Zenas BioPharma Announces Positive Results from Phase 3 INDIGO Registrational Trial of Obexelimab in Immunoglobulin G4-Related Disease (IgG4-RD)

January 5, 2026

- Obexelimab met the primary endpoint demonstrating a clinically meaningful and highly statistically significant 56% reduction in risk of IgG4-RD flare -

- Obexelimab also met and demonstrated statistically significant activity on all four key secondary efficacy endpoints -

- Obexelimab was well tolerated and no new safety signals were observed -

- Zenas anticipates submitting a Biologics License Application (BLA) to the FDA in the second quarter of 2026 and a Marketing Authorization Application (MAA) to the EMA in the second half of 2026 -

- Zenas to host a conference call today, January 5, 2026, at 8:00 a.m. ET -

WALTHAM, Mass., Jan. 05, 2026 (GLOBE NEWSWIRE) -- Zenas BioPharma, Inc. ("Zenas," "Zenas BioPharma" or the "Company") (Nasdaq: ZBIO), a clinical-stage global biopharmaceutical company committed to being a leader in the development and commercialization of transformative therapies for patients living with autoimmune diseases, today announced positive results from the Phase 3 INDIGO trial of obexelimab in Immunoglobulin G4-Related Disease (IgG4-RD). Obexelimab met the primary endpoint, demonstrating a highly statistically significant and clinically meaningful 56% reduction in the risk of IgG4-RD flare compared to placebo (Hazard Ratio 0.44, p=0.0005) during the 52-week randomized placebo-controlled period. Obexelimab also met and demonstrated highly statistically significant activity compared to placebo on all four key secondary endpoints, which were reduction in investigator assessed IgG4-RD flare, the number of flares requiring rescue therapy, the proportion of patients achieving complete remission and the cumulative use of IgG4-RD rescue therapy. Rates of infections, including Grade 3, were lower in the obexelimab arm compared to placebo, and the incidence of injection site reactions was similar across both study arms. The Company expects that full data from the INDIGO trial will be presented at a future medical meeting.

"Given obexelimab's significant clinical activity and the compelling safety and tolerability profile observed in the INDIGO trial, we believe obexelimab may have an important role as a first line therapy in the long-term management of IgG4-RD," said Lonnie Moulder, Founder and Chief Executive Officer of Zenas. "With its unique inhibitory mechanism, tolerability profile, at-home subcutaneous self-administration and potential to pause for vaccination or management of intercurrent illness, obexelimab has the potential to be a meaningful treatment option for patients. IgG4-RD represents a significant commercial opportunity for obexelimab and Zenas, and today's data support obexelimab as a potential franchise molecule for rheumatic diseases. We look forward to submitting our Biologics License Application to the FDA in the second quarter of 2026 and our Marketing Authorization Application to the EMA in the second half of this year."

"Patients living with IgG4-RD have faced limited treatment choices for far too long," said John Stone, M.D., M.P.H., Professor of Medicine at Harvard Medical School and the Edward A. Fox Chair in Medicine at Massachusetts General Hospital. "The INDIGO study results suggest that obexelimab, with its intriguing mechanism of action – emphasizing B cell inhibition rather than B cell depletion – and self-administration by patients, may be an important new therapy for people living with IgG4-RD."

"These INDIGO trial results build upon the highly positive results observed in our Phase 2 MoonStone trial in Relapsing Multiple Sclerosis and further validate obexelimab's mechanism of action, optimized subcutaneous dosing and its potential to address the unmet medical needs of patients living with autoimmune diseases," said Lisa von Moltke, M.D., Head of Research and Development and Chief Medical Officer of Zenas. "Without treatment, IgG4-RD meaningfully contributes to organ fibrosis, damage and failure. Obexelimab's unique inhibitory mechanism, combined with its weekly subcutaneous dosing chosen for optimal pharmacokinetic and clinical activity, has the potential to sustain B cell inhibition and durably impact disease activity. The INDIGO trial results are supported by the largest body of clinical data ever reported in this indication and strengthen confidence in the ongoing Phase 2 SunStone trial in Systemic Lupus Erythematosus (SLE), which remains on track to report data later this year. On behalf of the Zenas team, I would like to thank the patients and healthcare professionals who took part in the INDIGO trial."

