 6.92	<0.001

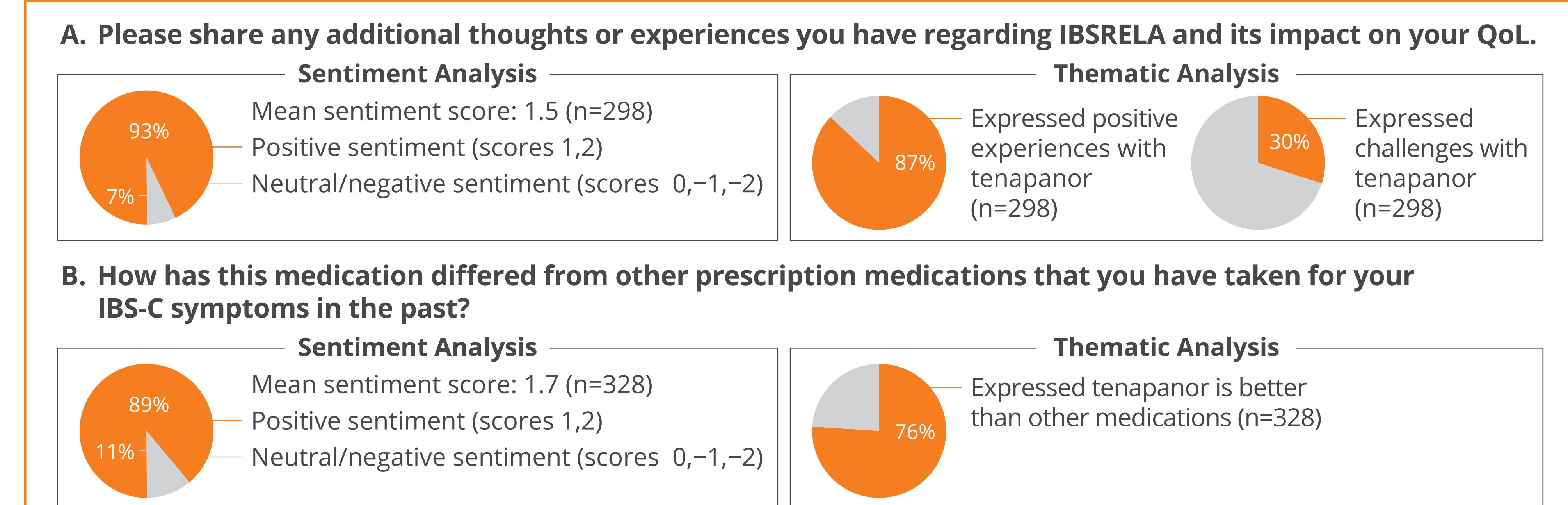
#### C. Predictors of treatment satisfaction

Factors <sup>b</sup>	OR	95% CI	P
Improvement in constipation	3.19	1.23 to 8.23	0.02
Improvement in bloating	1.57	0.82 to 3.02	ns
Improvement in abdominal pain	1.93	0.93 to 4.01	0.08
Improved participation in work	2.58	0.95 to 7.05	0.06
Improved participation in social activities/exercise	0.72	0.25 to 2.04	ns

<sup>a</sup>Multifactor ordered logistic regression analysis was performed, including all factors listed in the table. <sup>b</sup>Multifactor standard logistic regression analysis was performed, including all factors listed in the table.

- In sentiment analysis of open-ended questions, a high percentage of patients expressed positive sentiment when sharing their experiences with tenapanor (Figure 4A) and when comparing tenapanor with other IBS-C medications (Figure 4B).
- Two main themes were identified from the open-ended responses about experience with tenapanor (Figure 4A):
  - 87% of patients expressed positive experiences, including improved QoL, improved gastrointestinal symptoms, superiority over other medications, and/or gratitude for tenapanor.
  - 30% shared challenges, including side effects and partial symptom resolution, with <3% mentioning that potential side effects impacted their QoL.
- One main theme was identified from open-ended responses about patients' perspectives on tenapanor in comparison with other IBS-C medications (Figure 4B):
  - 76% of patients expressed that tenapanor is better than other IBS-C medications they have used, generally because it works better and/or has fewer side effects.

### Figure 4: Sentiment and Thematic Analysis of (A) Patient Experiences With Tenapanor and (B) Patient Perspectives on Tenapanor in Comparison With Other IBS-C Medications



## Limitations

- Patient characteristics were not obtained as part of the survey data.
- Since only patients taking tenapanor for  $\geq 6.5$  weeks were included, the findings do not represent the experiences of patients who stopped taking tenapanor early in their course of treatment.
- There was no placebo control.
- A potential source of bias is that patients were receiving free products at the time of the survey.

## Conclusions

This real-world survey highlights the effectiveness of tenapanor in the management of IBS-C. The majority of patients reported treatment satisfaction, improvements in constipation, bloating, abdominal pain, and QoL with tenapanor, and that tenapanor worked better and/or had fewer side effects than other IBS-C medications.

## Disclosures

This study was supported by Ardelyx, Inc. Luisa Scott, Johannah Ruddy, and Laura Williams are employees of Ardelyx, Inc. Belinda Gist was an employee of Ardelyx, Inc., at the time of the study. Alice Sibelli has undertaken consultancy work for Ardelyx, Inc.

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Dr. Scott can be contacted for further information on this study at lscott@ardelyx.com.

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**IBSRELÀ® (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**

- IBSRELÀ 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 IBSRELÀ 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 IBSRELÀ have not been established in pediatric patients less than 18 years of age. [see *PI Use in Specific Populations (8.4)*].

**CONTRAINDICATIONS**

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

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

**WARNINGS AND PRECAUTIONS**

**Risk of Serious Dehydration in Pediatric Patients**

IBSRELÀ is contraindicated in patients below 6 years of age. The safety and effectiveness of IBSRELÀ 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 IBSRELÀ 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 IBSRELÀ 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 IBSRELÀ-treated patients. If severe diarrhea occurs, suspend dosing and rehydrate patient.

**MOST COMMON ADVERSE REACTIONS**

The most common adverse reactions in IBSRELÀ-treated patients (incidence  $\geq 2\%$  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 additional safety information, including the Boxed Warning, please see full Prescribing Information: [click here](#).