Zenas BioPharma and InnoCare Pharma Announce License Agreement Granting Zenas Rights for Three Autoimmune Product Candidates, Including Orelabrutinib, a BTK Inhibitor in Phase 3 Development for Multiple Sclerosis

October 8, 2025

- Orelabrutinib, a highly selective CNS-penetrant, oral small molecule Bruton's Tyrosine Kinase (BTK) inhibitor with best-in-class potential now in Phase 3 development for progressive forms of Multiple Sclerosis (MS) -

- Pivotal Phase 3 clinical trial evaluating orelabrutinib in patients with Primary Progressive MS (PPMS) initiated; Pivotal Phase 3 clinical trial in patients with Secondary Progressive MS (SPMS) expected to initiate in 1Q 2026 -

- A novel oral IL-17AA/AF inhibitor, and an oral, brain-penetrant, TYK2 inhibitor, expected to begin Phase 1 clinical trials in 2026 -

- Zenas also announces $120.0 million private placement financing -

- Zenas to host a conference call today, October 8, 2025, at 8:00 a.m. ET -

- InnoCare to host a conference call on October 9, 2025, at 8:30 a.m. Beijing time -

WALTHAM, Mass. and BEIJING, Oct. 08, 2025 (GLOBE NEWSWIRE) -- Zenas BioPharma, Inc. ("Zenas," "Zenas BioPharma" or the "Company") (Nasdaq: ZBIO) and InnoCare Pharma Limited ("InnoCare" or "InnoCare Pharma") (HKEX: 09969; SSE: 688428) today announced a transformational license agreement granting Zenas global development and commercialization rights to orelabrutinib for Multiple Sclerosis (MS) and across all therapeutic areas other than oncology. Zenas also secured rights to a novel, oral, IL-17AA/AF inhibitor, and an oral, brain-penetrant, TYK2 inhibitor.

Orelabrutinib is a potentially best-in-class, highly selective CNS-penetrant, oral, small molecule BTK inhibitor with the potential to address compartmentalized inflammation and disease progression in MS. A global, Phase 3, multicenter, randomized, double-blind, placebo-controlled clinical trial evaluating the safety and efficacy of orelabrutinib dosed 80 mg once daily (QD) in patients with Primary Progressive MS (PPMS) has been initiated. Zenas plans to initiate a second global, Phase 3, multicenter, randomized, double-blind, placebo-controlled clinical trial evaluating orelabrutinib in patients with Secondary Progressive MS (SPMS) in the first quarter of 2026.

In a previously completed global Phase 2 clinical trial in patients with Relapsing-Remitting MS (RRMS), orelabrutinib demonstrated significant reductions in new Gd+ T1 lesions versus placebo at weeks 12 and 24, with sustained reductions in inflammatory activity through week 96 as demonstrated by meaningful impact on endpoints indicative of disease progression. The safety and tolerability profile of orelabrutinib is consistent with other BTK inhibitors in development for MS and is well characterized across multiple prior autoimmune disease and hematologic cancer trials.

"InnoCare is a globally recognized company with a successful track record of drug discovery, development and commercialization. This transformative collaboration with InnoCare further positions Zenas to execute on its vision to become a global, fully integrated development and commercial-stage autoimmune-focused biopharmaceutical company. With global rights to orelabrutinib, we are advancing a potential blockbuster franchise for progressive MS. Orelabrutinib, with its best-in-class potential, is strongly positioned to address disease progression independent of relapse activity, the highest unmet medical need in MS, and to improve the lives of patients living with progressive MS. We are also excited to add two potentially best-in-class molecules, a novel, oral, IL-17AA/AF inhibitor and an oral, brain-penetrant, TYK2 inhibitor, to our pipeline. We plan to advance each of these programs to human clinical trials in 2026 and expect to have initial patient data from the oral IL-17AA/AF clinical program in 2027," said Lonnie Moulder, Founder and Chief Executive Officer (CEO) of Zenas.

