



Entera Health Announces Approval of COVID-19 Clinical Trial using EnteraGam in Spain

Ankeny, Iowa, USA – July 2, 2020 – Entera Health, in cooperation with Lemus Buhils, has received IRB approval to conduct a clinical trial in Barcelona Spain using EnteraGam to manage the symptoms associated with COVID-19 infections. The trial titled “Randomized Open-Label Clinical Study Evaluating the Impact of EnteraGam, a Nutritional Intervention containing Bovine **P**lasma-Derived **I**mmunoglobulin **C**o**N**centrate, on Clinical Outcomes **I**n People with **C**COVID-19 (Spanish **P**IC**N**IC Study)” will investigate the use of EnteraGam to manage inflammation and symptom severity in patients with mild-to-moderate SARS-CoV-2 infections.

The Spanish PICNIC Study is a randomized open-label clinical trial which aims to enroll 420 subjects with SARS-CoV-2 infection. Patients will be randomized in a 2:1 ratio to receive EnteraGam in addition to standard of care, or standard of care alone. Patients enrolled in this trial will have mild-to-moderate symptom severity, including respiratory distress such as coughing and shortness of breath, but will not require invasive mechanical ventilation or management in the intensive care unit. The primary endpoints of the trial are the change in plasma IL-6 levels between entry and Week 2, and the percentage of patients with disease progression by Week 2. A number of secondary endpoints will focus on specific COVID-19 associated symptoms, including diarrhea, and other markers of gut associated inflammation and permeability.

Netanya Utay, MD, Assistant Professor at McGovern Medical School at the University of Texas Health Science Center at Houston, Principle Investigator of the trial, said: “Many COVID-19 studies focus on patients who have severe disease, with this study, we are assessing a serum protein supplement to see if it has the potential to prevent progression to severe disease by decreasing inflammation.”

Aage Lauridsen, CEO of Entera Health, added: “We appreciate the effort of everyone involved in the development of this clinical trial. The effort, collaboration, and speed at which this trial has become a reality is nothing short of amazing. During these uncertain times, everyone is looking for opportunities to help those affected most by COVID-19, this trial is our effort to advance the understanding of COVID-19 and help a population with mild disease return to a normal state of health faster.”

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EnteraGam (a serum-derived bovine immunoglobulin/protein isolate, SBI) is a medical food product intended for the dietary management of chronic diarrhea and loose stools. EnteraGam is administered under medical supervision in the USA. For more information about **EnteraGam**, please visit: www.enteragam.com

Entera Health is a biotechnology company focused on improving health by supporting everyday nutritional requirements. Entera Health develops and manufactures safe and effective protein-based nutritional products to support immune and gut health. For more information about **Entera Health**, please visit www.enterahealth.com

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