

***Real-World Effectiveness and Health-Related Quality of Life Improvements Using Fecal Microbiota, Live-jslm for the Prevention of Recurrent Clostridioides difficile Infection***

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\*employed at the time analysis was conducted

# Background

## Disease Burden of CDI<sup>1-4</sup>

- 25% successfully treated patients recur
- Up to 65% experience continued recurrent episodes
- Recurrence associated with decreased quality of life

## Fecal microbiota, live-jslm (RBL)<sup>5</sup>

- First in-class microbiome-based therapy for prevention of rCDI
- Rectally administered, single dose



## Study Design



## Study Cohort

Patient Characteristics (n=128)	
Female	71.9%
Median age	71 yrs
Median CCI	4
Hospitalization last 4 weeks	9.4%

rCDI Risk Factors (n=128)	
0 risk factors	11%
1 risk factor	47%
2 risk factors	27%
≥3 risk factors	16%

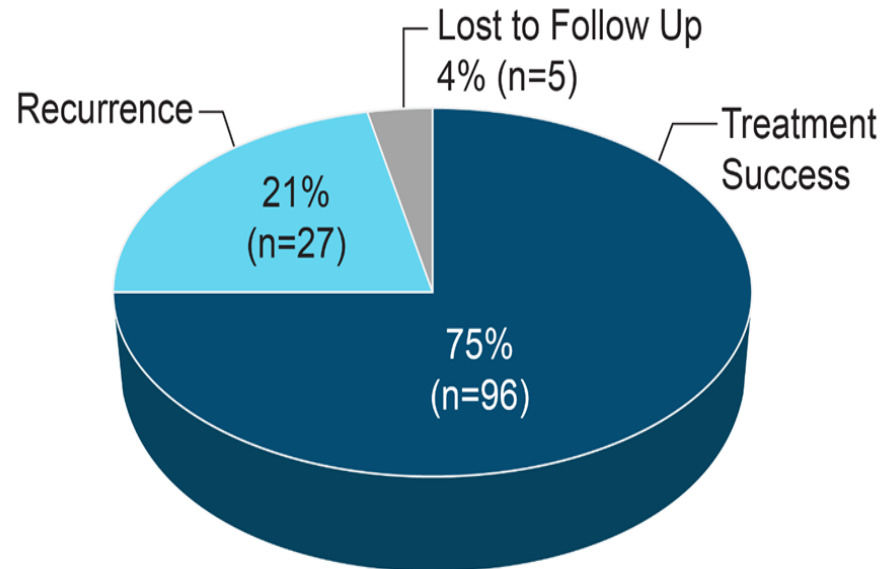
Abbreviations: CCI, Charlson Comorbidity Index; CDI, *Clostridioides difficile* infection; HR-QOL, health-related quality of life; rCDI, recurrent *Clostridioides difficile* infection

<sup>1</sup>Cornely OA, et al. Clin Infect Dis. 2012; 55(suppl 2):S154-S161. <sup>2</sup>McFarland LV, et al. Am J Gastroenterol. 2002; 97: 1769-1775. <sup>3</sup>Hengel RL, et al. J Patient Rep Outcomes. 2022; 6:49.

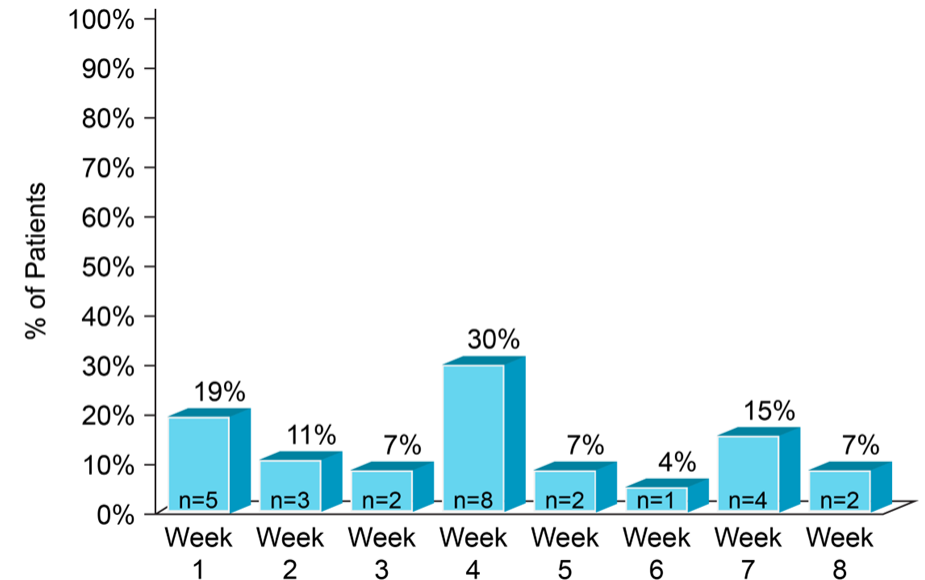
<sup>4</sup>Lurienne L, et al. J Patient Rep Outcomes. 2020; 4:14. <sup>5</sup>Rebyota (fecal microbiota, live - jslm) [package insert]. Roseville, MN: Ferring Pharmaceuticals; 2022.

