Zenas BioPharma Announces Publication of Phase 2 Study of Obexelimab, an Investigational Treatment for IgG4-Related Disease (IgG4-RD), in The Lancet Rheumatology

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Study found obexelimab produced rapid, strong, and sustained clinical improvement, including complete clinical remission, in most patients with active IgG4-RD

Results support the continued development of obexelimab for the treatment of IgG4-RD and potentially other B cell-mediated autoimmune conditions

WALTHAM, Mass, August 1, 2023 (GLOBE NEWSWIRE) – Zenas BioPharma, a global biopharmaceutical company committed to becoming a leader in the development and commercialization of immune-based therapies, announces The Lancet Rheumatology has published findings from a Phase 2 study evaluating obexelimab for the treatment of patients with IgG4-Related Disease (IgG4-RD). Based on the results of this study, a Phase 3 study in patients with IgG4-RD is ongoing to further investigate the efficacy and safety of obexelimab administered as a subcutaneous injection.

IgG4-RD is a chronic, immune-mediated fibro-inflammatory disease that can affect multiple organs including the major salivary glands, orbits, lacrimal glands, pancreas, biliary tree, lungs, kidneys, and retroperitoneum. Approximately 20,000 patients are diagnosed with IgG4-RD in the United States alone. Despite its increasing recognition, there remains a need for further research and effective therapeutic options for individuals living with this debilitating disease.

Across the world, the use of glucocorticoids is widely considered to be the standard of care for treating IgG4-RD. There are no approved treatment options for this condition. While commonly used, glucocorticoids and available B cell depleting therapies rarely lead to long-term, treatment-free remissions, and are associated with a high risk of toxicity in these patients. Such therapies also impair vaccine responses, including those for SARS-CoV-2 and influenza.

In a prospective, open-label, single arm, single-center pilot study to assess the efficacy and safety of obexelimab in the treatment of patients with IgG4-RD (clinicaltrials.gov registration NCT02725476), obexelimab demonstrated strong improvement in the IgG4-RD Responder Index, a measure of disease activity, by inhibiting B cell function, without depleting B cells.

The published manuscript, titled “Obexelimab for the Treatment of Patients with IgG4-Related Disease: An Open-Label, Single-Arm, Pilot Study to Evaluate Efficacy, Safety, and Mechanism of Action,” is available online and will appear in the August issue of The Lancet Rheumatology 2023;5(8) [E428-E429].

The following are the key findings in the paper:

- Obexelimab produced rapid, strong, and sustained clinical improvement, including complete remission (IgG4-RD Responder Index score of 0), in most patients with active IgG4-RD.
- During obexelimab treatment, reductions in circulating B cells, including plasmablasts, were observed without evidence of cell death.
- Additionally, reduction of circulating B cells and rapid return to near normal levels after treatment discontinuation suggests that obexelimab may lead to B cell sequestration in lymphoid organs or the bone marrow.
- Obexelimab was well tolerated. The majority of treatment-related adverse events were grades 1 or 2, with the most common adverse events being gastrointestinal infusion-related events, most of which were mild.

“Our findings are a significant step forward in understanding the underlying mechanisms of IgG4-Related Disease; paving the way for more targeted treatment strategies,” said John Stone, MD, MPH, Professor of Medicine at Harvard Medical School, and the Edward A. Fox Chair in Medicine at Mass General Hospital. “Our team is honored to have our research recognized by The Lancet Rheumatology, and we are immensely grateful to the patients who participated in this groundbreaking study.”

About Obexelimab

Obexelimab is an investigational Phase 3-stage, bifunctional, non-cytolytic, humanized monoclonal antibody that mimics the action of antigen-antibody complexes by binding CD19 and FcγRIIb to inhibit B-lineage cell activity. In several early-stage clinical studies in various autoimmune diseases, 198 subjects were treated with obexelimab. In these clinical studies, obexelimab demonstrated effective inhibition of B cell function without depleting the cells, resulting in encouraging treatment effect in patients with various autoimmune diseases. Zenas acquired exclusive worldwide rights to obexelimab from Xencor, Inc.

More information on the Phase 3 (INDIGO) study for the treatment of IgG4 Related Disease is available at clinicaltrials.gov: NCT05662241.

About Zenas BioPharma

Zenas BioPharma is a global biopharmaceutical company committed to becoming a leader in the development and commercialization of immune-based therapies for patients around the world. With clinical development and operations globally, Zenas is advancing a deep and balanced

global portfolio of potential first- and best-in-class autoimmune therapeutics in areas of high unmet medical need while meeting the value requirements of the dynamic global healthcare environment. The company's pipeline continues to grow through our successful business development strategy. Our experienced leadership team and network of business partners drive operational excellence to deliver potentially transformative therapies to improve the lives of those facing autoimmune and rare diseases. For more information about Zenas BioPharma, please visit www.zenasbio.com and follow us on Twitter at @ZenasBioPharma and LinkedIn.

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