Zenas BioPharma Completes Targeted Enrollment of the Phase 3 INDIGO Trial of Obexelimab in Immunoglobulin G4-Related Disease (IgG4-RD)

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-INDIGO is the largest clinical trial conducted in patients living with IgG4-RD-

-Topline INDIGO results expected by the end of 2025-

WALTHAM, Mass., Nov. 12, 2024 (GLOBE NEWSWIRE) -- Zenas BioPharma, Inc. ("Zenas" or the "Company") (Nasdaq: ZBIO), a clinical-stage global biopharmaceutical company committed to being a leader in the development and commercialization of transformative immunology-based therapies, today announced the completion of its targeted enrollment for the Phase 3 INDIGO trial of its lead product candidate, obexelimab, for the treatment of patients with IgG4-RD.

"With the completion of targeted enrollment in our INDIGO trial, the largest IgG4-RD clinical trial ever conducted, Zenas has demonstrated its capabilities to execute on our expansive clinical development plans for obexelimab," said Lonnie Moulder, Founder and Chief Executive Officer of Zenas. "Importantly, we expect to report topline results by the end of next year and advance the Company toward our goal of becoming a leader in the development and commercialization of transformative immunology-based therapies for patients in need."

About the Phase 3 INDIGO Trial in IgG4-RD

The Phase 3 INDIGO trial is a global, registration-directed, double-blind, placebo-controlled trial designed to evaluate the safety and efficacy of obexelimab in approximately 190 patients with active IgG4-RD and is being conducted at approximately 100 sites in 20 countries. Following an initial screening period, patients were randomized 1:1 to 250 mg of obexelimab or placebo administered as a subcutaneous injection every seven days for 52 weeks, followed by an opportunity for eligible patients to continue in an open-label extension period where all patients will receive treatment with obexelimab.

The primary efficacy endpoint of INDIGO is the time to first IgG4-RD flare, as determined per protocol by the investigator and the adjudication committee. Secondary endpoints include annualized flare rate, the proportion of patients achieving complete remission, and use and quantity of rescue medication.

More information on the INDIGO trial (NCT05662241) is available at clinicaltrials.gov

About Obexelimab

Obexelimab is a bifunctional monoclonal antibody designed to bind both CD19 and FcγRIIb, which are broadly present across B cell lineage, to inhibit the activity of cells that are implicated in many autoimmune diseases without depleting them. This unique mechanism of action and self-administered, subcutaneous injection regimen may broadly and effectively address the pathogenic role of B cell lineage in chronic autoimmune disease.

Obexelimab has been evaluated in five completed clinical trials in a total of 198 patients who received obexelimab either as an intravenous infusion or as a subcutaneous injection. Obexelimab was well tolerated and demonstrated clinical activity across these five clinical trials, providing the Company an initial clinical proof of concept for obexelimab as a B cell inhibitor for the treatment of patients living with certain autoimmune diseases. Currently, Zenas is conducting multiple Phase 2 and Phase 3 trials of obexelimab in several autoimmune diseases including IgG4-RD, Multiple Sclerosis, Systemic Lupus Erythematosus, and warm Autoimmune Hemolytic Anemia.

About IgG4-RD

IgG4-RD is a chronic fibro-inflammatory disease that can affect virtually all organ systems, including the pancreas, biliary tract, salivary and lacrimal glands, lungs, and kidneys. Patients with IgG4-RD may present with a single organ involved but more frequently present with multiple organ involvement. As the disease progresses and patients experience new or worsening symptoms (i.e., flares), lesions develop in additional organs and the cellular inflammation characterizing early disease moves toward a more fibrotic stage, which can lead to major irreversible tissue damage and ultimately organ failure. We estimate that the currently diagnosed population of IgG4-RD patients in the U.S. is approximately 20,000, with comparable prevalence rates globally.

Despite the growing recognition of IgG4-RD and advances in the understanding of its pathophysiology, there are no approved therapies for the treatment of this disease and there remains high unmet medical need. The current standard of care is treatment with glucocorticoids (GCs). Although GCs are initially effective, treatment with GCs can often result in various complications and co-morbidities. Most patients can relapse within 12 months of discontinuing GC treatment, and maintenance therapy with GCs has not been shown to prevent recurrence of disease.

