NEWS RELEASE

More Real-World Data and New Analyses of Data for REBYOTA® (fecal microbiota, live – jslm) Presented at IDWeek 2023

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- Analysis looks at early experience with REBYOTA in clinical practice
- Additional analyses evaluate efficacy and safety of REBYOTA in patients with kidney disease and whether patients treated with REBYOTA remained recurrence free after antibiotic therapy for another illness
- Analysis from pivotal Phase 3 clinical trial suggests a correlation between a healthier gut microbiome and health-related quality of life (HRQL)

PARSIPPANY, N.J.--(BUSINESS WIRE)-- Ferring Pharmaceuticals today announced four poster presentations at Infectious Disease Week (**IDWeek**) 2023 for REBYOTA® (fecal microbiota, live – jslm), the first and only single-dose microbiome-based treatment approved by the U.S. Food and Drug Administration (FDA) for the prevention of recurrent Clostridioides difficile (C. diff) infection in individuals 18 years of age and older, following antibiotic treatment for recurrent C. diff infection.

“The real-world and clinical data presented at IDWeek reinforce the potential of REBYOTA to prevent recurrent C. diff infection and help patients suffering from this devastating disease,” said Elizabeth Garner, M.D., M.P.H., Chief Scientific Officer, Ferring Pharmaceuticals U.S.“Initial experiences with REBYOTA in physicians’ offices are promising and this is a positive step forward in changing the treatment paradigm for recurrent C. diff infection.”

One analysis (poster number 685) evaluated the initial experience of 25 patients receiving REBYOTA following development and initiation of a protocol for use at 12 physician office infusion centers (POICs). Electronic health records, administration records and internal databases were reviewed for patient demographics, setting of care, time from order to treatment, logistics from order to administration and payor details. Early experience with

REBYOTA showed an administration time of six minutes followed by 15 minutes of observation. No one was denied insurance coverage for REBYOTA or the instillation procedure.

“In a routine office practice, the treatment of recurrent C. diff infection with REBYOTA took minutes and administration was simple,” said Timothy Ritter, M.D., GI Alliance, Southland, Tex. “These initial results support the use of REBYOTA as a practical office-based treatment to prevent recurrent C. diff infection in adults.”

Efficacy and Safety Analysis in Patients With Kidney Disease

An ad hoc subgroup analysis (poster number 706) of PUNCH™ CD3-OLS — an ongoing, open-label Phase 3 REBYOTA trial — looked at efficacy and safety for participants with renal comorbidity. Within a modified intent-to-treat (mITT) population (n=402), 98 had renal comorbidity, including chronic kidney disease (CKD) (n=29) and end-stage renal failure (n=5).

Overall, 66% (65 of 98) and 77% (235 of 304) of participants with and without renal comorbidity, respectively, achieved treatment success, defined as remaining free of C. diff infection recurrence for eight weeks following REBYOTA treatment. Treatment-emergent adverse events (TEAEs) through six months post treatment occurred in 71% (70 of 98) and 64% (194 of 304) of participants with and without renal comorbidity, respectively. Most TEAEs were moderate in severity and related to pre-existing conditions.

Efficacy Outcomes With Subsequent Antibiotic Use

A post hoc subgroup analysis (poster number 702) from the PUNCH Open-Label Phase 2 trial evaluated whether patients with multiple episodes of recurrent C. diff infection who received two doses of REBYOTA remained recurrence free when they were later exposed to antibiotic therapy for another condition, such as a urinary tract infection. Among participants who received systemic antibiotics within eight weeks, six months, 12 months and 24 months of REBYOTA administration, 91.6% (11 of 12), 95.7% (22 of 23), 90.6% (29 of 32) and 83.3% (30 of 36) remained free of C. diff infection recurrence, respectively. Among all participants (n=43), 86% were recurrence-free at their last evaluable timepoint.

Healthier Gut Microbiome Linked to Health-Related Quality of Life

In this analysis of patients in the Phase 3 PUNCH CD3 clinical trial, investigators evaluated the relationship between the gut microbiome and patient-reported health-related quality of life (HRQL) (poster number 366). The analysis measured the relative abundance of beneficial gut microbiota (Bacteroidia and Clostridia) versus other bacteria (Gammaproteobacteria and Bacilli) based on the Microbiome Health Index (MHI), in which a score greater than 7.2 indicates a healthier gut microbiome. Comparing MHI data with HRQL, as measured using the disease-specific C. difficile Quality of Life Survey (Cdiff32) — which examines physical, mental and social domains — the analysis found that an MHI score of at least 7.2 was associated with a 14.2 to 18.4 Cdiff32 point increase, suggesting a correlation between a healthier gut microbiome and HRQL in patients with recurrent C. diff infection.

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).1 C. 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. REBYOTA is approved and marketed in the U.S. only.

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:

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