



## **Zenas BioPharma Announces First Patient Dosed in Phase 3 Clinical Study of Obexelimab for the Treatment of Immunoglobulin G4-Related Disease (IgG4-RD)**

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*Global Phase 3 INDIGO study will evaluate the efficacy and safety of obexelimab in patients with IgG4-RD, a chronic and serious fibroinflammatory disease typically affecting multiple organs*

*IgG4-RD is the first of several potential disease indications to be pursued for obexelimab given its unique non-depleting, B-cell inhibition*

**WALTHAM, Mass, January 11, 2023** (GLOBE NEWSWIRE) — Zenas BioPharma, a global biopharmaceutical company committed to becoming a leader in the development and commercialization of immune-based therapies, today announced that the first patient has been dosed in the INDIGO Phase 3 registrational study of obexelimab. The INDIGO study will evaluate the clinical efficacy and safety of obexelimab treatment in the prevention of IgG4-related disease (IgG4-RD) flare. Obexelimab is a high-affinity bifunctional antibody that inhibits B-cell lineages by simultaneously binding to CD19 and FcγRIIB, thereby downregulating B-cell activity in patients with autoimmune diseases associated with autoantibodies, such as IgG4-RD.

"IgG4-RD is a chronic and serious fibroinflammatory condition that can affect nearly any organ system and can have a profound impact on many patients, leading to severe organ damage or death," said Hua Mu, M.D., Ph.D., Chief Executive Officer at Zenas. "There are no currently approved treatments for patients living with IgG4-RD. Based upon the promising data from a Phase 2 study of obexelimab in IgG4-RD patients, we are excited to continue to evaluate the potential of obexelimab in the INDIGO study."

### **About the INDIGO Study**

The INDIGO study is a global multicenter, randomized, double-blind, placebo-controlled study enrolling up to 200 adults with active IgG4-RD signs/symptoms (i.e., flare) that require steroid therapy. Patients will be randomized in a ratio of 1:1 to receive either obexelimab or placebo, administered as subcutaneous injections.

The primary endpoint of INDIGO is time to first IgG4-RD flare (defined as the reappearance of previous signs/symptoms or appearance of new signs/symptoms of IgG4-RD) that requires initiation of rescue therapy from randomization to Week 52. Safety will be evaluated throughout the study duration.

More information on the INDIGO study (NCT05662241) is available at [clinicaltrials.gov](https://clinicaltrials.gov).

### **About Obexelimab**

Obexelimab is an investigational Phase 3-stage, novel bifunctional antibody with first-in-class potential that inhibits B-cell lineages that express CD19. Simultaneous binding to CD19 and FcγRIIB by obexelimab mimics a natural antigen-antibody complex and downregulates B cell activity. In several early-stage clinical studies, 198 subjects were treated with obexelimab. In these clinical studies, the molecule demonstrated effective inhibition of B cell function without depleting the cells and generated an encouraging treatment effect in patients with multiple autoimmune diseases. Zenas acquired exclusive worldwide rights to obexelimab from Xencor, Inc.

### **About IgG4-RD**

IgG4-RD is a chronic and serious fibroinflammatory disease typically affecting multiple organs (e.g., pancreas, liver, kidney, bile duct, salivary and lacrimal glands). Approximately 20,000 people are diagnosed with IgG4-RD in the US, with similar prevalence rates across geographies. Many patients have some degree of irreversible organ damage at the time of diagnosis. Although nearly all patients initially respond to glucocorticoid (GC) therapy, a majority of patients will relapse/flare within a few months of discontinuing treatment, requiring rescue therapy. Chronic GC therapy is also associated with toxicity in many patients.

### **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 living with autoimmune and rare diseases. For more information about Zenas BioPharma, please visit [www.zenasbio.com](http://www.zenasbio.com) and follow us on Twitter at [@ZenasBioPharma](https://twitter.com/ZenasBioPharma) and [LinkedIn](https://www.linkedin.com/company/zenasbiopharma).

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