# Effectiveness

## Treatment Response at 8 Weeks (N=128)



## Recurrence over Time by Week (N=27)



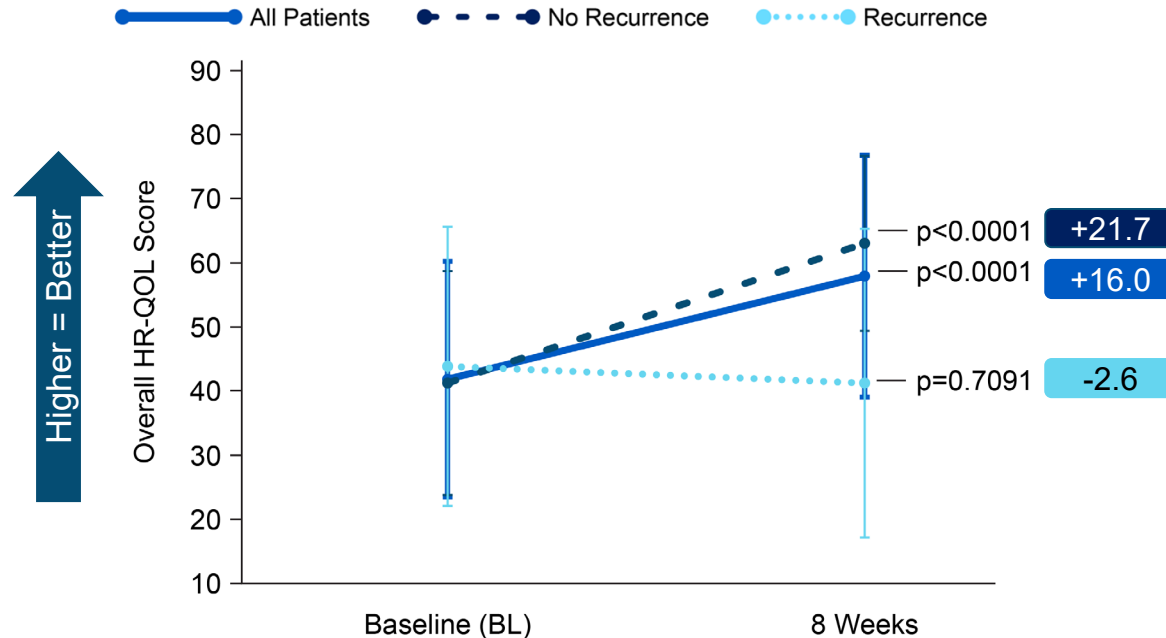
- **75%** of patients treated with RBL experienced treatment success at 8 weeks
- Median time to recurrence was 26 days (IQR 12-35)
- Age  $\geq 65$  years was a risk factor associated with recurrence
- RBL-related AEs occurred in 9 patients, none serious
  - 7 had incomplete retention with 6 of those experiencing a recurrence

**RBL is safe and effective at prevention of recurrent CDI**

# HR-QOL

## Change in Cdiff32<sup>6</sup> Score from Baseline to Week 8 (N=42)

### All Domains



### Physical Domain

**+15.7** (p=0.0002)  
No Recurrence: **+21.8** (p<0.0001)  
Recurrence: **-4.0** (p=0.5895)

### Mental Domain

**+18.7** (p=<0.0001)  
No Recurrence: **+25.0** (p<0.0001)  
Recurrence: **-1.1** (p=0.8850)

### Social Domain

**+8.5** (p=<0.0016)  
No Recurrence: **+12.0** (p<0.0001)  
Recurrence: **-2.5** (p=0.6537)

- Significant improvements overall in total score and each major domain
- Significantly increased HR-QOL scores at 8 weeks in patients with no recurrence
- No significant difference in scores from BL to 8 weeks in those with recurrence

**Significant improvements in HR-QOL were observed, driven by the treatment success achieved with RBL.**

