

Alba Therapeutics Announces Enrollment of Its First European Patient in Global Phase IIb Study of Larazotide Acetate for Treatment of Active Celiac Disease

- Milestone Marks the First Time a European Patient with Active Celiac Disease has Enrolled in a Clinical Trial for an Investigational Medication from Alba Therapeutics -

BALTIMORE, MD, November 11, 2008/PRNewswire -- Alba Therapeutics Corporation announced today that for the first time, a European patient with active celiac disease has been enrolled in its clinical trial to investigate a treatment for the disease. Alba has enrolled and randomized the newly diagnosed patient from Spain in an eight-week Phase IIb trial with oral larazotide acetate, a tight junction regulator, for the treatment of patients with active celiac disease (CD). The global multi-center, randomized, double-blind, placebo-controlled study will evaluate the clinical and histological efficacy, safety and tolerability of larazotide acetate in 106 active CD subjects adhering to a gluten-free diet, while assessing improvement in the clinical signs and symptoms of celiac disease.

"These are decisive times for our desire to one day be able to offer our celiac patients a treatment that allows them to live more normal lives," said Dr. Gemma Castillejo, MD, a pediatric gastroenterologist and principal investigator in the study. Dr. Castillejo, a leading European celiac expert from the Sant Joan de Reus University Hospital in Reus, Spain added, "I believe this clinical trial has the potential to be a turning point in the search for treatments for celiac disease."

"This is a major milestone for the celiac community in Europe," stated Francisco Leon, MD, PhD, Vice President, Clinical Development and Medical Affairs of Alba. "This is Alba's sixth human trial with larazotide acetate, and we are excited to be advancing our investigational program for larazotide acetate in this important region of the world."

About Celiac Disease

Celiac disease is an inherited autoimmune disorder where gluten has been identified as the environmental trigger of the disease. Gluten is an ingested protein found in wheat, barley and rye. Gluten is broken down into gliadin which can pass through the intestinal epithelial barrier during times of increased intestinal permeability. The ingestion of gluten causes an immune response which triggers an inflammatory reaction in the small intestine. This then causes damage to the villi in the small intestine and can lead to total villous atrophy in celiac disease. This results in varying symptoms such as fatigue, skin rash, anemia, fertility issues, joint pain, weight loss, pale sores inside the mouth, tooth discoloration or loss of enamel, depression, chronic diarrhea or constipation, gas and abdominal pain. The immunology and nutritional abnormalities in celiac disease can potentially result in long-term complications such as osteoporosis, refractory sprue, small intestinal cancer, and lymphoma.

Celiac disease is a growing public health concern, affecting approximately 3 million people in the United States and over 6.5 million people worldwide. The only current management of celiac disease is complete elimination of gluten from the diet, which can be very difficult to implement in practice. Additionally, the response to the gluten-free diet is poor in up to 30% of patients, and dietary nonadherence is the chief cause of persistent or recurrent symptoms.¹

About “Larazotide Acetate”

Larazotide acetate is an experimental medicine and a tight junction regulator that acts locally by inhibiting the opening of tight junctions in epithelial cells lining the small intestine. In celiac disease, gluten crosses the epithelial barrier and stimulates the immune system, leading to cytokine release, gut inflammation, and opening of tight junctions. This leads to increased paracellular permeability, increased entry of gluten and the establishment of an intestinal permeability-inflammation loop. Larazotide acetate inhibits tight junction opening triggered by both gluten and inflammatory cytokines, thus reducing uptake of gluten. Larazotide acetate disrupts the intestinal permeability-inflammation loop, and reduces symptoms associated with celiac disease. Larazotide acetate is orally formulated, has been granted “Fast Track” designation by the U.S. Food and Drug Administration for the treatment of celiac disease, and is also being evaluated for the treatment of Crohn’s Disease. For more information about Alba’s clinical trials, please visit the www.clinicaltrials.gov web site and search for Alba Therapeutics.

¹ Green, P, and Cellier, C, Review Article, Medical Progress, Celiac Disease, *N ENGL J MED* 2007;357:1731-43

About Alba

Alba Therapeutics Corporation is a privately held, clinical-stage biopharmaceutical company focused on the discovery, development, and commercialization of therapies to treat autoimmune and inflammatory diseases and is located in Baltimore, Maryland. Alba's technology platform is based upon a key pathway that regulates the assembly and disassembly of tight junctions in cell barriers throughout the body. As a result of its unique technology platform, Alba is a leader in mucosal biology and has developed a pipeline of innovative therapeutic candidates that has the potential to modify the course of disease and significantly improve upon existing treatments for a wide range of diseases such as celiac disease, Crohn's disease, and Asthma/COPD or acute lung injury.

Media: Mariesa Kemble
Sam Brown Communications
608-850-4745
kemblem@aol.com

Corporate: Wendy Perrow, MBA
Alba Therapeutics Corporation
410-878-9850
info@albatherapeutics.com
<http://www.albatherapeutics.com>

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