"We are delighted to partner with Zenas BioPharma. The partnership with Zenas BioPharma represents a significant milestone in our journey, and we will continue to enhance and advance our globalization efforts in the future," said Dr. Jasmine Cui, Co-Founder, Chairwoman and CEO of InnoCare Pharma. "Orelabrutinib has a differentiated mechanism of action and strong clinical data underscoring its promising potential as a treatment for patients with progressive forms of MS. We are confident in Zenas' management team given their exceptional track record of successful drug development, global regulatory approvals and commercial launches, and their commitment to driving innovation for autoimmune diseases."

Mr. Moulder continued, "With this transaction, we have established a balanced portfolio of complementary mechanisms and modalities with best-in-class blockbuster potential across multiple therapeutic areas. With our two franchise programs, obexelimab concluding Phase 3 development for IgG4-RD, and now orelabrutinib for progressive forms of MS, Zenas is well positioned to meaningfully impact the lives of patients living with autoimmune diseases. We are prioritizing the tremendous opportunity ahead with orelabrutinib in PPMS and SPMS. We expect to report obexelimab topline 12-week primary endpoint results from the Phase 2 MoonStone trial in patients with RMS early in the fourth quarter of 2025 and 24-week data in the first quarter of 2026. We anticipate making a program decision based on these data and the evolving landscape for the development of new therapies for RMS in early 2026."

"This strategic collaboration will leverage our shared focus to accelerate the development of orelabrutinib and help maximize its clinical and commercial potential on a global scale, particularly in MS," added Dr. Cui, "Given the statistically significant and clinically meaningful data from the Phase 2 trial, and promising blood-brain barrier penetration capability, orelabrutinib has the potential to transform the treatment paradigm for this devastating disease. In addition to orelabrutinib, we have fortified our powerful discovery engine to focus on cutting-edge targets for the development of autoimmune therapeutics through B-cell and T-cell pathways, with the aim of delivering first-in-class and/or best-in-class treatments to address the massive unmet medical needs and strong market potential in China and worldwide."

"BTK inhibition is a validated mechanism for the treatment of progressive forms of MS, and there is immense scientific interest in its potential to impact inflammation compartmentalized in the CNS and thereby potentially impact disability progression independent of relapse activity. We believe the differentiated, potentially best-in-class profile of orelabrutinib could make a meaningful difference for patients with PPMS and SPMS, which have few treatment options. With our late-stage development capabilities and expertise in MS, we are well positioned to execute on the pivotal, global, Phase 3 development of orelabrutinib, as well as advance two early candidates into clinical development," said Lisa von Moltke, M.D., Head of Research and Development and Chief Medical Officer of Zenas.

Pipeline Overview

Obexelimab, a CD19 and FcγRIIb inhibitor of B cell function

- Immunoglobulin G4-Related Disease (IgG4-RD) Phase 3 INDIGO trial, a global registration-directed, multicenter, randomized, double-blind, placebo-controlled trial, to evaluate the efficacy and safety of obexelimab in patients with IgG4-RD. INDIGO is the largest clinical trial conducted in patients living with IgG4-RD to date. Target enrollment of the INDIGO trial concluded in November 2024, and Zenas expects to report topline results around year-end 2025.
- Relapsing Multiple Sclerosis (RMS) Phase 2 MoonStone trial, a multicenter, randomized, double-blind, placebo-controlled trial, to evaluate the efficacy and safety of obexelimab in patients with RMS. Zenas expects to report results from this trial, including the 12-week primary endpoint results, early in the fourth quarter of 2025.
- Systemic Lupus Erythematosus (SLE) Phase 2 SunStone trial, a multicenter, randomized, double-blind, placebo-controlled trial to evaluate the efficacy and safety of obexelimab in patients with SLE. Zenas expects to complete enrollment of the Phase 2 SunStone trial around year-end 2025 and report topline results in mid-2026.

