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Rebiotix Receives Breakthrough Therapy Designation for RBX2660 – A Microbiota Restoration Therapy (MRT) for the Treatment of Recurrent *Clostridium difficile* Infection

Milestone reinforces Rebiotix as a leader in microbiota-based drug development and product commercialization

ROSEVILLE, MN (October 12, 2015) – Rebiotix Inc. today announced that U.S. Food and Drug Administration (FDA) has designated its lead Microbiota Restoration Therapy (MRT) RBX2660 as a Breakthrough Therapy for the treatment of recurrent *Clostridium difficile* (C diff) infection, a challenging to treat gastrointestinal (GI) infection that causes 29,000 deaths in the U.S. annually.[1] Rebiotix is a clinical stage biotechnology company that was founded to revolutionize the treatment of debilitating GI diseases by harnessing the power of the human microbiome. MRT is the Rebiotix drug platform for delivering healthy, live, human-derived microbes into a sick patient's intestinal tract to treat disease.

Studies have shown that most cases of C diff infection occur after the normal microorganisms that reside in the gut have been disrupted by antibiotic use. Restoring the balance of microbes is thought to be key to breaking the cycle of recurrence. Lead Rebiotix product, RBX2660, is targeted at treating recurrent C diff.

"The development of RBX2660 represents our commitment to harnessing the microbiome to develop therapies for debilitating and sometimes fatal disease for which there is currently no FDA-approved alternative," said Rebiotix CEO Lee Jones. "The Breakthrough Therapy Designation marks the third regulatory milestone for our lead product, RBX2660, in the past two years, and reinforces our leading efforts that have brought us to the cusp of delivering a revolutionary and validated treatment to patients living with recurrent C diff."

About the Breakthrough Therapy Designation

According to the FDA, Breakthrough Therapy designation is a process designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s). For more information please visit http://www.fda.gov/forpatients/approvals/fast/ucm405397.htm

About *Clostridium difficile* Infection

Clostridium difficile (C diff) infection is a serious and potentially fatal disease, characterized by severe diarrhea, fever, and loss of appetite. It is a leading healthcare acquired infection, and in the U.S. alone, there are over 29,000 deaths annually from the disease.[2] Currently, 20-30% of patients with C diff go on to experience more than one episode of the disease, which is known as recurrent C diff infection.[3] Recurrent C diff infection is especially challenging to treat as, to date, there are no approved drugs to treat patients with two or more recurrences.

About Rebiotix Inc.

Rebiotix Inc. is a results-oriented biotechnology company revolutionizing the treatment of challenging gastrointestinal diseases by harnessing the power of the human microbiome. The Roseville, Minn. based company is pioneering Microbiota Restoration Therapy (MRT) for delivering healthy, live, human-derived microbes into a sick patient's intestinal tract to treat disease. Rebiotix's lead candidate RBX2660 was granted orphan drug status and fast tract status from the FDA. For more information, visit www.rebiotix.com.

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[1] Lessa FC et al. Burden of *Clostridium difficile* Infection in the United States. *NEJM*. 2015. 372:825-834.
[2] Lessa FC et al. Burden of *Clostridium difficile* Infection in the United States. *NEJM*. 2015. 372:825-834.
[3] Cornely OA, Miller MA, Louie TJ, Crook DW, Gorbach SL. Treatment of first recurrence of *Clostridium difficile* infection: fidaxomicin versus vancomycin. *CID* 2012;55 .(Suppl 2):S154-S161.