

Press Release

Lund, Sweden, June 10 2020

ImmuneBiotech: starts clinical trial of GutMagnific® in ME/CFS in collaboration with Stora Sköndal ME clinic

ImmuneBiotech Medical Sweden AB, the probiotic and microbiome company, is pleased to announce the start of a clinical evaluation of GutMagnific® in Myalgic Encephalomyelitis (ME) also called Chronic Fatigue Syndrome (CFS) or post-viral fatigue.

ME/CFS is a disabling and often long-lasting disease that can drastically impair quality of life and physical/ social functioning of the patients. As there are no disease modifying treatments for ME/CFS there is an enormous need to find a solution that can serve this group.

GutMagnific® is a super-consortium (combination) of five probiotic lactobacillus strains, scientifically designed to address the underlying key causes of IBS and is sold as a food supplement www.GutMagnific.com. GutMagnific® is the first product in a new probiotic category ImmuneBiotics™ where products are developed using pharmaceutical precision focused on achieving a healthy balance between the microbiome, the immune system, and the intestinal barrier.

The clinical trial is a collaboration with the ME/CFS clinic, Neurological Rehabilitation Clinic, Stora Sköndal, Stockholm, associated with Karolinska Institute, Stockholm, Sweden. As some 70% of ME/CFS patient also suffers from IBS, the hypothesis of the trial is that if the IBS can be ameliorated by GutMagnific® then the ME symptoms could also be improved.

“I’m extremely pleased that our more than 15 years of experience in probiotics, immunology, microbiology and research in the gut-brain-axis also has attracted interest by clinicians and sparked their interest to investigate GutMagnific® in ME/CFS. I’m also proud that we could start the trial despite the COVID-19 pandemic by integrating a distance management strategy considering the safety of the participants as well as the staff during this global health crisis” said Shahram Lavasani, CEO of ImmuneBiotech.

“As medical doctors and daily meeting ME/CFS patients, we know how much this highly unserved group are suffering. Unfortunately, we have no disease modifying treatments to offer, that is why it is highly prioritized to identify a treatment that can help.” says Dr. Anders Rehnström physician at the ME/CFS clinic, Neurological Rehabilitation Clinic, Stora Sköndal, Stockholm.

“Research has shown that the gut flora is involved in several indications such as IBS and as most ME/CFS patients also suffer of gut problems it is possible that they will benefit of a scientifically



designed probiotic. We very much look forward to run this randomized, double blinded, placebo controlled 3-arm study in collaboration with ImmuneBiotech. The timing of this trial also coincides with coronavirus and concerns for an increased risk for ME. Viral infections have previously been linked to ME/CFS and experiences from SARS outbreaks hint an increased risk for some COVID-19 patients to develop post-viral fatigue syndrome.” says Dr. Per Julin the responsible physician at the ME/CFS clinic, Neurological Rehabilitation Clinic, Stora Sköndal, Stockholm.

About ME/CFS

Myalgic Encephalomyelitis also called Chronic Fatigue Syndrome (ME/CFS) or post-viral fatigue is a disabling and often long-lasting disease that can drastically impair quality of life and physical/social functioning of the patients. ME/CFS is often triggered by viral or bacterial infections, but the mechanisms and pathophysiology are still unknown. Recent research suggests autoimmune mechanisms involving the autonomic nervous system and the gastrointestinal tract leading to IBS like symptoms as part of the disease in many cases. Patients have unexplained persistent fatigue; alongside muscle and/or joint pain, sleep disturbances, cognitive impairment, orthostatic intolerance, headaches and post-exertional malaise. ME/CFS is often unrecognized by healthcare systems and with no treatment options, patients rely on family support.

Despite striking more people than multiple sclerosis, lupus, and many forms of cancer, ME gets very little research funding. As a relatively ‘new’ disease, its prevalence is hard to determine but has been estimated at 40 000 in Sweden alone and global numbers of 17-24 million. The disease affects three times more women than men and often presents in the 40s-50s or adolescence. With very low recovery rates the cost to health care systems is enormous.

About GutMagnific® www.GutMagnific.com.

GutMagnific® is a super-consortium of five probiotic strains scientifically designed to address the underlying key causes of IBS. It is a patent pending combination of proprietary lactobacillus strains and will be sold as a food supplement supported by clinical data. GutMagnific® has potential application in several severe and prevalent conditions such as IBS, diarrhea, antibiotic induced diarrhea, *Clostridium difficile* infection (CDI) and Chronic Fatigue Syndrome (ME/CFS). It has also the ability to target symptoms such as leaky gut and small intestine bacterial overgrowth (SIBO).

About ImmuneBiotech Medical AB

ImmuneBiotech discovers and markets science-based probiotic food supplements. Based on our multi-disciplinary scientific foundation, we have created a new probiotic category ImmuneBiotics™ where products are developed using pharmaceutical precision focused on achieving a healthy balance between the microbiome, the immune system, and the intestinal barrier.

Shahram Lavasani, CEO

ImmuneBiotech Medical AB
s.lavasani@immunebiotech.com
+46 707 40 86 61
www.immunebiotech.com