Following these positive Phase 3 INDIGO results, Zenas anticipates submitting the obexelimab Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for the treatment of IgG4-RD in the second quarter of 2026. Zenas also intends to submit a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) in the second half of 2026. Zenas' partner Bristol Myers Squibb holds exclusive development and commercialization rights for obexelimab in Japan, South Korea, Taiwan, Hong Kong, Singapore and Australia.

Zenas also expects to report topline results, including a biomarker analysis, of the obexelimab Phase 2 SunStone trial in SLE in the fourth quarter of 2026. In addition, orelabrutinib, a potentially best-in-class, highly selective central nervous system (CNS)-penetrant, oral, small molecule Bruton's Tyrosine Kinase (BTK) inhibitor, is being studied in a global Phase 3 clinical trial in patients with Primary Progressive Multiple Sclerosis (PPMS). A global Phase 3 trial of orelabrutinib in patients with non-active Secondary Progressive Multiple Sclerosis (naSPMS) is expected to initiate in the first quarter of 2026. Subject to Investigational New Drug (IND) clearance, Zenas expects to initiate Phase 1 clinical development for ZB021, a potentially best-in-class oral IL-17AA/AF inhibitor, in 2026. Pending Phase 1 data, Zenas expects to advance development of ZB021 for rheumatic and/or dermatologic diseases. In addition, subject to IND clearance, Zenas expects to initiate Phase 1 clinical development for ZB022, a potentially best-in-class brain penetrant TYK2 inhibitor, in 2026. Pending Phase 1 data, Zenas expects to advance development of ZB022 for neurologic diseases.

Conference Call Information
Zenas will host a conference call and webcast today, January 5, 2026, at 8:00 a.m. ET to discuss the positive results from the Phase 3 INDIGO trial of obexelimab in IgG4-RD. To access the live webcast of the call, please visit the "Events and Presentations" page in the Investor & Media Relations section of the Zenas BioPharma website. A replay of the webcast will be available following the call.

About Immunoglobulin G4-Related Disease
Immunoglobulin G4-Related Disease (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 may 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, treatment options are limited. The pathogenesis of IgG4-RD suggests that B cell-targeted therapies may provide therapeutic benefit. One B cell depleting agent is currently approved to treat IgG4-RD in the U.S. and others (e.g., rituximab) are occasionally administered to patients with IgG4-RD. However, B cell depleting agents can compromise a patient's ability to mount a response to vaccinations and can compromise response to infections including serious and opportunistic infections should they occur.

Glucocorticoids (GCs), while not approved for the treatment of IgG4-RD, are commonly used to treat disease flares. Although GC treatment is initially effective, long-term treatment can often result in various complications and co-morbidities. GCs do not address underlying disease activity that can meaningfully contribute to organ fibrosis, damage and failure. Most patients treated with GCs relapse within 12 months of discontinuing treatment, and maintenance therapy with GCs has not been shown to prevent recurrence of disease.

About the Phase 3 INDIGO Trial
The Phase 3 INDIGO trial, which enrolled 194 patients, is a global, registration-directed, double-blind, placebo-controlled trial, designed to evaluate the safety and efficacy of obexelimab in patients with IgG4-RD. After 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, that requires initiation of rescue therapy as determined by the investigator and the adjudication committee (AC) from randomization to week 52. Key secondary endpoints included time to first IgG4-RD flare as determined per protocol, that requires initiation of rescue therapy as determined by the investigator from randomization to week 52; the number of investigator and AC-determined flares requiring initiation of rescue therapy from randomization to week 52; the proportion of patients achieving complete remission at week 52; and the cumulative dose of IgG4-RD rescue therapy from randomization to week 52.

