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Zymeworks Announces FDA Clearance of Investigational New Drug Application for ZW191, a Novel Folate Receptor- α Targeted Topoisomerase I Inhibitor Antibody-Drug Conjugate

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VANCOUVER, British Columbia, July 22, 2024 (GLOBE NEWSWIRE) -- Zymeworks Inc. (Nasdaq: ZYME), a clinical-stage biotechnology company developing a diverse pipeline of novel, multifunctional biotherapeutics to improve the standard of care for difficult-to-treat diseases, today announced that the United States Food and Drug Administration (FDA) has cleared the investigational new drug (IND) application for ZW191, the Company's novel folate receptor- α (FR α) targeted topoisomerase I inhibitor (TOPO1i) antibody-drug conjugate (ADC).

"ZW191 is a differentiated product candidate in our pipeline that reflects the strength of our approach in developing best-in-class antibody-drug conjugates," said Paul Moore, Chief Scientific Officer of Zymeworks. "Developed to target FR α , which is expressed in several types of difficult-to-treat cancers, ZW191 incorporates a novel antibody and drug-linker that provide a unique combination of antibody-linker stability and payload potency, together with strong bystander activity, which could result in improved efficacy and enable targeting lower levels of FR α compared to previously developed drug candidates. We are pleased to reach this R&D milestone following on the heels of our recent FDA clearance for ZW171 in June and look forward to initiating clinical development of both ZW191 and ZW171 during 2024."

ZW191 was designed using the Company's drug conjugate platforms, including the novel TOPO1i-based payload technology, ZD06519, to target FR α -expressing tumors including ovarian and other gynecological cancers, as well as non-small cell lung cancer (NSCLC). A drug-antibody-ratio (DAR) of eight was selected to balance both tolerability and efficacy. The FR α monoclonal antibody incorporated in ZW191 was generated in-house and selected based on enhanced internalization characteristics to enable targeting of high, mid, and low levels of FR α expression. FR α is a clinically validated target that is expressed in approximately 75% of ovarian carcinomas and 70% of NSCLC. ZW191 has demonstrated robust anti-tumor activity and a strong safety profile in preclinical models.

The Company expects to file applications seeking regulatory authorization to initiate clinical studies for ZW191 in non-US jurisdictions in the second half of 2024. ZW191 is the first of three ADC molecules incorporating the Company's proprietary ZD06519 payload designated for clinical development, with IND filings for ZW220 (NaPi2b ADC) and ZW251 (GPC3 ADC) on schedule for 2025.

About Zymeworks Inc.

Zymeworks is a global clinical-stage biotechnology company committed to the discovery, development, and commercialization of novel, multifunctional biotherapeutics. Zymeworks' mission is to make a meaningful difference in the lives of people impacted by difficult-to-treat cancers and other diseases. The Company's complementary therapeutic platforms and fully integrated drug development engine provide the flexibility and compatibility to precisely engineer and develop highly differentiated antibody-based therapeutic candidates. Zymeworks engineered and developed zanidatamab, a HER2-targeted bispecific antibody using the Company's proprietary Azymetric™ technology. Zymeworks has entered into separate agreements with BeiGene, Ltd. (BeiGene) and Jazz Pharmaceuticals Ireland Limited (Jazz), granting each exclusive rights to develop and commercialize zanidatamab in different territories. Zanidatamab is currently being evaluated in multiple global clinical trials as a potential best-in-class treatment for patients with HER2-expressing cancers. A Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) seeking accelerated approval for zanidatamab as a treatment for previously-treated, unresectable, locally advanced, or metastatic HER2-positive biliary tract cancer (BTC) has been accepted and granted Priority Review. A BLA has also been accepted for review by the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) in China. If approved, zanidatamab would be the first HER2-targeted treatment specifically approved for BTC in each of the U.S. and China. Zymeworks is rapidly advancing a deep pipeline of product candidates based on its experience and capabilities in both antibody-drug conjugates and multispecific antibody therapeutics across multiple novel targets in indications that represent areas of significant unmet medical need. In addition to Zymeworks' wholly owned pipeline, its therapeutic platforms have been further leveraged through strategic partnerships with global biopharmaceutical companies. For information about Zymeworks, visit www.zymeworks.com and follow [@ZymeworksInc](https://twitter.com/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 the potential addressable market of Zymeworks' product candidates; Zymeworks' development of its product candidates; the timing and status of ongoing and future studies and the related data; expectations and timing regarding future regulatory filings and approvals; the timing of and results of interactions with regulators; potential safety profile and therapeutic effects of zanidatamab and Zymeworks' other product candidates; the commercial potential of technology platforms and product candidates and other information that is not historical information. When used herein, words such as "plan", "believe", "expect", "may", "continue", "anticipate", "potential", "will", "progress", 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; Zymeworks may not achieve milestones or receive additional payments under its collaborations; regulatory agencies may impose additional requirements or delay the initiation of clinical trials; the impact of new or changing laws and regulations; market conditions; 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; clinical trials may not demonstrate safety and efficacy of any of Zymeworks' or its collaborators' product candidates; Zymeworks' assumptions and estimates regarding its financial condition, future financial performance and estimated cash runway may be incorrect; 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.sedar.com).

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.

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