FOR IMMEDIATE RELEASE

Crestovo Doses Patients in PRISM 3, a Clinical Trial of CP101, a Microbiome Therapy for the Prevention of Recurrent *Clostridium difficile* Infection

- *CP101 is the lead, orally-administered product generated from Crestovo's Full-Spectrum Microbiota™ (FSM™) platform*
- *PRISM 3 includes 240 patients at clinical sites with broad coverage throughout the U.S.*
- *The company is based on foundational clinical research from gut microbiota-based treatment pioneers, Dr. Thomas J. Borody, Dr. Alexander Khoruts and Dr. Michael J. Sadowsky*

CAMBRIDGE, MASS. – June 27, 2017 – Crestovo, a clinical-stage biopharmaceutical company developing Full-Spectrum Microbiota™ (FSM™) that harnesses the human gut microbiome, today announced that patients have been enrolling since the beginning of June in the company's PRISM 3 clinical trial, evaluating its lead product candidate, CP101, for the prevention of recurrent *Clostridium difficile* infection (CDI).

"We are pleased to have dosed patients in the PRISM 3 trial with CP101 as the leading candidate from our Full-Spectrum Microbiota™ platform. CP101 has the potential to be the first therapy seeking FDA-approval utilizing the human gut microbiome," said Joseph Lobacki, Crestovo's chief operating officer and interim chief executive officer.

PRISM 3 builds on the clinical success of Crestovo's academic collaborators, Dr. Alexander Khoruts and Dr. Michael Sadowsky, who developed a leading early-stage oral formulation of a microbiota-based product in 2014. As published in *The American Journal of Gastroenterology*, Dr. Khoruts' clinical team administered their product to 49 patients with recurrent CDI. Overall, 88% of patients achieved a clinical success, defined as no recurrence of CDI over two months. Additionally, sequence analysis of the fecal microbiome demonstrated near normalization of the fecal microbial community one month following treatment.

"The PRISM 3 trial represents a major milestone towards bringing a restorative, full-spectrum, orally-administered microbiome therapy to the many patients with dysbiosis-related diseases in need," said Dr. Khoruts.

"There is a critical, unmet medical need for new treatments for recurrent CDI in the U.S., with antibiotics often further exacerbating the problem of dysbiosis in such patients," said Dr. Thomas Borody, a scientific founder of Crestovo. "Unlike other therapies in development across the industry, CP101 combines the ease of oral administration with the potential clinical benefits of a Full-Spectrum Microbiota™ composition. We are excited to further the work of Dr. Khoruts and Dr. Sadowsky in restoring proper ecological diversity to patients' microbiomes to break the cycle of CDI recurrence."

PRISM 3 is a multicenter, randomized, placebo-controlled trial to evaluate the efficacy and safety of CP101 in approximately 240 patients with recurrent CDI at clinical sites throughout the U.S. The primary endpoint of PRISM 3 is prevention of recurrence of CDI through eight weeks following administration of CP101, compared to placebo. Prevention of recurrence of CDI is defined as absence of symptomatic, laboratory confirmed CDI. The trial is actively enrolling patients, and Crestovo expects to report top-line data in 2018.

About CP101

CP101 is Crestovo's potential first-in-class, lead microbiome therapy generated from the company's Full-Spectrum Microbiota™ (FSM™) platform. As an encapsulated, orally-administered FSM™ therapy, CP101 contains the full complement of functional microorganisms that may help restore the dysbiotic microbiota (or microbial imbalance) to a normal, functioning gut microbial community. Beyond CP101, Crestovo is developing a pipeline of FSM™ therapeutics to treat a range of serious diseases.

About Dr. Thomas J. Borody

Dr. Borody is a world-renowned leader in the clinical microbiota dating back to 1988 when he started performing what is now called Fecal Microbiota Transplantation (FMT). As a practicing clinician leading the Centre for Digestive Diseases in Australia, he has overseen over 12,000 FMTs, creating a wealth of proprietary clinical data and insights. In addition, Dr. Borody has established novel therapies in the gastrointestinal field, including areas such as Inflammatory Bowel Disease, Irritable Bowel Syndrome, CDI, Parasite infestation, and Resistant *Helicobacter pylori* via a bismuth-based 'Triple Therapy'. His knowledge and expertise are sought after by patients from around the world, and he is a reviewer for leading medical journals such as *Clinical Journal of Gastroenterology*, the *Medical Journal of Australia*, the *American Journal of Gastroenterology* and *Digestive Diseases and Sciences*, among others. He is a scientific founder of Crestovo and serves as an active scientific advisor to the company.

About Dr. Alexander Khoruts and Dr. Michael Sadowsky

Dr. Khoruts, a prominent gastroenterologist and immunologist, partnered with Dr. Sadowsky, a microbiologist and microbial ecologist, to develop the foundational protocols of standardizing fecal microbiota preparation and preservation. They were the first to demonstrate sustained engraftment of donor bacteria into a patient suffering from recurrent CDI, a finding that led to coining the treatment as 'Fecal Microbiota Transplantation' (FMT). The team has continued their focus on mechanistic investigations of FMT and developing next-generation microbiota products that can be used in treatment of CDI and for other clinical indications. They both are key academic collaborators with the Crestovo team.

About *Clostridium difficile* infection (CDI)

CDI is a bacterial infection causing patients to suffer from diarrhea, fever, nausea and abdominal pain. The Centers for Disease Control (CDC) has named it an urgent public health threat and the leading hospital-acquired infection in the U.S., with more than 700,000 patients infected annually and 29,000 deaths per year. CDI is estimated to cause approximately $4.8 billion in excess health care costs for acute care facilities alone, given the high number of hospitalizations to treat the disease. Historically, standard-of-care antibiotic treatment presents a risk of recurrence in approximately 60 percent of patients who have experienced multiple recurrences, highlighting a clear unmet medical need.

About Crestovo

Crestovo is a clinical-stage biopharmaceutical company developing Full-Spectrum Microbiota™ (FSM™) that harnesses the human gut microbiome. Crestovo is advancing the foundational clinical research of the company's academic collaborators, Dr. Thomas Borody, Dr. Alexander Khoruts and Dr. Michael Sadowsky, which demonstrated in-human validation of an orally-available, microbiota-based product across a variety of serious diseases and unmet medical needs, including recurrent *Clostridium difficile* infection (CDI). Crestovo's lead FSM™ product, CP101, is currently being evaluated in the PRISM 3 clinical trial in patients with recurrent CDI. For more information, please visit www.crestovo.com.

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