# Live Meeting

# AN INTRODUCTION TO REBYOTA®, THE PATIENT EXPERIENCE & ADMINISTRATION TRAINING

The first and only FDA-approved single-dose microbiota-based live biotherapeutic to prevent recurrence of *C. difficile* infection starting at first recurrence<sup>1,2,a</sup>

eIn the pivotal phase 3 trial, 32.8% of patients were treated at first recurrence of CDI following antibiotic treatment of CDI.

## **Program Educational Objectives:**

- Understand the microbiome composition, potency, and standardized manufacturing process of REBYOTA
- Review the efficacy and safety data for REBYOTA
- Discuss the use of REBYOTA in clinical practice

#### **Event details:**

## Featuring



**Who**Candace L. Cotto, RN

Clinical Research Nurse Medical Research Center of Connecticut, LLC, Medical Research Center of Connecticut, LLC



Where

The Park Event Center, 500 Division Street Waite Park, MN 56387



#### When

Friday, October 4, 2024 6:30 PM

## **Register Now:**

pharmethodportal.com/ferring/register Registration Program ID: 11147



Program Contact: Tina Goede, tina.goede@ferring.com

#### **INDICATION**

REBYOTA (fecal microbiota, live - jslm) is indicated for the prevention of recurrence of *Clostridioides difficile* infection (CDI) in individuals 18 years of age and older, following antibiotic treatment for recurrent CDI.

#### **Limitation of Use**

REBYOTA is not indicated for treatment of CDI.

#### **IMPORTANT SAFETY INFORMATION**

#### Contraindications

Do not administer REBYOTA to individuals with a history of severe allergic reaction (eg. anaphylaxis) to any of the known product components.

#### **Adverse Reactions**

The most commonly reported (>3%) adverse reactions in adults following a single dose of REBYOTA were abdominal pain (8.9%), diarrhea (7.2%), abdominal distention (3.9%), flatulence (3.3%), and nausea (3.3%).

Please see additional Important Safety Information on the following page.



#### **IMPORTANT SAFETY INFORMATION (continued)**

## Warnings and Precautions

### Transmissible infectious agents

Because REBYOTA is manufactured from human fecal matter, it may carry a risk of transmitting infectious agents. Any infection suspected by a physician possibly to have been transmitted by this product should be reported by the physician or other healthcare provider to Ferring Pharmaceuticals Inc.

#### Management of acute allergic reactions

Appropriate medical treatment must be immediately available in the event an acute anaphylactic reaction occurs following administration of REBYOTA.

#### Potential presence of food allergens

REBYOTA is manufactured from human fecal matter and may contain food allergens. The potential for REBYOTA to cause adverse reactions due to food allergens is unknown.

## Use in Specific Populations Pediatric Use

Safety and efficacy of REBYOTA in patients below 18 years of age have not been established.

#### **Geriatric Use**

Of the 978 adults who received REBYOTA, 48.8% were 65 years of age and over (n=477), and 25.7% were 75 years of age and over (n=251). Data from clinical studies of REBYOTA are not sufficient to determine if adults 65 years of age and older respond differently than younger adults.

You are encouraged to report negative side effects of prescription drugs to FDA. Visit www.FDA.gov/medwatch, or call 1-800-332-1088.

1. REBYOTA. Prescribing information. Parsippany, NJ: Ferring Pharmaceuticals Inc; 2022. 2. US Food and Drug Administration. FDA Approves First Fecal Microbiota Product. <a href="https://www.fda.gov/news-events/press-announcements/fda-approves-first-fecal-microbiota-product">https://www.fda.gov/news-events/press-announcements/fda-approves-first-fecal-microbiota-product</a>. Accessed December 1, 2022.

Please see accompanying full Prescribing Information at www.REBYOTAHCP.com.

#### **RESTORE HOPE**

To facilitate a meaningful educational discussion, this program is only intended for healthcare professionals having appropriate medical specialties. Please be advised that spouses and other guests are not permitted to participate unless they are also HCPs with the same medical specialty and background as the invited HCP. This is a promotional program and no CME credits are offered.

Please note that the Sunshine Act requires all pharmaceutical manufacturers to submit an annual report to CMS identifying items of value (including meals) provided to prescribers. The meal being provided at this event falls within that reporting requirement.

Thank you in advance, and we look forward to your participation.

