



Steve Poretz, RN, MSHA, MBA
Executive Director

An important clinical study for people with recurrent *Clostridium difficile* (c Diff) infection

Annandale, VA; March 10, 2022 – The leaders and researchers at the Clinical Alliance for Research and Education-Infectious Diseases (CARE-ID) are very pleased to announce their collaboration with Ferring Pharmaceuticals Inc. for a pivotal, new research study addressing recurrent *Clostridium difficile* infection (C. diff or CDI). This study will involve treating these infections with a novel fecal transplant compound, RBX2660, an enema-based material derived from healthy stool donors.

“C. diff infection requires urgent and aggressive action”, stated Ken Blount, PhD Chief Science Officer, Rebiotix and VP Microbiome Research (Rebiotix is the US subsidiary of Ferring Pharmaceuticals). “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”

CARE-ID received its approval to begin recruiting and enrolling participants on March 4 and the process will begin immediately. The purpose of this study is to learn about the safety of RBX2660 in patients with recurrent CDI. This study will take place in up to 80 hospitals or clinics in the United States and Canada. Up to 600 people will be treated in this study.

Epidemiological studies indicate that *C. difficile* 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. The latest study found that 1 out of every 5 patients with a healthcare-associated *C. difficile* infection experienced a recurrence of the infection. The Ferring/Rebiotix PUNCH CD3-OLS clinical study will evaluate the safety and tolerability of Rebiotix RBX2660 for the prevention of recurrent CDI. With this study option, many more people that suffer from recurrent C. diff may now qualify for study participation.

“Fecal microbiota transplantation (FMT) can be highly effective for treating *Clostridium difficile* infections (CDI)”, stated CARE-ID Medical Director, David Wheeler, MD, FACP, FIDSA. “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. Healthy donors are screened for bloodborne pathogens (Hepatitis, HIV) as well as parasites and other infectious stool pathogens. Once the product is synthesized, it goes through the screening process again for repeat testing of infectious stool pathogens so we know the recipient is receiving a healthy and therapeutic amount of the good gastrointestinal bacteria required for a normal functioning GI tract.”

There are no direct costs to an individual who agrees to participate in this study. All the study related research costs for the required study visits, phone calls, examinations, laboratory procedures, supplies and the enema study drug(s) will be provided by Rebiotix. To be eligible for the study a person must be:

- 18 years and older
- Have experienced more than one C. diff infection
- Currently taking or just prescribed antibiotics to control C. diff diarrhea
- Willing and able to meet all study requirements

“A new investigational Microbiota Restoration Therapy (MRT™), the RBX2660 formulation (a microbiota-based live biotherapeutic), will be the foundation for this study”, stated Executive Director, Steve Poretz. “Fecal transplantation isn’t a new technique. But the approach and formulation Ferring and Rebiotix are using is a somewhat unique approach. Because C. diff is a very difficult condition to treat, we are anticipating this novel therapy will produce greater participation among the community of C. diff patients. For this study there will not be a placebo meaning all participants will receive the actual treatment therapy”

Anyone interested in participating in this study or needed more information about the study should contact CARE-ID directly.

CARE-ID is located and can be contacted at:

3289 Woodburn Rd. Suite 250

Annandale, Virginia 22003

info@careidresearch.com

703-560-4821 (phone)

703-641-8654 (fax)

<http://www.careidresearch.com/>

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.

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.

<https://microbiome.ferring.com/about-ferring-pharmaceuticals/>