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 inhibitory mechanism of action and self-administered, subcutaneous injection regimen may broadly and effectively address the pathogenic role of the B cell lineage in chronic autoimmune disease.

Obexelimab has been evaluated in eight clinical trials in a total of 383 subjects, including INDIGO. Obexelimab was well tolerated and demonstrated clinical activity across these clinical trials. The registrational Phase 3 INDIGO trial for Immunoglobulin G4-Related Disease met its primary endpoint and all four key secondary endpoints with high statistical significance. The trial continues to evaluate patients in the 3-year open label extension period which will further build upon the largest body of clinical data reported for IgG4-RD patients to date. In October 2025, Zenas reported that the Phase 2 MoonStone trial for Relapsing Multiple Sclerosis met its 12-week primary endpoint demonstrating a highly statistically significant 95% relative reduction in the cumulative number of new gadolinium-enhancing T1 hyperintense lesions over week 8 and week 12 compared with placebo (p=0.0009). A randomized Phase 2 trial for Systemic Lupus Erythematosus is ongoing and Zenas expects to report topline results, including biomarker data from this trial in the fourth quarter of 2026.

About Zenas BioPharma, Inc.
Zenas is a clinical-stage global biopharmaceutical company committed to becoming a leader in the development and commercialization of transformative therapies for patients living with autoimmune diseases. 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 meaningful clinical benefits to patients living with autoimmune diseases. Zenas is advancing two late-stage, potential franchise molecules, obexelimab and orelabrutinib. Obexelimab, Zenas' lead product candidate, 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 inhibitory 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. Orelabrutinib is a potentially best-in-class, highly selective central nervous system (CNS)-penetrant, oral, small molecule BTK inhibitor. Orelabrutinib's mechanism of action targets pathogenic B cells not only in the periphery but also within the CNS. Additionally, it directly modulates macrophages and microglial cells in the CNS, with the potential to address compartmentalized inflammation and disease progression in Multiple Sclerosis (MS). Zenas' earlier stage programs include ZB021, a preclinical, potentially best-in-class, oral, IL-17AA/AF inhibitor, and ZB022, a preclinical, potentially best-in-class, oral, brain-penetrant, TYK2 inhibitor. For more information about Zenas BioPharma, please visit https://zenasbio.com/ and follow us on LinkedIn.

Zenas BioPharma 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, forward-looking statements can be identified 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 milestones, expectations and intentions, including the potential for obexelimab to become a meaningful therapy across multiple autoimmune diseases and to address the pathogenic role of B cells in autoimmune diseases, the timing of the initiation of, results and data from clinical trials, including the timing of reporting the topline results from the SunStone trial and the timing of initiation of the Phase 3 clinical trial of orelabrutinib in patients with naSPMS; the timing of regulatory submissions, including timing of our submission of a BLA to FDA for obexelimab in IgG4-RD, our plans to submit a marketing application to the EMA for obexelimab in IgG4-RD; subject to IND clearance, the initiation of Phase 1 clinical studies and indications selections of ZB021 and ZB022; the potential of obexelimab to address underlying disease activity; and the potential benefits, development and commercialization of orelabrutinib and obexelimab. 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, the risk that the data from our clinical trials is not sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a biologics license application or other comparable submission or to obtain regulatory approval for our product candidates for which we seek approval in the U.S. or elsewhere, 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; significant political, trade, regulatory developments, including changes in relations between the U.S. and China; 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 obexelimab drug substance and drug product, WuXi Biologics (Hong Kong) Limited, and our partner, InnoCare, both of which are 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, 2025, as well as other information we file with the Securities and Exchange Commission. The forward-looking statements in this press release are inherently uncertain, speak only as of the date of this press release and may prove incorrect. These statements are based upon information available to the Company as of the date of this press release and while the Company believes such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that the Company has conducted an exhaustive inquiry into, or review of, all potentially available relevant information. 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, these forward-looking statements should not be relied upon as guarantees of future events. 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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