

BALTIMORE, Oct. 26 /PRNewswire/ -- Alba Therapeutics Corporation ("Alba")

today announced successful completion of its first Phase I trial for the drug candidate AT-1001, and that the FDA has granted "Fast Track" designation to AT-1001 for treatment of Celiac Disease (CD). "We are pleased to have concluded our first human study of oral AT-1001 and delighted that the FDA has granted fast track status to AT-1001. These two events are important additional milestones in our efforts to help those suffering from CD, a disease for which there is no effective treatment," said Blake Paterson, MD, President and CEO of Alba. Alba plans to begin a proof of concept study demonstrating efficacy of AT-1001 in celiac patients within the next few months.

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Fast track process is designed to facilitate development and expedite the review of new drugs with the potential to address significant unmet medical needs for the treatment of serious or life-threatening conditions. Potential fast track benefits include FDA input into development, submitting new drug applications in sections rather than all at once and the option of requesting Accelerated Approval.

About Celiac Disease

Celiac Disease is a T-cell mediated auto-immune disease that occurs in genetically susceptible individuals and is characterized by small intestinal inflammation, injury and intolerance to gluten. Gluten is a mixture of proteins found in common food grains such as wheat, rye and barley. According to the NIH, CD affects approximately 3 million Americans, although the diagnosis is rarely made. The only treatment for CD is complete elimination of gluten from the diet, which results in remission for some patients.

About Zonulin

Zonulin is an endogenous signaling protein that transiently and reversibly opens the tight junctions ("tj") between the cells of epithelial and endothelial tissues such as the intestinal mucosa, blood brain barrier and pulmonary epithelia. Discovered by Alba co-founder Dr. Alessio Fasano, zonulin appears to be involved in many disease states in which leakage occurs via paracellular transport across epithelial and endothelial tight junctions (tj), and thus may play an important potential role in the treatment of auto-immune diseases.

About Alba

Alba Therapeutics Corporation is a privately held biopharmaceutical company based in Baltimore, Maryland. Alba is dedicated to commercializing disease-modifying therapeutics and drug delivery adjuvants based on the zonulin pathway. Alba's lead molecule, AT-1001, is targeted towards the treatment of Celiac Disease and Type 1 Diabetes.

Contact: Dr. Blake Paterson

Alba Therapeutics Corporation
410-522-8708