Zenas BioPharma Announces Key 2024 Accomplishments and 2025 Business Objectives to Support the Global Development and Commercialization of Therapies for Autoimmune Diseases

February 5, 2025

- Advancing Phase 2 and Phase 3 trials of obexelimab, a unique CD-19 x FcγRIIb inhibitor of B cell function-

-Topline results from Phase 2 Trial in Relapsing Multiple Sclerosis (MoonStone) expected in third quarter 2025-

-Topline results from pivotal Phase 3 Trial in Immunoglobulin G4-Related Disease (INDIGO) expected year-end 2025-

- Enrollment of Phase 2 Trial in Systemic Lupus Erythematosus (SunStone) expected to be completed in 2025-

- Out-licensed greater-China anti-IGF-1R Thyroid Eye Disease programs to Zai Lab -

WALTHAM, Mass., Feb. 05, 2025 (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 therapies for autoimmune diseases, today announced its 2024 accomplishments, outlined its key business objectives for 2025 and announced preliminary unaudited cash balance as of year-end 2024.

“Based upon the progress achieved across all of our corporate goals and objectives during 2024, we enter 2025 with an opportunity to achieve major value-driving milestones with the anticipated results from our ongoing obexelimab Phase 2 and Phase 3 clinical trials,” said Lonnie Moulder, Founder and Chief Executive Officer of Zenas. “We are extremely proud of the accomplishments of our dedicated team as we enter the year well-financed and able to focus on execution, and achievement of our key objectives for the year.”

The Company enters 2025 well-capitalized to deliver its key milestones with approximately $350 million in cash, cash equivalents, and short-term investments as of December 31, 2024, [1] which is expected to fund its operating expenses and capital expenditure requirements into the fourth quarter of 2026.

2024 Accomplishments and Recent Achievements

During 2024, the Company achieved the following objectives and announced a recent business development transaction:

- Completed enrollment of the Phase 3 INDIGO trial, a global Phase 3 registration-directed, randomized, double-blind placebo-controlled trial of obexelimab in patients with Immunoglobulin-G4 Related Disease (IgG4-RD), the largest clinical trial ever conducted in this patient population.

- Initiated the Phase 2 MoonStone trial, a Phase 2, multicenter, randomized, double-blind, placebo-controlled trial, to evaluate the efficacy and safety of obexelimab in patients with Relapsing Multiple Sclerosis (RMS).

- Initiated the Phase 2 SunStone trial, a Phase 2, multicenter, randomized, double-blind, placebo-controlled trial, to evaluate the efficacy and safety of obexelimab to reduce disease activity in patients with Systemic Lupus Erythematosus (SLE).

- Provided initial data from the Phase 2 SApHiAre trial, a global, multicenter, open-label safety and dose confirmation run-in period (SRP) to evaluate the safety and activity of obexelimab in patients with warm Autoimmune Hemolytic Anemia (wAIHA). Obexelimab achieved clinical proof-of-mechanism by increasing hemoglobin levels and red blood cells, and decreasing LDH and total bilirubin levels. Obexelimab was well tolerated in the SRP.

- Completed an upsized Series C and initial public offering, raising approximately $458.7 million in aggregate gross proceeds to fund its planned activities for obexelimab and the Company’s growth strategy.

- Bolstered its leadership team with the appointments of Chief Commercial Officer, Orlando

Oliveira, and Chief Legal Officer, Jeff Held.

- Out-licensed ZB005, a human IgG4 monoclonal antibody designed to bind only to the active form of C1s, for which Zenas held the development and commercialization rights in China, Hong Kong, Macau and Taiwan (Greater China) through an exclusive license with Dianthus.

- The Company recently out-licensed regional rights to its thyroid eye disease programs, including ZB001, an insulin-like growth factor-1 receptor (anti-IGF-1R) monoclonal antibody, to Zai Lab (Zai). Zenas received an upfront fee and is eligible to receive milestone payments and royalties in the future, as consideration for an exclusive sublicense to Zai to develop and commercialize ZB001 and related programs in Greater China.

Anticipated 2025 Clinical Milestones for 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 mechanism of action and self-administered, subcutaneous once-weekly injection regimen may broadly and effectively address the pathogenic role of B cell lineage in chronic autoimmune disease. Obexelimab has been evaluated in five completed clinical trials in a total of 198 patients who received obexelimab either as an intravenous infusion or as a subcutaneous injection. Obexelimab was well tolerated and demonstrated clinical activity across these five clinical trials, providing the Company an initial clinical proof of concept for obexelimab as a potent B cell inhibitor for the treatment of patients living with certain autoimmune diseases.

During 2025, the Company expects to achieve the following key clinical milestones:

- Report the 12-week primary endpoint results in the third quarter of 2025 from the Phase 2 MoonStone trial in patients with RMS.

The role of B cells in the pathogenesis of multiple sclerosis including RMS has been demonstrated through the successful clinical development, approval and clinical use of anti-CD20 B cell targeting therapies of other companies, including OCREVUS® (ocrelizumab) and KESIMPTA® (ofatumumab), which selectively deplete CD20-expressing B cells. The Company believes obexelimab's unique mechanism of action to potently inhibit but not deplete a broader B cell lineage than CD20, nonclinical data, and a subcutaneous injection regimen, supports its potential for the treatment of RMS.

