



Zenas BioPharma Announces Submission of Biologics License Application (BLA) to U.S. FDA for Obexelimab in IgG4-RD

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- BLA submission based on positive results from Phase 3 INDIGO trial -

WALTHAM, Mass., May 28, 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 the submission of its Biologics License Application (BLA) to the U.S. Food and Drug Administration for obexelimab in Immunoglobulin G4-Related Disease (IgG4-RD). IgG4-RD is a debilitating chronic fibro-inflammatory disease affecting multiple organ systems, often resulting in irreversible tissue damage and organ failure. Obexelimab, an investigational therapy, is a bifunctional monoclonal antibody designed to bind both CD19 and FcγRIIb to inhibit B cell function.

"Our obexelimab BLA submission brings us one step closer to our goal of delivering this meaningful treatment option to patients living with IgG4-RD. Based on the significant clinical activity and the favorable safety and tolerability profile observed in the INDIGO study, we believe obexelimab may have an important role as a first line therapy in the long-term management of IgG4-RD," said Lisa von Moltke, M.D., Head of Research & Development & Chief Medical Officer of Zenas. "This regulatory submission marks a significant milestone for Zenas, and we would like to thank the patients, healthcare professionals and the Zenas team whose contributions made this submission possible."

The BLA submission is supported by the results of the Phase 3 INDIGO registrational trial of obexelimab for the treatment of IgG4-RD. In INDIGO, 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 and was generally well tolerated. Data from the INDIGO trial will be presented during an oral session at the European Alliance of Associations for Rheumatology (EULAR) 2026 Congress in London, UK, on June 4, 2026.

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 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. Zenas believes 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 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 regarding the Company's product candidates, including the timing, progress and results of preclinical studies and clinical trials; the Company's ability to obtain and maintain regulatory approvals for obexelimab; the Company's belief that obexelimab may have an important role as a first time therapy in the long-term management of IgG4-RD; and the Company's plans for development of its pipeline and potential commercialization of 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, and 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 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, 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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