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Rebiotix and McMaster Children's Hospital Announce First Patient treated in Largest Randomized Clinical Trial of Fecal Microbial Transplant (FMT) for Pediatric Ulcerative Colitis

Findings of this pilot study to inform development of a multicenter trial of FMT in pediatric ulcerative colitis

ROSEVILLE, MN and HAMILTON, ON (December 14, 2015) – Rebiotix Inc. and McMaster Children's Hospital announced the first patient treated in the PediFETCh (Pediatric FEcal microbial Transplant for ulcerative Colitis) trial. This is the largest randomized, placebo-controlled clinical trial to date evaluating fecal microbial transplant (FMT) in children with ulcerative colitis (UC).

UC is an often debilitating gastroenterological condition that affects approximately 500,000 people in North America.¹ Ulcerative colitis is characterized by chronic inflammation in the large intestine. In children, this condition can have profound effects on growth and development, and quality of life is affected by flares of abdominal pain, bloody diarrhea and treatments that may cause significant toxicity, lymphoma and serious infections.²

The PediFETCh trial is being conducted through McMaster Children's Hospital's Division of Pediatric Gastroenterology and Nutrition, in collaboration with Rebiotix Inc., a clinical stage biotechnology company. RBX2660 is the company's lead drug platform for microbial restoration therapy, containing live microbes collected from screened human donors.



“We are excited to launch this study using RBX2660, to help understand the role of intestinal bacteria in the treatment of pediatric ulcerative colitis,” said Nikhil Pai, MD FAAP FRCPC, the study’s principal investigator who is a Pediatric Gastroenterologist at McMaster Children’s Hospital and Assistant Professor of Pediatrics at McMaster University’s Michael G. DeGroote School of Medicine. “By delivering a series of enemas containing live human bacteria into the intestines of children with UC, we may be able to alter the immune disruption that characterizes a disease that can be debilitating for children and their families.”

“Our collaboration with McMaster Children’s Hospital exemplifies the passion and commitment of Rebiotix to apply our microbial restoration therapy platform to a range of challenging diseases such as ulcerative colitis,” said Rebiotix CEO Lee Jones, “We remain focused on realizing the potential of the human microbiome to treat challenging gastrointestinal diseases.”

The results of this pilot trial will help inform the design of a future, multicenter pediatric study that will evaluate fecal microbial transplant as a potential treatment option for inflammatory bowel disease.

Dr. Robert Issenman, (Division Chief of Pediatric Gastroenterology, McMaster Children’s Hospital and Professor of Pediatrics at the Michael G. DeGroote School of Medicine at McMaster) has generously provided support and mentorship for the PediFETCh Trial. The study involves the expertise of co-investigators Dr. Christine Lee (Medical Director, Infection Prevention and Control, St. Joseph’s Healthcare Hamilton and Professor of Pathology and Molecular Medicine at the Michael G. DeGroote School of Medicine at McMaster), Dr. Paul Moayyedi (Chair of Gastroenterology, Hamilton Health Sciences and Professor of Medicine at the Michael G. DeGroote School of Medicine at McMaster) and study coordinator, Ms. Jelena Popov, BSc (McMaster University).³

About Rebiotix Inc.

Rebiotix Inc. is a results-oriented biotechnology company focused on the treatment of challenging diseases by harnessing the power of the human microbiome. The Roseville, Minn. based company is pioneering Microbiota Restoration Therapy (MRT) for delivering live microbes into a sick patient’s intestinal tract to treat disease. Rebiotix’s lead candidate RBX2660 was granted Orphan Drug status, Fast Track status and Breakthrough Therapy Designation from the FDA for its potential that it may treat recurrent *C diff* infection. For more information, visit www.rebiotix.com.



About McMaster Children's Hospital

McMaster Children's Hospital is a dedicated pediatric academic health sciences center, providing care to 2.3 million children across South Central Ontario and beyond. It is the regional centre for children and teens requiring emergency care, inpatient and outpatient subspecialty services, and is home to the largest neonatal intensive care unit in Ontario. McMaster Children's Hospital is closely affiliated with the Farncombe Family Digestive Health Research Institute of McMaster University, a world-renowned multidisciplinary intestinal disease research facility, focused on the role of the gut microbiome in chronic intestinal disease. The Hospital's Division of Pediatric Gastroenterology maintains strong clinical and basic science collaborations with the Farncombe Institute, exploring the frontiers of inflammatory, functional, and diet-induced pediatric gastrointestinal disorders. For more information, visit www.mcmasterchildrenshospital.ca.

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¹ Fuller-Thomson E, Sulman J. Depression and inflammatory bowel disease; findings from two nationally representative Canadian surveys. *Inflamm Bowel Dis.* 2006; 12:697-707

² Talley NJ, Abreu MT, Achkar JP, Bernstein CN, Dubinsky MC, Hanauer SB, Kane SV, Sandborn WJ, Ullman TA, Moayyedi P. An evidence-based systematic review on medical therapies in inflammatory bowel disease. *Am J Gastroenterol* 2011; 106 supp 1: S2-S25.

³ Moayyedi P, Surette MG, Kim PT, et al. Fecal Microbiota Transplantation Induces Remission in Patients With Active Ulcerative Colitis in a Randomized Controlled Trial. *Gastroenterology.* 2015;149(1):102-109.e6.