

Alba Therapeutics Presents New Data for Larazotide Acetate at the 2008 American College of Gastroenterology Annual Scientific Meeting

Study Showed Larazotide Acetate Prevented Immunologic Changes Induced by Gluten in Patients with Celiac Disease

Additional Data Indicates Potential in Treating Inflammatory Bowel Disease

ORLANDO, FL, October 7, 2008/PRNewswire - Alba Therapeutics Corporation presented results from two clinical studies this week at the American College of Gastroenterology (ACG) 2008 Annual Scientific Meeting. Data from study CLIN 1001-004, the first Phase IIa trial conducted in celiac disease and the first to assess the prevention of immunologic changes in celiac disease, showed that larazotide acetate (AT-1001) successfully demonstrated prevention of gluten-induced immunologic changes in celiac patients.

Results from the study showed that larazotide acetate is the first pharmacologic agent to prevent changes in blood mononuclear cell populations (specifically T-reg cells and B Cells) and other markers of immunological change associated with active celiac disease. This data suggests that larazotide acetate offers potential as a future treatment of celiac disease.

Results from a second poster presented at ACG showed that larazotide acetate also inhibited the effect of inflammatory cytokines, including tumor necrosis factor (TNF- α) and interleukin (IL-4) on intestinal epithelial permeability, in vitro, further suggesting that the product offers potential as a future treatment for inflammatory bowel disease (IBD).

Larazotide Acetate is a novel, non-absorbed peptide currently being studied in Phase IIb trials for the treatment of celiac disease. Larazotide acetate has the potential to become the first approved medicine to treat celiac disease and has been granted "Fast Track" designation from the U.S. Food and Drug Administration (FDA) for this indication.

Celiac disease affects approximately one percent of individuals in the United States and Europe, or approximately 6.5 million individuals. The only accepted management for the disease is a strict gluten-free diet; however, the response to therapy is poor or incomplete in up to 30 percent of patients. These facts suggest that there is a need for therapeutic modalities beyond dietary modification.

Related data presented in a third poster at ACG include results from a qualitative study conducted to investigate the validity of the Gastrointestinal Symptom Rating Scale (GSRS) in patients with celiac disease. The GSRS is a validated measure used in clinical trials for irritable bowel syndrome and peptic ulcer disease. GSRS has been utilized in studies to assess larazotide acetate, including CLIN 1001-004 and CLIN 1001-006. Results from the poster presentation suggest that certain subscales of the GSRS may have relevance for use in establishing the efficacy of novel treatments for celiac disease. This is the first time the validity of the GSRS clinical scale has been studied in celiac disease to assess efficacy of treatments.

"There are currently no products approved by the FDA to treat celiac disease and a clear need exists for a therapeutic option," said Daniel Leffler, MD, gastroenterologist, Beth Israel Deaconess Medical Center and one of the lead investigators for CLIN 1001-004. "This study showed that larazotide acetate prevented immunologic changes induced by gluten in patients with celiac disease. In addition, studies to establish the validity of scales such as GSRS are an important step forward in the development of effective treatments for celiac disease."

“Alba is excited to be advancing the first therapy for celiac disease and we are encouraged by these breakthrough findings,” said Dr. Francisco Leon, head of Clinical Research and Development at Alba Therapeutics, Inc. “These results will be further tested in Phase III clinical trials to evaluate safety, efficacy, and maintenance of effect of larazotide acetate in treating celiac disease. In addition, we are excited by early preclinical study results showing signs of efficacy in inflammatory bowel disease targets and look forward to future research to uncover the product’s potential in this important therapeutic area.”

About the Studies

Results from CLIN 1001-004 were presented at ACG in a poster entitled “*Larazotide Acetate Prevents Immunologic Changes Induced by Gluten Challenge in Celiac Disease Patients*” (Poster 446). The randomized, double-blind, placebo-controlled study was designed to evaluate the effects of larazotide acetate on the systemic immunologic changes induced by a two week gluten challenge in patients with celiac disease. Study results showed that larazotide acetate was well tolerated and showed signs of efficacy in preventing immunologic changes induced by gluten challenge in patients with celiac disease, consistent with the beneficial effects observed on intestinal permeability, signs and symptoms. Clinical findings included:

- Gluten challenge in the placebo (control) group resulted in an increase in circulating regulatory T cells (CD4, CD25, FOXP3+) and a decrease in B cells (CD3, CD19+). These changes were completely prevented in the group on larazotide acetate.
- There was a small, not statistically significant increase in the anti-tTG titer in the placebo (control) group, which was prevented in the group on larazotide acetate.
- Other trends in specific monocyte populations induced by gluten challenge were also prevented to varying extents by larazotide acetate.

The second presentation, “*Larazotide Acetate, a Tight Junction Inhibitor Peptide, Inhibits Epithelial Permeability Induced by TNF- α and IL-4*” (Poster 1052) included results from a study investigating the effect of larazotide acetate on tumor necrosis factor (TNF- α) and interleukin (IL-4) induced permeability. The study showed that larazotide acetate inhibited increased permeability mediated with TNF- α and IL-4, which suggests the potential of larazotide acetate as a therapeutic agent for the treatment of celiac disease and IBD.

The third poster presentation, “*Relevance of the Gastrointestinal Symptom Rating Scale (GSRS) in Patients with Celiac Disease*” (Poster 1023), includes results from a qualitative study conducted to investigate the validity of the GSRS in patients with celiac disease and to explore if the GSRS would constitute an appropriate and relevant scale to demonstrating the efficacy of novel treatments for celiac disease. Results showed that relevant subscales of the GSRS may be useful in clinical trials of novel treatments for celiac disease.

About Celiac Disease

Celiac disease (CD) is an inherited, lifelong T-cell mediated auto-immune disorder where the environmental trigger has been identified as gluten, which is found in wheat, barley, and rye. It is characterized by small intestinal inflammation and injury. CD is a growing public health concern, affecting approximately 3 million people in the United States and over 6.5 million people worldwide. 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 CD. This results in varying symptoms such as fatigue, skin rash, anemia, fertility issues, stillborn births, joint pain, weight loss, pale sores inside the mouth, tooth discoloration or loss of enamel, depression, chronic diarrhea or constipation, and abdominal pain and bloating. 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. The only current management of CD is complete elimination of gluten from the diet, which can be very difficult to implement in practice.

About “Larazotide Acetate”

Larazotide acetate is an experimental medicine and an inhibitor of barrier dysfunction that has been shown to block abnormally increased intestinal permeability and the genesis of some autoimmune diseases, either as a result of reduction of antigen presentation to the body’s immune system, or through inhibitory, direct effects on gastrointestinal associated lymphoid tissue. Larazotide acetate is a non-absorbed peptide which improves mucosal barrier function by inhibiting cytoskeletal reorganization and tight junction disassembly. 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. Results of the Company’s first study in patients with celiac disease are available online at: <http://www.blackwell-synergy.com/doi/abs/10.1111/j.1365-2036.2007.03413.x>

For more information about Alba’s clinical trials, please visit the www.clinicaltrials.gov web site and search for Alba Therapeutics.

About Alba Therapeutics Corporation

Alba Therapeutics Corporation is a privately held, clinical-stage biopharmaceutical company focused on the discovery, development, and commercialization of therapies to treat auto-immune, immune mediated 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.

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