Zenas BioPharma Announces Upcoming Presentation of Results from Phase 3 INDIGO Registrational Trial of Obexelimab in Immunoglobulin G4-Related Disease (IgG4-RD) at EULAR 2026 Congress

May 19, 2026

- Safety and efficacy results from the Phase 3 INDIGO trial to be presented by Emanuel Della Torre, M.D., Ph.D., on Thursday June 4, 2026, at 2:45 PM GMT -

WALTHAM, Mass., May 19, 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 that safety and efficacy outcomes from the Phase 3 INDIGO trial evaluating obexelimab in Immunoglobulin G4-Related Disease (IgG4-RD) will be presented in an oral presentation at the upcoming European Alliance of Associations for Rheumatology (EULAR) 2026 Congress, held from June 3-6, 2026, in London, England.

INDIGO, the largest randomized, double-blind, placebo-controlled study conducted in IgG4-RD, met the primary endpoint demonstrating a highly statistically significant and clinically meaningful 56% reduction in the risk of IgG4-RD flare compared to placebo (HR 0.443; 95% CI 0.277–0.711; 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: time to first investigator-determined flare requiring rescue therapy (p=0.0001), number of investigator- and AC-determined flares requiring rescue therapy (p=0.0008), proportion of patients achieving complete remission (p=0.0049), and cumulative glucocorticoid rescue therapy use (p=0.0042). Obexelimab was well tolerated with no new safety signals observed. Treatment-emergent adverse events (TEAEs) occurred in 97.9% vs 95.9% of participants (obexelimab vs placebo). Incidence of Grade ≥3 TEAEs was less with obexelimab (11.3% vs 23.7%), and the incidence of serious adverse events was 10.3% vs 18.6%. Infections occurred in 53.6% vs 62.9% of participants. Injection-site reactions were reported in 3.5% vs 2.3% of total patient doses. Hypersensitivity occurred in 16.5% vs 11.3% of participants. There were no deaths in the obexelimab group and one death (1.0%) in the placebo group.

Details of EULAR Presentation:

- **Title:** Obexelimab, a B Cell Inhibitor, in IgG4-Related Disease: Results From the Phase 3 INDIGO Trial
- **Presenting Author:** Emanuel Della Torre, M.D., Ph.D., Associate Professor of Rheumatology, Vita-Salute San Raffaele University, Milan, Italy
- **Session:** New Perspectives in IgG4-Associated Diseases
- **Session Date & Time:** Thursday, June 4, 2026, at 2:45 PM GMT
- **Abstract Number:** OP018
- **Location:** Excel London, Room N1

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. Enrollment in a randomized Phase 2 trial for Systemic Lupus Erythematosus is completed and Zenas expects to report topline results, including biomarker data from this trial in the fourth quarter of 2026.

About Zenas BioPharma
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. Zenas' 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 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 Fc γRIIb, which are broadly present across B cell lineage, to inhibit the activity of cells that are implicated in many autoimmune diseases without depleting them. Zenas believes 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. Orelabrutinib is a potentially best-in-class, highly selective 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 MS. Zenas' earlier stage programs include ZB021, a novel, potentially best-in-class, oral small molecule IL-17AA/AF inhibitor, ZB022, a preclinical, potentially best-in-class, oral, brain-penetrant, TYK2 inhibitor, and ZB014, a preclinical, half-life extended anti-CD19 and FcγRIIb monoclonal antibody. 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 address the pathogenic role of B cell lineage in chronic autoimmune disease; the timing of results and data from clinical trials, including the timing of reporting the topline results from the SunStone trial; and the potential for orelabrutinib to address compartmentalized inflammation and disease progression in MS. 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; the risk that the Company's indebtedness resulting from the Company's loan agreement with Pharmakon Advisors LP, and the guarantors party to such agreement, or future indebtedness could adversely affect the Company's financial condition or restrict the Company's future operations; and other risks and uncertainties described in the section "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 31, 2025 and Quarterly Report on Form 10-Q for the first quarter ended March 31, 2026, 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, neither we, nor our affiliates, advisors or representatives, undertake any obligation 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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