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Rebiotix®
Microbiota Restoration Therapy
A FERRING COMPANY

Statement

Response to FDA Safety Alert Regarding the Use of Fecal Microbiota for Transplantation

Parsippany, New Jersey – 14 June 2019 – Rebiotix and Ferring Pharmaceuticals were saddened to learn about the patients mentioned in the FDA's safety alert regarding the use of Fecal Microbiota for transplantation and risk of serious adverse reactions due to transmission of multi-drug resistant organisms*. We do not have any details regarding the patients mentioned in the safety alert, as they were not enrolled in our clinical trials. Our thoughts are with their families. These unfortunate events reinforce our commitment to bringing safe and effective FDA-approved products to market.

We are aligned with and remain committed to the FDA's additional protections as outlined in the safety alert. Rebiotix and Ferring are strong proponents of the appropriate screening of donor derived microbiota products as a means to avoid a public health incident, as described in the FDA safety alert. Rebiotix was the first company to engage the FDA in defining a regulatory pathway for microbiota-based therapies. We continue to work closely with the FDA to sponsor high quality clinical trials with stringent donor screening programs, as we conduct our fourth clinical trial on our lead candidate RBX2660.

About Rebiotix

Rebiotix Inc., part of the Ferring Pharmaceuticals Group, is a late-stage clinical microbiome company focused on harnessing the power of the human microbiome to revolutionise the treatment of challenging diseases. Rebiotix has a diverse pipeline of investigational drug products built on its pioneering microbiota-based MRT™ drug platform. The MRT platform is a standardised, stabilised drug technology that is designed to rehabilitate the human microbiome by delivering a broad consortium of live microbes into a patient's intestinal tract. The lead drug candidate, RBX2660, is currently in Phase 3 clinical development for the prevention of recurrent *Clostridium difficile* (C. diff) infection. RBX2660 has been granted Fast Track status, Orphan Drug and Breakthrough Therapy designation from the US FDA for its potential to prevent recurrent C. diff infection. Rebiotix's clinical pipeline also features RBX7455, a lyophilized, non-frozen, oral capsule part of a recently completed investigator-sponsored Phase 1 trial for the prevention of recurrent C. diff infection. For more information on Rebiotix and its pipeline of human microbiome-directed therapies for diverse disease states, visit www.rebiotix.com.

About Ferring Pharmaceuticals

Ferring Pharmaceuticals is a research-driven biopharmaceutical company devoted to identifying, developing and marketing innovative products in the fields of reproductive health, women's health, urology, gastroenterology, endocrinology, oncology, and orthopaedics. For more information, call 1-888-FERRING (1-888-337-7464); visit www.FerringUSA.com.

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***** **https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/important-safety-alert-regarding-use-fecal-microbiota-transplantation-and-risk-serious-adverse**