Zymeworks Receives U.S. FDA Fast Track Designation for ZW191, an FRα-Targeting Antibody-Drug Conjugate

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- *U.S. FDA Fast Track designation granted to ZW191, an antibody-drug conjugate targeting folate receptor-α (FRα), for the treatment of patients with advanced or metastatic platinum-resistant ovarian cancer (PROC)*
- *Ongoing Phase 1 clinical trial of ZW191 enrolling patients with advanced solid tumors to evaluate safety, tolerability, pharmacokinetics, and preliminary anti-tumor activity*

VANCOUVER, British Columbia, March 30, 2026 (GLOBE NEWSWIRE) -- Zymeworks Inc. (Nasdaq: ZYME), a biotechnology company managing a portfolio of licensed healthcare assets, while developing a diverse pipeline of novel, multifunctional biotherapeutics, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to ZW191, an antibody-drug conjugate (ADC) targeting folate receptor-α (FRα), for the treatment of patients with advanced or metastatic platinum-resistant ovarian cancer (PROC).

ZW191 is an ADC engineered to target FRα, a protein expressed in several tumor types, including approximately 75% of high-grade serous ovarian carcinomas[1], over 50% of endometrial cancers,[2,3] and ~70% of lung adenocarcinomas[4]. ZW191's differentiated design strongly supports its ability to internalize into FRα-expressing cells with the potential to release bystander active topoisomerase-1 inhibitor (ZD06519), a novel proprietary payload developed by Zymeworks to kill tumor cells.

The FDA's Fast Track designation program is designed to expedite the development and review timelines of drugs that demonstrate the potential to treat serious conditions, aiming to deliver therapeutics to patients more quickly in areas of unmet need.

"Receiving Fast Track Designation for ZW191 highlights the potential of this program to address significant unmet medical needs for patients with previously treated advanced ovarian cancer. Notably, the designation was granted irrespective of FRα expression highlighting ZW191's potential of extending treatment benefits to a broad group of patients without need for biomarker selection," said Sabeen Mekan, M.D., Senior Vice President and Chief Medical Officer at Zymeworks. "This designation also further reinforces our expertise in ADC development, and we look forward to working closely with the FDA to advance this program for patients with difficult-to-treat cancers."

Zymeworks is currently evaluating ZW191 in a Phase 1 clinical study (NCT06555744) designed to assess safety, tolerability, pharmacokinetics, and preliminary anti-tumor activity in patients with advanced solid tumors. The study is designed to further characterize ZW191's clinical activity and safety to inform its future development strategy.

About Zymeworks Inc.

Zymeworks is a global biotechnology company managing a portfolio of licensed healthcare assets and developing a diverse pipeline of novel, multifunctional biotherapeutics to improve the standard of care for difficult-to-treat diseases, including cancer, inflammation, and autoimmune disease. Zymeworks' asset and royalty aggregation strategy focuses on optimizing positive future cash flows from an emerging portfolio of licensed products such as Ziihera® (zanidatamab-hrii) and other licensed products and product candidates, such as pasritamig. In addition, Zymeworks is also building a portfolio of healthcare assets that can generate strong cash flows, while supporting the development of innovative medicines. Zymeworks engineered and developed Ziihera, a HER2-targeted bispecific antibody using the Zymeworks' proprietary Azymetric™ technology and has entered into separate agreements with BeOne Medicines Ltd. (formerly BeiGene, Ltd.) and Jazz Pharmaceuticals Ireland Limited granting each exclusive rights to develop and commercialize zanidatamab in different territories. Zymeworks is rapidly advancing a robust pipeline of product candidates, leveraging its expertise in both antibody drug conjugates and multispecific antibody therapeutics targeting novel pathways in areas of significant unmet medical need. Zymeworks' complementary therapeutic platforms and fully integrated drug development engine provide the flexibility and compatibility to precisely engineer and develop highly differentiated antibody-based therapeutics. These capabilities have been further leveraged through strategic partnerships with global biopharmaceutical companies. For information about Zymeworks, visit www.zymeworks.com and follow @ZymeworksInc on X.

Cautionary Note Regarding Forward-Looking Statements

This press release includes "forward-looking statements" or information within the meaning of the applicable securities legislation, including Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements in this press release include, but are not limited to, statements that relate to Zymeworks' implementation of its long-term strategy to maximize value creation; Zymeworks' development of ZW191 and enrollment in clinical trials; the potential benefits of ZW191's fast track designation; potential safety profile and therapeutic effects of Zymeworks' product candidates; the timing of and results of interactions with regulators; and other information that is not historical information. When used herein, words such as "plan", "believe", "expect", "may", "continue", "anticipate", "potential", "will", "on track",

“progress”, “preserve”, “intend”, “could”, and similar expressions are intended to identify forward-looking statements. In addition, any statements or information that refer to expectations, beliefs, plans, projections, objectives, performance or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking. All forward-looking statements are based upon Zymeworks’ current expectations and various assumptions. Zymeworks believes there is a reasonable basis for its expectations and beliefs, but they are inherently uncertain. Zymeworks may not realize its expectations, and its beliefs may not prove correct. Actual results could differ materially from those described or implied by such forward-looking statements as a result of various factors, including, without limitation: any of Zymeworks’ or its partners’ product candidates may fail in development, may not receive required regulatory approvals, or may be delayed to a point where they are not commercially viable; regulatory agencies may impose additional requirements or delay the initiation of clinical trials; the impact of new or changing laws and regulations; potential negative impacts of FDA regulatory delays and uncertainty around recent policy developments, changes in the leadership of federal agencies such as the FDA, staff layoffs, budget cuts to agency programs and research, and changes in drug pricing controls; the impact of pandemics and other health crises on Zymeworks’ business, research and clinical development plans and timelines and results of operations, including impact on its clinical trial sites, collaborators, and contractors who act for or on Zymeworks’ behalf; zanidatamab may not be successfully commercialized; Zymeworks’ business strategy related to anticipated and potential future milestones and royalty streams and existing and potential new partnerships may not be successfully implemented; Zymeworks’ evolution of its business strategy may not deliver meaningful shareholder returns; ongoing and future clinical trials may not demonstrate safety and efficacy of any of Zymeworks’ or its collaborators’ product candidates; data providing early validation of our antibody drug conjugate platform and next generation pipeline programs may not be replicated in future studies; inability to maintain or enter into new partnerships or strategic collaborations; and the factors described under “Risk Factors” in Zymeworks’ quarterly and annual reports filed with the Securities and Exchange Commission (copies of which may be obtained at www.sec.gov and www.sedarplus.ca).

Although Zymeworks believes that such forward-looking statements are reasonable, there can be no assurance they will prove to be correct. Investors should not place undue reliance on forward-looking statements. The above assumptions, risks and uncertainties are not exhaustive. Forward-looking statements are made as of the date hereof and, except as may be required by law, Zymeworks undertakes no obligation to update, republish, or revise any forward-looking statements to reflect new information, future events or circumstances, or to reflect the occurrences of unanticipated events.

Contacts:

Investor Inquiries:
Shrinal Inamdar
Vice President, Investor Relations
(604) 678-1388
ir@zymeworks.com

Media Inquiries:
Diana Papove
Vice President, Corporate Communications
(604) 678-1388
media@zymeworks.com

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[2] May B, Conway N, Truong T, Linhart S, et al. FRα, B7-H4, & HER2 Expression in Endometrial Cancer: Assessing the Promise of Antibody Drug Conjugate Therapies. Presented at: SGO 2025 Winter Meeting; January 30 - February 1, 2025; Whistler, British Columbia, Canada.

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Source: Zymeworks Inc.