Orelabrutinib, a highly selective CNS-penetrant, oral, small molecule BTK inhibitor

- PPMS Phase 3 trial, a global registration-directed, multicenter, randomized, double-blind, placebo-controlled trial, to evaluate the efficacy and safety of orelabrutinib for patients with PPMS initiated in the third quarter of 2025.
- SPMS Phase 3 trial, a global registration-directed, multicenter, randomized, double-blind, placebo-controlled trial, to evaluate the efficacy and safety of orelabrutinib for patients with SPMS is expected to initiate in the first quarter of 2026.

Oral, IL-17AA/AF inhibitor that blocks IL-17 AA homodimer and IL-17AF heterodimer signaling

- Currently in Investigational New Drug (IND) enabling studies. Zenas expects to submit an IND and initiate Phase 1 clinical development in 2026.

Oral, brain-penetrant, TYK2 inhibitor

- Currently in IND enabling studies. Zenas expects to submit an IND and initiate Phase 1 clinical development in 2026.

License Agreement
Under the license agreement, Zenas will pay InnoCare upfront and near-term milestone payments of up to $100 million in cash, including milestone achievements expected in 2026, and up to 7,000,000 shares of Zenas common stock, including shares issuable upon a milestone expected to be achieved in early 2026. The total of the upfront payment, near term milestone and potential development and regulatory milestone payments, along with potential commercial sales achievement milestone payments for all three programs, exceeds $2 billion.

In addition, InnoCare is entitled to receive tiered royalties of up to high teens percentages on annual net sales of the licensed products.

Zenas will have the exclusive right to develop, manufacture and commercialize orelabrutinib in the field of MS globally, and non-oncology fields in all territories outside Greater China and Southeast Asia, while InnoCare retains full global rights in the field of oncology. Zenas will also have the exclusive right to develop, manufacture and commercialize the oral, IL-17AA/AF inhibitor in all territories outside Greater China and Southeast Asia, and the oral, brain-penetrant, TYK2 inhibitor globally.

Private Placement Financing
Zenas has entered into a securities purchase agreement for a private placement financing of shares of its common stock (the "Private Placement"). The Private Placement is expected to result in gross proceeds to Zenas of approximately $120.0 million, before deducting placement agent fees and other Private Placement expenses payable by Zenas.

Pursuant to the terms of the securities purchase agreement, at the closing of the Private Placement, Zenas will issue approximately 6.3 million shares of its common stock to (i) certain institutional and accredited investors at a price of $19.00 per share and (ii) certain directors and officers of the Company at a price of $20.85 per share. The closing of the Private Placement is expected to occur on or about October 9, 2025, subject to the satisfaction of customary closing conditions.

Jefferies and Evercore ISI served as exclusive placement agents for the Private Placement.

The Private Placement included participation from a syndicate of new and existing investors, including mutual funds and healthcare dedicated funds.

Upon closing of the Private Placement, Zenas expects that its cash, cash equivalents and investments will be sufficient to fund its operating expenses and capital expenditure requirements into the fourth quarter of 2026, and assuming receipt of the potential $75 million milestone from Royalty Pharma for the defined success criteria in the Phase 3 INDIGO trial, into the first quarter of 2027.

The sale and issuance of the foregoing shares are being made in a transaction not involving a public offering and have not been registered under the Securities Act of 1933, as amended (the "Securities Act"). The shares being issued in the Private Placement may not be offered or sold in the United States absent registration or pursuant to an exemption from the registration requirements of the Securities Act and applicable state securities laws. Zenas has agreed to file a registration statement with the Securities and Exchange Commission covering the resale of the shares acquired by the investors in the Private Placement.

This press release does not constitute an offer to sell or the solicitation of an offer to buy the securities, nor shall there be any sale of the securities in any state in which such offer or sale would be unlawful prior to the registration or qualification under the securities laws of such state. Any offering of the shares under the resale registration statement will only be by means of a prospectus.

Conference Call Information
Zenas BioPharma will host a conference call and webcast today, October 8, 2025, at 8:00 a.m. ET to discuss the transformational license agreement and to provide an update on the Company's business and strategy. To access the live webcast of the call, please visit the " Events and Presentations" page in the Investor & Media Relations section of the Zenas BioPharma website. A replay of the webcast will be available following the call.

