



Celimmune Commences Screening in Phase 2 Clinical Study in Refractory Celiac Disease Type II

Multinational Study to Evaluate the Potential of Anti-IL-15 Antibody, AMG 714, to Treat Rare in situ Small Bowel T cell Lymphoma

Lebanon, NJ and Bethesda, MD, March 31, 2016 --- Celimmune LLC, a clinical development-stage immunotherapy company focused on treating and preventing immune-mediated diseases, announced that it has commenced screening patients in its Phase 2 clinical study for AMG 714, an investigational anti-IL-15 monoclonal antibody for the treatment of refractory celiac disease Type II (RCD-II).

The randomized, double-blind, parallel-group study is expected to enroll 24 patients with a confirmed diagnosis of RCD-II. Study duration is 20 weeks and visits to the site take place every two weeks to receive intravenous infusion of AMG 714 or placebo. Intestinal biopsies will be taken before and after treatment to evaluate the efficacy of AMG 714. Patients enrolled will maintain a strict gluten-free diet during the study.

Francisco Leon, M.D., Ph.D., CEO and Chief Medical Officer of Celimmune, commented, “We are pleased to have commenced patient screening in this unprecedented industry-sponsored clinical trial evaluating an experimental therapeutic in refractory celiac disease Type II, an *in situ* T cell lymphoma that appears in the intestine of certain individuals with celiac disease as a rare complication of years of exposure to gluten. Refractory celiac disease Type II has been treated with cladribine and bone marrow transplants, but these approaches have a limited response rate and carry their own risks. AMG 714, which neutralizes a molecule believed to be a key driver of this disease, IL-15, is an exciting new experimental approach that could provide a treatment option for patients diagnosed with refractory celiac disease Type II.”

Dr. Leon continued, “In addition to this trial, we recently started screening patients in another Phase 2 clinical study evaluating AMG 714 as a potential therapeutic for gluten-free diet non-responsive celiac disease, which reflects our commitment towards developing high-potential therapeutics for priority immune-mediated diseases.”

AMG 714 is a fully human immunoglobulin monoclonal antibody that binds to IL-15 and neutralizes its effects. IL-15 is considered to have a central role in celiac disease and to be a key driver of the generation of aberrant and malignant intraepithelial lymphocytes (IELs) in RCD-II. In four previous clinical studies, AMG 714 has been well



tolerated by healthy volunteers, as well as by patients diagnosed with rheumatoid arthritis or psoriasis.

Refractory celiac disease (RCD), also known as refractory sprue, is a rare but specific complication of celiac disease that is believed to appear after many years of inadvertent or intentional exposure to gluten. Approximately 1 in 200 celiac patients will be diagnosed with RCD-II, which occurs when the proportion of abnormal IELs exceeds 20%. The risk of developing enteropathy-associated T cell lymphoma (EATL) increases to greater than 50% in RCD-II patients. Currently, there is no medication approved or standard of care treatment for those with RCD-II, with average survival falling between 3-10 years post-diagnosis due to intractable diarrhea and/or high-grade lymphomas, or more rarely, metastasis to other parts of the body, such as the skin or lungs.

To learn more about RCD-II, AMG 714 or the Phase 2 clinical study, visit www.celimmune.com or www.clinicaltrials.gov, using Identifier NCT02633020.

About Celimmune

Celimmune LLC is a clinical development-stage immunotherapy company focused on treating and preventing immune-mediated diseases and is headquartered in Lebanon, NJ and Bethesda, Maryland. Celimmune will initially focus its distinctive core competence in translational medicine, immunotherapy clinical development and commercialization on combating celiac disease and other serious immune-mediated diseases. Celimmune has an exclusive licensing agreement with Amgen to develop, manufacture and commercialize AMG 714, a Phase 2-stage anti-IL-15 monoclonal antibody.

For more information on Celimmune, please visit www.celimmune.com.

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