



Zenas BioPharma's Partner, InnoCare Pharma, Announces Achievement of Primary Endpoint in Phase 2b Study of Orelabrutinib, a BTK Inhibitor, for Systemic Lupus Erythematosus

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- Orelabrutinib is the first BTK inhibitor to demonstrate significant clinical activity in a Phase 2 clinical trial for SLE -

- Zenas acquired the exclusive right to develop, manufacture and commercialize orelabrutinib in the field of Multiple Sclerosis globally, and non-oncology fields in all territories outside Greater China and Southeast Asia, in October 2025 license agreement with InnoCare -

WALTHAM, Mass., Dec. 15, 2025 (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 its partner, InnoCare Pharma (HKEX: 09969; SSE: 688428), announced the achievement of the primary endpoint in a Phase 2b study of orelabrutinib, a potentially best-in-class, highly selective CNS-penetrant, oral, small molecule BTK inhibitor, in patients with Systemic Lupus Erythematosus (SLE). InnoCare also received approval from China's Center for Drug Evaluation (CDE) to conduct a Phase 3 registrational clinical trial as InnoCare develops orelabrutinib for the treatment of SLE in China.

In the Phase 2b study of orelabrutinib, a total of 187 patients were enrolled and randomized (1:1:1) into three groups: orelabrutinib 75 mg once-daily (QD), orelabrutinib 50 mg QD and placebo. The primary endpoint of the study was the SLE Response Index-4 (SRI-4) response rate at week 48. At week 48, the orelabrutinib 75 mg QD group achieved a statistically significant improvement in SRI-4 response rate compared with placebo (57.1% vs. 34.4%, $p < 0.05$), meeting the primary endpoint. Additionally, a dose-dependent improvement trend of the orelabrutinib 75 mg QD group compared to the 50 mg QD group was observed.

At week 48, the orelabrutinib 75 mg QD group demonstrated significantly higher SRI-6 and British Isles Lupus Assessment Group-based Composite Lupus Assessment (BICLA) response rates compared to the placebo group ($p < 0.05$), meeting these secondary endpoints.

Orelabrutinib was well tolerated with a safety profile consistent with the mechanism of action of BTK inhibition and the underlying disease biology of SLE.

Results of a previous Phase 2a clinical trial of orelabrutinib for SLE were previously presented as a late breaking oral presentation at the European Union Congress of Rheumatology (EULAR 2022).

In October 2025, Zenas and InnoCare announced a transformational license agreement. Zenas acquired the exclusive right to develop, manufacture and commercialize orelabrutinib in the field of Multiple Sclerosis (MS) globally, and non-oncology fields in all territories outside Greater China and Southeast Asia, while InnoCare retained full global rights in the field of oncology. Zenas also gained the exclusive right to develop, manufacture and commercialize ZB021, an oral, IL-17AA/AF inhibitor in all territories outside Greater China and Southeast Asia, and ZB022, an oral, brain-penetrant, TYK2 inhibitor globally.

About Orelabrutinib

Orelabrutinib is a late-stage, potentially best-in-class, highly selective CNS-penetrant, oral, small molecule Bruton's Tyrosine Kinase (BTK) inhibitor. In Multiple Sclerosis (MS), Zenas is advancing a Phase 3 trial in Primary Progressive MS (PPMS). A Phase 3 trial in Secondary Progressive MS (SPMS) is expected to initiate in the first quarter of 2026. Orelabrutinib is approved for B cell malignancies in mainland China and Singapore, marketed by our partner InnoCare.

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 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 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. 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, orelabrutinib 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 a potentially best-in-class, oral, IL-17AA/AF inhibitor, and a potentially best-in-class, oral, brain-penetrant, TYK2 inhibitor, both in IND enabling studies. For more information about Zenas BioPharma, please visit <https://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, 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' 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, the timing of initiation of the Phase 3 clinical trial of orelabrutinib in SPMS, the timing to submit an IND and initiate clinical development in ZB021 and ZB022; the potential benefits, development opportunities and commercialization of orelabrutinib and obexelimab; and the expansion of the Zenas pipeline. 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 single source contract manufacturing organizations for drug substance and drug product, WuXi Biologics (Hong Kong) Limited, and 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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