Prebiotin™ Tested in NIH/NIDDK Pilot Study with End-Stage Renal Disease Patients (ESRD)

Prebiotin comments on Gut Microbiome and p-Inulin in Hemodialysis (TarGut-ESRD).

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HARRISBURG, Pa., October 17, 2017 /PRNewswire/ – Why is one more National Institute of Health (NIH) study involving the microbiome so important? Because, says Prebiotin CEO Ron Walborn Jr., “This one featured a natural prebiotic fiber supplement, rather than a pharmaceutical intervention.”

The NIDDK (National Institute of Diabetes and Digestive and Kidney Diseases) Hemodialysis Novel Therapies (HDNT) Study Group has been conducting early phase studies of novel interventions with the long-term goal to test promising therapies in full-scale clinical trials.

The preliminary findings from the “Gut Microbiome and p-Inulin in Hemodialysis (TarGut-ESRD)” study noted that 11 of the 13 study participants, who received treatment with Prebiotin™ prebiotic fiber, tolerated the treatment schedule.

One of the recipients of the original multi-million grant, Dominic Raj, M.D., director of the division of nephrology and professor of medicine at the George Washington University (GW) School of Medicine and Health Sciences, explains, "This research is focused on finding a safe and effective treatment that reduces inflammation and promotes well-being in these patients."

Previous work from Raj’s laboratory showed that patients with kidney disease may have a higher level of release of endotoxin from the bacteria in the gut, which can move into the bloodstream and promote inflammation.

In the study, the 13 participants were studied in three phases: 8 weeks without prebiotic fiber treatment, 12 weeks of treatment with two daily 8-gram doses of the fiber, for a total of 16 grams per day dissolved in beverages, and a third phase similar to the first phase without Prebiotin. In each phase blood and stool samples were obtained.

Preliminary results indicate that not only was Prebiotin well tolerated among 11 of 13 participants over the 8-week treatment period, but that differences in concentrations of selected stool metabolites were evident between the pre-treatment and Prebiotin-treatment periods. One patient withdrew before starting p–inulin to have a kidney transplant, and one patient decided not to continue participating.

HDNT is a collaborative study group involving the following institutions and principal investigators: the Harvard Brigham and Women's Hospital (D. Charytan), George Washington University (D. Raj), University of Washington (J. Himmelfarb), Vanderbilt University (T.A. Ikizler*); Data Coordinating Center*: University of Pennsylvania (L. Dember, J.R. Landis); *Steering Committee Chair*: (A. Kliger), Yale University. The study is funded by cooperative agreements from the *NIDDK*.

Prebiotin was provided by Jackson GI Medical.

"Prebiotin™ prebiotic fiber's inclusion in a study of this magnitude is yet another indicator that a growing number of researchers understand the fundamental importance of the microbiome in health and wellbeing," says Greg Cooper, Prebiotin's director of Business Development. "They also are recognizing the possibility that a prebiotic like Prebiotin can have an impact on balancing the microbiome by stimulating the growth of good bacteria."

Prebiotin's full-spectrum prebiotic fiber is comprised of oligofructose-enriched inulin (OEI) derived from chicory root through a proprietary process. Prebiotin™ Prebiotic Fiber is currently involved in several research studies including two with the NIH, one with Health Canada, and several with prestigious universities.

Jackson GI Medical/Prebiotin was founded by visionary gastroenterologist Dr. Frank W. Jackson in 2008, and is dedicated to the responsible development and marketing of medically credible nutritional supplements backed by third-party research. Located in Harrisburg, PA, the company can be reached at 855-466-3488 or online at www.prebiotin.com**.**

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