Bovine Immunoglobulin Protein Isolates For The Nutritional Management Of Enteropathy

*Entera Health, Inc. Announces the Publication of a Scientific Article Summarizing Preclinical and Clinical Studies Evaluating the Ability of Serum- or Plasma-Derived Protein Preparations to Promote Intestinal Health and Recovery from Intestinal Disorders.*

(PRWEB) September 16, 2014 -- Entera Health, Inc. announced today the publication of a new scientific article in the World Journal of Gastroenterology (WJG) supporting the potential benefits of EnteraGam™ (serum-derived bovine immunoglobulin/protein isolate, SBI) in restoring intestinal homeostasis (e.g. gut barrier function, immune regulation) following episodes of enteropathy associated with human disease conditions such as HIV infection, inflammatory bowel disease (IBD), or irritable bowel syndrome (IBS). Authors include Bryon Petschow, PhD; Anthony T. Blikslager, PhD; Eric M. Weaver, PhD; Joy M. Campbell, PhD; Javier Polo, PhD; Audrey L. Shaw, PhD; Bruce P. Burnett, PhD; Gerald L. Klein, MD; and J. Marc Rhoads, MD.

Orally administered, immunoglobulin-containing plasma protein preparations such as SBI, specially-formulated to contain high levels of IgG and other proteins, have been extensively studied in animal models and recently found to be safe to manage enteropathy associated with IBS-D and HIV infection (1, 2). The purpose of this review in WJG is to summarize the scientific evidence supporting the intended use of plasma protein preparations for nutritional support in patients with conditions associated with enteropathy. His review affirms the concept that immunoglobulin-containing protein preparations provide for a 'distinctive nutritional requirement' for restoration of homeostasis in the intestinal tract of patients with enteropathy. The article can be accessed on line through the link provided below: [http://www.wjgnet.com/1007-9327/full/v20/i33/11713.htm](http://www.wjgnet.com/1007-9327/full/v20/i33/11713.htm)

**About Enteropathy**

Enteropathy is frequently found in association with several human disease conditions, including IBS or HIV infection, and is caused by pathological changes in the lining of the intestinal tract. Such changes disrupt the homeostasis of the GI tract and lead to symptoms of abdominal pain and discomfort, bloating, and abnormal bowel function (e.g., diarrhea, urgency, constipation). While the precise mechanisms that lead to enteropathy are not well understood, combinations of trigger factors (e.g. diet, stress, exposure to external antigens, environmental insults including infection) are believed to develop into a continuing cycle of altered gut microbiota, immune dysregulation, gut barrier dysfunction with permeability changes, and nutrient malabsorption, which serves to further amplify and prolong this cycle of events.


The study’s purpose is to evaluate the safety and effectiveness of oral nutritional therapy Serum-Derived Bovine Immunoglobulin (SBI) on nutritional status, epithelial barrier function, and mucosal expression of pivotal genes including tight junction, secretory mechanisms, tissue repair proteins and chemokines in subjects with IBS-D.

**About EnteraGam™**

EnteraGam™ (serum-derived bovine immunoglobulin/protein isolate, SBI) is a prescription medical food product indicated for the clinical dietary management of enteropathy [e.g., in diarrhea-predominant irritable
bowel syndrome (IBS-D) and HIV-associated enteropathy. EnteraGam™ is required to be used under physician supervision as part of ongoing medical care for a specific condition or disease. EnteraGam™ is also indicated for the clinical dietary management of enteropathy in patients who, because of therapeutic or chronic medical needs, have limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients. For full prescribing information, please visit our product website at http://enteragam.com/.

Important Safety Information
EnteraGam™ is a specially formulated protein source for the management of intestinal disorders. The product has been extremely well tolerated for up to a year in HIV patients and up to 8 months in infants. The major side effects in clinical trials (2-5%) have included mild nausea, constipation, stomach cramps, headache, and increased urination. EnteraGam™ is contraindicated for patients with a hypersensitivity (allergy) to beef, or any components in EnteraGam™. Therefore, patients who have an allergy to beef or any component of EnteraGam™ should not take this product. EnteraGam™ has not been studied in pregnant and nursing mothers. The choice to administer EnteraGam™ in pregnant or nursing mothers is at the clinical discretion of the physician. Medical foods like EnteraGam™ are required by FDA regulations to be dosed and monitored by physicians as part of ongoing care for patients with chronic conditions or diseases.

About Entera Health, Inc.
Entera Health, Inc. is focused on improving worldwide health through the development of clinically safe biotherapeutics to address unmet needs. Our passion is to help people thrive through healthier living. Our motivation for conducting basic research, clinical studies, and appropriately educating patients and healthcare providers is driven to meet this goal. Visit us at http://www.enterahealth.com/.

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