NEWS RELEASE

Ferring to Present New Data Analyses at ACG 2023 for REBYOTA® (fecal microbiota, live – jslm), the First and Only Single-Dose, FDA Approved Microbiome-Based Treatment for the Prevention of Recurrent C. difficile Infection

10/3/2023

PARSIPPANY, N.J.--(BUSINESS WIRE)-- Ferring Pharmaceuticals today announced it will present two analyses of data for REBYOTA® (fecal microbiota, live – jslm), the first and only single-dose, FDA approved microbiome-based treatment to prevent recurrent Clostridioides difficile (C. diff) infection after antibiotic treatment. The data will be presented as part of the American College of Gastroenterology's (**ACG**) 2023 Annual Scientific Meeting, being held October 20 – 25 in Vancouver, Canada.

One analysis to be presented at ACG will evaluate the association between the gut microbiome and health-related quality of life (HRQL) in adults with recurrent C. diff infection. The other presentation is an ad hoc analysis from an open-label Phase 3 study on the efficacy and safety of REBYOTA in recurrent C. diff infection patients who are 65 years of age or older and living with other illnesses, such as chronic kidney disease, cardiac disease or gastrointestinal disorders.

Descriptions of the abstracts accepted for presentation are as follows:

Poster P2222 Description – An Analysis From the REBYOTA PUNCH™ CD3 Phase 3 Clinical Trial on the Association Between Microbiome Composition and HRQL in Patients With Recurrent C. diff Infection

Presenting Author: Paul Feuerstadt, M.D., F.A.C.G., A.G.A.F., PACT Gastroenterology, Hamden, Conn.; Assistant Clinical Professor of Medicine, Yale University School of Medicine, New Haven, Conn.

EMBARGOED UNTIL: Sunday, October 22, 2023, at 3:00 p.m. ET

Poster P0181 Description – An Ad Hoc Analysis From the PUNCH CD3-Open-Label Study (OLS) on the Efficacy and Safety of REBYOTA in Older Participants With Recurrent C. diff Infection and Underlying Comorbidities

Presenting Author: Paul Feuerstadt, M.D., F.A.C.G., A.G.A.F., PACT Gastroenterology, Hamden, Conn.; Assistant Clinical Professor of Medicine, Yale University School of Medicine, New Haven, Conn.

EMBARGOED UNTIL: Sunday, October 22, 2023, at 3:00 p.m. ET

ACG 2023 has made abstracts available on its **website**.

About C. diff infection

C. diff infection is a serious and potentially deadly infection that impacts people across the globe. The C. diff bacterium causes debilitating symptoms, such as severe diarrhea, fever, stomach tenderness or pain, loss of appetite, nausea and colitis (an inflammation of the colon).1C. diff infection can be the start of a vicious cycle of recurrence, causing a significant burden for patients and the healthcare system.2,3 It has been estimated that up to 35% of C. diff infection cases recur after initial diagnosis and people who have had a recurrence are at significantly higher risk of further infections.4,5,6,7 After the first recurrence, it has been estimated that up to 65% of patients may develop a subsequent recurrence.6,7 Antibiotics – the current standard of care for treatment of C. diff infection – treat the disease but can also be a contributing factor to the cycle of recurrence.1

About REBYOTA

REBYOTA is a pre-packaged, single-dose 150 mL microbiota suspension for rectal administration consisting of a liquid mix of up to trillions of live microbes – including Bacteroides. REBYOTA is delivered directly to the gut microbiome and is administered by a healthcare professional in one visit.

INDICATION

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

Limitation of Use

REBYOTA is not indicated for the treatment of C. diff infection.

IMPORTANT SAFETY INFORMATION

- You should not receive REBYOTA if you have a history of a severe allergic reaction (e.g., anaphylaxis) to REBYOTA or any of its components.
- You should report to your doctor any infection you think you may have acquired after administration.

- REBYOTA may contain food allergens.
- Most common side effects may include stomach pain (8.9%), diarrhea (7.2%), bloating (3.9%), gas (3.3%), and nausea (3.3%).
- REBYOTA has not been studied in patients below 18 years of age.
- Clinical studies did not determine if adults 65 years of age and older responded 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.

Please click to see the full **Prescribing Information**.

About Ferring Pharmaceuticals

Ferring Pharmaceuticals is a research-driven, specialty biopharmaceutical group committed to helping people around the world build families and live better lives. In the United States, Ferring is a leader in reproductive medicine and maternal health, uro-oncology and in specialty areas within gastroenterology, including microbiome therapeutics, and orthopaedics. For more information, call 1-888-FERRING (1-888-337-7464) or visit **http://www.ferringusa.com/**.

Connect with us on our dedicated microbiome therapeutics development channels on **Twitter** and **LinkedIn**.

References:

1. Centers for Disease Control and Prevention. What is C. diff? 7 Sep. 2022. Available at: **https://www.cdc.gov/cdiff/what-is.html**.
2. Centers for Disease Control and Prevention. 2019 Antibiotic Resistance Threats Report: Clostridioides difficile. 23 Nov. 2021. Available at: **https://www.cdc.gov/drugresistance/pdf/threats-report/clostridioides-difficile-508.pdf**.
3. Feuerstadt P, et al. Healthcare resource utilization and direct medical costs associated with index and recurrent Clostridioides difficile infection: a real-world data analysis. J Med Econ. 2020;23(6):603-609.
4. Riddle DJ, Dubberke ER. Clostridium difficile infection in the intensive care unit. Infect Dis Clin North Am. 2009;23(3):727-743.
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6. Kelly, CP. Can we identify patients at high risk of recurrent Clostridium difficile infection? Clin Microbiol Infect. 2012; 18 (Suppl. 6):21–27.
7. Smits WK, et al. Clostridium difficile infection. Nat Rev Dis Primers. 2016;2:16020. doi: 10.1038/nrdp.2016.20.

Lisa Ellen
Director, Brand Communications
E:**lisa.ellen@ferring.com**
P: +1-862-286-5696

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