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Chief Operating Officer

Recent, Encouraging News for People With Recurrent Clostridium difficile (C. diff) infection

Annandale, VA; December 17, 2022 – The leaders and researchers at Ferring Pharmaceuticals Inc. announced earlier this month Food and Drug Administration (FDA) approval of its microbiota-based therapy for a type of debilitating intestinal infection making it the first drug of its kind for U.S. market. This is also an exciting announcement for the Clinical Alliance for Research and Education-Infectious Diseases (CARE-ID) because of its role as a clinical research site earlier in 2022. The treatment, called Reybota, is cleared for use in adults 18 and older who have recurrent infections of Clostridioides difficile, or C. diff, and have completed a round of antibiotics. Epidemiological studies indicate that C. diff has become the most common microbial cause of healthcare-associated infections in U.S. hospitals and costs up to \$4.8 billion each year in excess health care costs for acute care facilities alone.

“It isn’t often that we see such positive results and so quickly in the research process, stated CARE-ID Medical Director, David Wheeler, MD, FACP, FIDSA. “CARE-ID received its approval to begin recruiting and enrolling participants in March of this year and the process began immediately. In this case, the FDA’s recognition of the importance of this treatment makes us that much more gratified that we were able to participate in this study.

“According to the US Centers for Disease Control and Prevention (CDC), C. diff is a major and urgent threat. It is one of the most common healthcare-associated infections in US hospitals, affecting approximately half a million people annually”, stated Ken Blount, PhD Chief Science Officer, Rebiotix and VP Microbiome Research (Rebiotix is the US subsidiary of Ferring Pharmaceuticals). “C. diff infection requires urgent and aggressive action so our study took place in nearly 80 hospitals and clinics around the United States and Canada with approximately 600 people.”

According to a Ferring Pharmaceutical spokesperson, “ Reybota is a single-dose enema manufactured from donor samples of gut bacteria. After an infection, treatment with Reybota is meant to restore balance to the microbiome, the trillions of microbes that inhabit the human body. It’s a regulated, standardized alternative to the fecal transplants that the agency has allowed under investigational use since 2013.

“Fecal microbiota transplantation (FMT) can be highly effective for treating Clostridium difficile infections (CDI)”, stated David Wheeler, MD. “FMT is a procedure in which healthy donor stool is inserted to correct the recipient’s intestinal microbial community by introducing a highly concentrated healthy gastrointestinal (GI) flora.

In recommending Reybota for approval one of the FDA’s advisory panel members noted, “a standardized option could be better monitored for efficacy and safety than an unregulated fecal transplant”.

“Fecal transplantation isn’t a new technique, stated CARE-ID COO, Steve Poretz. “But the approach and formulation Ferring and Reybota are using is somewhat unique. Because C. diff is a very difficult condition to treat, our study did not use a placebo. Each study participant received the actual therapeutic treatment. We anticipate this novel therapy will gain great interest among the community of C. diff patients.”

About CARE-ID

CARE-ID conducts clinical research trials in the field of infectious diseases with particular focus on the safety and confidentiality of our participants, quality of our data, and integrity of our results. We partner with pharmaceutical and biotechnology companies to develop experimental therapies for both the prevention and treatment of infectious diseases.

Anyone interested in participating in any of our clinical studies or needing more information about CARE-ID is welcome to contact us directly.

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About Ferring

Ferring Pharmaceuticals Inc. is a private, Swiss research-driven, specialty biopharmaceutical group. As a leader in reproductive medicine and maternal health, and in specialty areas within gastroenterology and orthopedics, Ferring is committed to helping people around the world build families and live better lives. Ferring along with its US subsidiary Rebiotix, are taking a different approach to recurrent C. diff through transforming the potential of microbiome restoration into novel live biotherapeutics.

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