

Alba Therapeutics Announces the Enrollment and Randomization of the First Patient in the Phase IIb Clinical Trial for Larazotide Acetate (AT-1001) for the Treatment of Active Celiac Disease

BALTIMORE, MD., May 16, 2008/PRNewswire/ -- Alba Therapeutics Corporation announced today that it has enrolled and randomized its first patient in a eight-week Phase IIb trial with oral larazotide acetate, an inhibitor of intestinal barrier dysfunction, 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 also testing components of a celiac disease activity rating index, a new patient reported outcomes instrument. "This is Alba's sixth human trial with larazotide acetate and highlights our efforts to improve the treatment of celiac disease and help the celiac community by raising the awareness of this important and neglected disease" stated Dr. Francisco Leon, Head of Clinical Research and Development at Alba. "Alba is committed to studying new treatment options for patients with celiac disease. By conducting this important pioneering clinical study we believe we can learn more about celiac disease and provide insights for physicians and celiac patients," stated Bruce Peacock, CEO of Alba. For more information about Alba's clinical trials, please visit the www.clinicaltrials.gov web site and search for Alba Therapeutics.

About Celiac Disease

Celiac disease is a lifelong T-cell mediated auto-immune disorder, which occurs in individuals who are genetically susceptible and is characterized by small intestinal inflammation, injury and intolerance to gluten. CD is a growing public health concern, affecting approximately 3 million people in the United States and over 6.5 million people worldwide. People with CD cannot tolerate gluten proteins and have an inflammatory response to the gluten in wheat, barley and rye. 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. The only current treatment for CD is complete elimination of gluten from the diet, which results in remission for most patients, but can be very difficult to implement in practice. "However, 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 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 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

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

evaluated for the treatment of Crohn's Disease. Results of the Company's first study in celiac patients are available online at:

<http://www.blackwell-synergy.com/doi/abs/10.1111/j.1365-2036.2007.03413.x>

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.

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