BROOMFIELD, Colo., Sept. 11, 2013 /PRNewswire/ -- MicroBiome Therapeutics LLC, (MBT), a biotechnology company developing pharmaceutical and medical food products that shift the human microbiome in specific ways for improved health, today reported publication of a case report suggesting a potentially important new application for its lead product, NM504. NM504 is in clinical development to promote healthy blood glucose levels and metabolic fitness in prediabetic and diabetic populations.

In the case report [1], currently available in the online edition of *Beneficial Microbes*, researchers describe how co-administration of NM504 eliminated the dose-limiting diarrhea caused by metformin in a patient with newly-diagnosed type 2 diabetes. Metformin, a safe, effective and inexpensive medication favoring weight loss, is the most widely prescribed diabetes drug worldwide, and it is recommended for initial treatment of type 2 diabetes by the American Diabetes Association. However, diarrhea is a well-known side effect of metformin therapy, affecting an estimated 20% of patients. Physicians report diarrhea as a frequent cause of metformin discontinuation or dosage limitation. The second-line therapies prescribed in these cases as a substitute for metformin are expensive and carry risks of potentially serious side effects.

"NM504 virtually eliminated the diarrhea caused by metformin in this patient with type 2 diabetes and was also associated with additional large decreases in his highly elevated blood glucose levels," commented Mark Heiman, Ph.D., a co-author of the case report and chief scientific officer of MicroBiome Therapeutics.

Dr. Heiman continued, "Research shows that the human GI microbiome plays an important role in the regulation of metabolic processes, including changes associated with type 2 diabetes. Modern diets often lack essential ingredients that support a healthy microbiome, so wedesigned NM504 to replace key missing elements that impact the GI microbiome in ways known to be beneficial to metabolic and gastrointestinal health. We look forward to completing our pilot trial that is further testing the hypothesis that NM504 may have utility as an adjunctive therapy to metformin."

MBT is developing evidence-based microbiome modulators—therapies designed to alter bacterial populations and their environment in the gastrointestinal (GI) tract to treat and prevent serious health conditions. MBT's microbiome modulators act on multiple factors in the GI environment, providing specialized ingredients that augment the growth of targeted desirable bacterial strains and discourage the growth of others that may be harmful. These shifts in the GI microbiome have the potential to have a major impact on factors affecting metabolism and weight, such as the endocrine response that affects appetite, metabolism and energy storage.

NM504 contains a proprietary combination of plant-derived soluble and insoluble fibers and antioxidants formulated to help prediabetic and diabetic individuals achieve healthy blood glucose levels and manage their body weight. NM504 is designed to shift the GI microbiome by replacing essential ingredients that are typically missing in the diets of prediabetic and diabetic individuals. This replacement strategy provides an advantage for beneficial members of the gut microbiota, while disadvantaging others that are harmful to metabolic health. The resulting microbiome shift produces an increase in the production of metabolites and signaling molecules that help regulate metabolic hormones, improve GI motility, maintain the protective intestinal mucosal barrier, reduce caloric absorption and reduce appetite.

NM504 is being studied in two placebo-controlled, double-blinded, proof-of-concept trials. The first is assessing its ability to alter the GI microbiome to enhance insulin sensitivity and fasting blood glucose levels in prediabetic individuals. The second trial is testing the utility of NM504 as an adjunctive therapy to metformin

MBT's initial products are combinations of naturally occurring components that are not digested but that act to modulate the GI microbiome in beneficial ways. They are being developed as evidence-based pharmaceutical and medical food products using rigorous scientific methods and clinical studies to assess and validate their beneficial activity.

1 - A novel cobiotic containing a prebiotic and an antioxidant augments the glucose control and gastrointestinal tolerability of metformin: a case report, F. Greenway, S. Wang, M. Heiman, Beneficial Microbes, DOI - 10.310.3920/BM2012.0063, http://wageningenacademic.metapress.com/content/FG7642372U410742

**About MicroBiome Therapeutics**

MicroBiome Therapeutics LLC (MBT), formerly NuMe Health, is a clinical stage biotechnology company developing pharmaceutical and medical food products that aim to improve health status by interacting with and altering the human microbiome. MBT is developing evidence-based microbiome modulators, which are designed to alter bacterial populations and their environment in the gastrointestinal (GI) tract in specific ways to treat and prevent serious health conditions. MBT's lead product, NM504, contains a proprietary combination of plant-derived soluble and insoluble fibers and antioxidants formulated to help prediabetic and diabetic individuals achieve healthy blood glucose levels and manage their body weight. It is currently being tested in clinical trials for the management of insulin sensitivity and blood glucose levels and as an adjunct to metformin in patients with prediabetes and type 2 diabetes. For more information, visit www.mbiome.com .

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