  - Following an initial screening period, patients in the MoonStone trial are being randomized 2:1 to 250 mg of obexelimab or placebo administered as a subcutaneous injection every seven days for a 12-week treatment period.
  - The primary objective of this double-blinded portion of the trial will be to assess the change from baseline in the cumulative number of gadolinium (Gd) enhancing lesions identified on T1-weighted magnetic resonance imaging (MRI).
  - Upon completion of the 12-week period, patients will enter an open-label period where patients on placebo will receive obexelimab treatment for at least three months, and patients initially randomized to obexelimab will continue treatment.
  - Important secondary endpoints during this open-label period include using standardized assessments, novel 3D imaging and biomarkers, including serum neurofilament light chain (NfL), to evaluate the impact of obexelimab on disease progression.

More information on the Phase 2 MoonStone trial (NCT06564311) is available at clinicaltrials.gov

- Report topline results year-end 2025 from the Phase 3 INDIGO trial in patients with IgG4-RD.

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 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, there are no approved therapies for the treatment of this disease and there remains high unmet medical need. The current standard of care is treatment with glucocorticoids (GCs). Although GCs are initially effective, treatment with GCs can often result in various complications and co-morbidities. Most patients can relapse within 12 months of discontinuing GC treatment, and maintenance therapy with GCs has not been shown to prevent recurrence of disease.

The pathogenesis of IgG4-RD suggests that B cell-targeted therapies may provide therapeutic benefit. Although not approved by any regulatory

authorities to treat IgG4-RD, certain B cell depleting agents (e.g., rituximab) are occasionally administered to patients with IgG4-RD. However, B cell depleting agents are often associated with infections, including serious opportunistic infections, and can compromise a patient's ability to mount a response to vaccinations.

The reported evidence for the role of B cells in the pathogenesis of IgG4-RD, the observed effects of B cell targeting agents in previous trials in IgG4-RD, the data from our Phase 2 IgG4-RD trials with obexelimab, and its unique, non-depleting mechanism and once-weekly, subcutaneous injection regimen support its development in patients with IgG4-RD.

- INDIGO is the largest clinical trial conducted in patients living with IgG4-RD and is designed to evaluate the safety and efficacy of obexelimab in approximately 190 patients with active IgG4-RD and being conducted at approximately 100 sites in 20 countries.
- Following 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 by the investigator and the adjudication committee.
- Secondary endpoints include annualized flare rate, the proportion of patients achieving complete remission, and use and quantity of rescue medication, including GCs.

More information on the Phase 3 INDIGO trial (NCT05662241) is available at clinicaltrials.gov

- Complete enrollment in 2025 in the Phase 2 SunStone trial in patients with SLE and report topline results in the first half of 2026.

The crucial role of B cells in SLE pathogenesis is well recognized, from producing autoantibodies to abnormal regulation of immune responses. Moreover, SLE is an autoimmune disease characterized by B cell dysfunction, the production of autoantibodies toward cellular and nuclear components, and multiorgan damage caused by immune complex deposition and inflammation within affected tissues. Current treatments are limited in number and modestly effective. Obexelimab has demonstrated clinical activity in a prior Phase 2 double-blind, randomized trial demonstrating proof-of-concept in the overall trial population and increased response in patients who maintained higher systemic exposure to obexelimab, and also in biomarker-defined subpopulations. Coupled with the safety data obtained to date, we believe these data provide support for the development of obexelimab in patients with SLE.

- Patients with active SLE determined at screening by the investigator and adjudication committee are randomized 1:1 to obexelimab 250 mg or placebo administered as a subcutaneous injection every seven days for 24 weeks.
- The 250 mg once-weekly subcutaneous injection dose has been selected to maximize the potential for clinical activity as higher systemic exposure (C_{trough}) correlated with greater clinical activity in the prior Phase 2 trial in SLE.
- The primary endpoint is the percentage of responders, defined by BILAG-based Composite Lupus Assessment, with a reduction of SLE disease activity at week 24.
- Biomarker analysis is planned to be conducted in all patients, including baseline RNA expression profiles to immunophenotype patients and evaluation of their differential responses to treatment.

More information on the Phase 2 SunStone trial (NCT06559163) is available at clinicaltrials.gov

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 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' lead product candidate, 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. 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. For more information about Zenas BioPharma, please visit www.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’s plans, objectives, expectations and intentions; the timing and results of ongoing and future clinical trials, including expectations on the timing of reporting INDIGO trial topline results, the 12-week primary endpoint data for the MoonStone trial and the anticipated timing of completing enrollment and reporting topline results for the SunStone trial; its growth strategy; the Company’s preliminary unaudited cash, cash equivalents and short-term investments as of December 31, 2024; and cash runway guidance. 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, 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; 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 drug substance and drug product, WuXi Biologics (Hong Kong) Limited, which is 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, 2024, 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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[1] This amount is preliminary and unaudited and is subject to completion of the Company’s financial closing procedures. As a result, this amount may differ materially from the amount that will be reflected in the Company’s consolidated financial statements for the year ended December 31, 2024.