InnoCare will host a conference call at 8:30 a.m. Beijing time on October 9, 2025, in Chinese. To access the conference call, please register in advance through the link: https://s.comein.cn/fufgvbun.

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), InnoCare initiated a Phase 3 trial for Primary Progressive MS (PPMS) in the third quarter of 2025. A Phase 3 trial for Secondary Progressive MS (SPMS) is expected to initiate in the first quarter of 2026. The Phase 3 PPMS and SPMS trials have obtained U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA) alignment. Orelabrutinib is approved for B cell malignancies in mainland China and Singapore.

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 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 six clinical trials in a total of 208 patients who received obexelimab either as an intravenous infusion or as a subcutaneous injection. Obexelimab was well tolerated and demonstrated clinical activity across these clinical trials, providing the Company with an initial clinical proof of concept for obexelimab as a potent B cell inhibitor for the treatment of patients living with certain autoimmune diseases. Zenas is conducting a fully enrolled Phase 3 trial in Immunoglobulin G4-Related Disease and Phase 2 trials for Relapsing Multiple Sclerosis and Systemic Lupus Erythematosus.

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 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 Bruton's Tyrosine Kinase (BTK) inhibitor with the potential to address compartmentalized inflammation and disease progression in Multiple Sclerosis (MS). Zenas' earlier stage programs include a preclinical, potentially best-in-class, oral, IL-17AA/AF inhibitor, and a preclinical, potentially best-in-class, oral, brain-penetrant, TYK2 inhibitor.

About InnoCare Pharma
InnoCare (SSE: 688428; HKEX: 09969) is a commercial stage biopharmaceutical company committed to discovering, developing, and commercializing first-in-class and/or best-in-class drugs for the treatment of cancers and autoimmune diseases with unmet medical needs in China and worldwide. InnoCare has branches in Beijing, Nanjing, Shanghai, Guangzhou, Hong Kong, and the United States.

InnoCare has established a comprehensive platform with strong in-house innovation capabilities focused on liquid and solid cancers as well as autoimmune diseases. To date, the company has developed a robust product pipeline comprising two approved drugs, more than ten innovative drug candidates in clinical development, and multiple programs in preclinical and IND-enabling stages. For more information about InnoCare, please visit https://www.innocarepharma.com/en 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 milestones under the license agreement, timing of the initiation of, results and data from clinical trials, including timing of reporting topline results from the INDIGO trial, the timing of reporting the 12-week and 24-week topline results from the MoonStone trial, the timing of the completion of enrollment and reporting the topline results from the SunStone trial, the timing of initiation of the Phase 3 clinical trial of orelabrutinib in patients with SPMS, the timing to submit an IND, and subject to IND clearance, the initiation of Phase 1 clinical studies of two preclinical assets, the timing of initial patient data from the first preclinical asset; the potential benefits, development and commercialization of orelabrutinib and obexelimab and orelabrutinib's potential as a blockbuster franchise for progressive MS; expansion of the Zenas pipeline; the Company's cash runway; and the expected closing of the Private Placement. 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; 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 drug substance and drug product, WuXi Biologics (Hong Kong) Limited, which is located in China; the risk that the conditions to closing of the Private Placement are not satisfied; 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 June 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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InnoCare Pharma Forward-Looking Statements
This release contains certain forward-looking statements. All statements, other than statements of fact, could be considered forward-looking statements, meaning statements regarding actions, events, or developments that we or our management intend, expect, project, believe, or anticipate will or may occur in the future. These statements are based on assumptions and estimates made by our management in light of their experience and perception of historical trends, current conditions, expected future developments, and other relevant factors. Forward-looking statements are not guarantees of future performance, and actual results, developments, and business decisions may differ materially from those contemplated by these forward-looking statements. Our forward-looking statements are subject to a number of risks and uncertainties that could affect our near- and long-term performance.

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