The pathogenesis of IgG4-RD suggests that B cell-targeted therapies may provide therapeutic benefit. Although not approved by any regulatory authorities to treat IgG4-RD, certain B cell depleting agents (e.g. rituximab) are occasionally administered to patients with IgG4-RD. However, B cell depleting agents are often associated with infections, including serious opportunistic infections, and can compromise a patient's ability to mount a response to vaccinations.

About Zenas BioPharma, Inc.

Zenas is a clinical-stage global biopharmaceutical company committed to becoming a leader in the development and commercialization of transformative immunology-based therapies for patients in need. Our core business strategy combines our experienced leadership team with a disciplined product candidate acquisition approach to identify, acquire and develop product candidates globally that we believe can provide superior clinical benefits to patients living with autoimmune diseases. Zenas' lead product candidate, obexelimab, is a bifunctional monoclonal antibody designed to bind both CD19 and FcγRIIb, which are broadly present across B cell lineage, to inhibit the activity of cells that are implicated in many autoimmune diseases without depleting them. We believe that obexelimab's unique mechanism of action and self-administered, subcutaneous injection regimen may broadly and effectively address the pathogenic role of B cell lineage in chronic autoimmune disease. For more information about Zenas BioPharma, please visit www.zenasbio.com and follow us on LinkedIn.

Forward looking statements

This press release contains “forward-looking statements” which involve risks, uncertainties and contingencies, many of which are beyond the control of the Company, which may cause actual results, performance, or achievements to differ materially from anticipated results, performance, or achievements. All statements other than statements of historical facts contained in this press release are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential” or “continue” or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements include, but are not limited to, statements concerning Zenas’s plans, objectives, expectations and intentions; and the timing and results of ongoing and future clinical trials, including expectations on the timing of reporting INDIGO trial topline results. The forward-looking statements in this press release speak only as of the date of this press release and are subject to a number of known and unknown risks, uncertainties and assumptions that could cause the Company’s actual results to differ materially from those anticipated in the forward-looking statements, including, but not limited to: the Company’s limited operating history, incurrence of substantial losses since the Company’s inception and anticipation of incurring substantial and increasing losses for the foreseeable future; the Company’s need for substantial additional financing to achieve the Company’s goals; the uncertainty of clinical development, which is lengthy and expensive, and characterized by uncertain outcomes, and risks related to additional costs or delays in completing, or failing to complete, the development and commercialization of the Company’s current product candidates or any future product candidates; delays or difficulties in the enrollment and dosing of patients in clinical trials; the impact of any significant adverse events or undesirable side effects caused by the Company’s product candidates; potential competition, including from large and specialty pharmaceutical and biotechnology companies, many of which already have approved therapies in the Company’s current indications; the Company’s ability to realize the benefits of the Company’s current or future collaborations or licensing arrangements and ability to successfully consummate future partnerships; the Company’s ability to obtain regulatory approval to commercialize any product candidate in the United States or any other jurisdiction, and the risk that any such approval may be for a more narrow indication than the Company seeks; the Company’s dependence on the services of the Company’s senior management and other clinical and scientific personnel, and the Company’s ability to retain these individuals or recruit additional management or clinical and scientific personnel; the Company’s ability to grow the Company’s organization, and manage the Company’s growth and expansion of the Company’s operations; risks related to the manufacturing of the Company’s product candidates, which is complex, and the risk that the Company’s third-party manufacturers may encounter difficulties in production; the Company’s ability to obtain and maintain sufficient intellectual property protection for the Company’s product candidates or any future product candidates the Company may develop; the Company’s reliance on third parties to conduct the Company’s preclinical studies and clinical trials; the Company’s compliance with the Company’s obligations under the licenses granted to the Company by others, for the rights to develop and commercialize the Company’s product candidates; risks related to the operations of the Company’s suppliers, many of which are located outside of the United States, including the Company’s current sole contract manufacturing organization for drug substance and drug product, WuXi Biologics (Hong Kong) Limited, which is located in China; and other risks and uncertainties described in the section “Risk Factors” in the Company’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, as well as other information we file with the Securities and Exchange Commission. The forward-looking statements in this press release are inherently uncertain and are not guarantees of future events. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond the Company’s control, you should not unduly rely on these forward-looking statements. The events and circumstances reflected in the forward-looking statements may not be achieved or occur and actual future results, levels of activity, performance and events and circumstances could differ materially from those projected in the forward-looking statements. Moreover, the Company operates in an evolving environment. New risks and uncertainties may emerge from time to time, and management cannot predict all risks and uncertainties. Except as required by applicable law, the Company does not undertake to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

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