Zenas BioPharma Announces First Subject Dosed in Phase 1 Clinical Trial of ZB021, a Novel, Potentially Best-in-Class Oral IL-17AA/AF Inhibitor

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- Phase 1 trial designed to evaluate the safety, tolerability, and pharmacokinetic properties of ZB021 in healthy volunteers and to establish proof-of-concept in patients with plaque psoriasis -

- Phase 1 SAD and MAD data expected by year-end 2026, with proof-of-concept data in psoriasis patients anticipated in 2027 -

WALTHAM, Mass., May 13, 2026 (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 therapies for patients living with autoimmune diseases, today announced that the first subject has been dosed in the Phase 1 trial of ZB021, a novel potentially best-in-class oral IL-17AA/AF inhibitor.

“Dosing the first subject in our Phase 1 trial of ZB021 marks an important milestone for Zenas as we rapidly advance our earlier-stage pipeline and broaden our presence in autoimmune and inflammatory diseases,” said Lonnie Moulder, Founder and Chief Executive Officer of Zenas. “The IL-17 pathway is well validated across a broad range of rheumatic and dermatologic indications, yet no oral therapies directed toward this pathway are approved or in late-stage clinical development. The strength of this established mechanism may support an accelerated path toward registration-directed trials, and we expect to report initial clinical data by year-end.”

The ZB021 Phase 1 trial is supported by robust preclinical data demonstrating a desirable pharmacology and toxicology profile. In addition to potent inhibition of IL-17AA/AF signaling, and anti-inflammatory activity demonstrated in animal models, excellent oral bioavailability was observed across multiple preclinical species, including non-human primates. Together, these data support the potential of ZB021 to be a differentiated oral therapy for autoimmune and inflammatory diseases associated with dysregulated IL-17 signaling.

The Phase 1 study is designed to evaluate the safety, tolerability, and pharmacokinetic profile of single ascending doses (SAD) and multiple ascending doses (MAD) of ZB021 in healthy volunteers and is being conducted in partnership with InnoCare Pharma in China. These data are expected by year-end 2026. Upon completion and evaluation of the SAD and MAD study, Zenas plans to initiate a proof-of-concept (POC) trial in North America to evaluate clinical activity and safety in psoriasis patients with results anticipated in 2027.Given the well-established and validated nature of the IL-17 mechanism, Zenas believes there is potential to advance ZB021 directly from POC into registration-directed trials, which could meaningfully accelerate the path to regulatory approval.

About ZB021
ZB021 is a novel potentially best-in-class oral small molecule IL-17AA/AF inhibitor being developed by Zenas BioPharma in partnership with InnoCare Pharma. ZB021 is designed to selectively block the signal transduction pathways of both the IL-17AA homodimer and IL-17AF heterodimer, inhibiting downstream pro-inflammatory cytokine and chemokine release. Preclinical studies have demonstrated potent anti-inflammatory activity, a favorable safety profile, and excellent Absorption, Distribution, Metabolism, and Excretion (ADME) properties. The IL-17 pathway has demonstrated broad utility across many rheumatic and dermatologic indications. Currently, no oral IL-17 inhibitors have been approved or are in late-stage development globally. ZB021's oral, small molecule profile may offer meaningful advantages over currently approved biologic IL-17 therapies in terms of convenience, compliance, and accessibility. Zenas licensed the exclusive rights from InnoCare Pharma to develop, manufacture, and commercialize ZB021 in all fields of use worldwide, excluding greater China and Southeast Asia.

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 FcgRIIb, 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 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 FcgRIIb 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 ZB021 to provide meaningful advantages over currently approved biologic IL-17 therapies and become a differentiated oral therapy for autoimmune and inflammatory diseases, the timing of the initiation of, results and data from clinical trials, including the timing of reporting Phase 1 clinical data and, if successful, the timing of initiation of and reporting clinical data in the Phase 1b clinical trial of ZB021 in patients with plaque psoriasis; and subject to clinical data and regulatory feedback, the potential to advance directly from POC into registration-directed trials. 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, 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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