Zymeworks Announces First Patient Dosed in Phase 1b/2 Trial of ZW25 in First-Line HER2-Positive Breast Cancer and Gastroesophageal Adenocarcinoma Conducted by BeiGene

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VANCOUVER--(BUSINESS WIRE)-- Zymeworks Inc. (NYSE: ZYME), a clinical-stage biopharmaceutical company developing multifunctional biotherapeutics, today announced that its partner, BeiGene, Ltd., has dosed the first patient in a two-arm Phase 1b/2 trial evaluating Zymeworks' HER2-targeted bispecific antibody ZW25 in combination with chemotherapy as a first-line treatment for patients with metastatic HER2-positive breast cancer and in combination with chemotherapy and BeiGene's PD-1-targeted antibody tislelizumab as a first-line treatment for patients with metastatic HER2-positive gastroesophageal adenocarcinoma (GEA). Zymeworks will receive a payment under its collaboration with BeiGene as a result of the achievement of this development milestone.

"To date, ZW25 has demonstrated promising activity in late-stage, treatment-refractory HER2 -expressing tumors. This new clinical trial provides a unique opportunity to evaluate the additional potential benefit of ZW25 in first-line metastatic breast tumors which have not developed resistance to multiple HER2-targeted therapeutics," said Diana Hausman, M.D., Chief Medical Officer at Zymeworks. "In addition, the GEA arm of this trial complements our ongoing Phase 2 trial of ZW25 plus chemotherapy in first-line GEA, and we are excited to examine possible synergies between ZW25 and BeiGene's PD-1 inhibitor tislelizumab. We look forward to the results of these trials, which have the potential to further expand the population of patients who may benefit from ZW25."

"Through this collaboration with Zymeworks, our broad development program for tislelizumab is expanding into HER2-expressing tumors as a potential first-line treatment," said Lai Wang, Ph.D., Senior Vice President, Head of Global Research and APAC Clinical Development at BeiGene. "ZW25 has demonstrated appealing clinical activity against HER2-positive tumors, and we are excited to gain additional understanding of its use as a monotherapy and in combinations as well."

This Phase 1b/2 clinical trial is a multicenter, open-label, two-arm study (NCT04276493). Arm one of the trial will evaluate the safety, tolerability, and preliminary antitumor activity of ZW25 in combination with docetaxel in patients with metastatic HER2-positive breast cancer. The second arm of the trial will evaluate the safety, tolerability, and preliminary antitumor activity of ZW25 in combination with tislelizumab and chemotherapy in patients with HER2-positive GEA, including gastric and gastroesophageal junction (GEJ) adenocarcinomas.

An ongoing Phase 1 trial is evaluating the safety and antitumor activity of ZW25 as a single agent and in combination with chemotherapy in HER2-expressing cancers that have progressed after prior standard of care treatments, including HER2-targeted agents (Phase 1: NCT02892123). ZW25 is also being evaluated in a Phase 2 trial in first-line HER2-positive GEA in combination with standard of care chemotherapy (Phase 2: NCT03929666) as well as in combination with the oral CDK4/6 inhibitor palbociclib (Ibrance®, Pfizer) and fulvestrant in advanced HER2-positive, HR-positive breast cancer (Phase 2: NCT04224272). Zymeworks, in collaboration with BeiGene, also plans to initiate registration-enabling studies of ZW25 in patients with previously treated HER2-positive biliary tract cancer and develop ZW25 as a potential first-line treatment for patients with HER2-positive GEA.

About ZW25

ZW25 is being evaluated in multiple Phase 1 and Phase 2 clinical trials globally. It is a bispecific antibody, based on Zymeworks' Azymetric™ platform, that can simultaneously bind two non-overlapping epitopes of HER2, known as biparatopic binding. This unique design results in multiple mechanisms of action including dual HER2 signal blockade, increased binding and removal of HER2 protein from the cell surface, and potent effector function leading to encouraging antitumor activity in patients. Zymeworks is developing ZW25 as a targeted treatment option for patients with solid tumors that express HER2. The FDA has granted two Fast Track Designations to ZW25, one as a single agent for refractory biliary tract cancer and one in combination with standard of care chemotherapy, for first-line GEA. ZW25 has also received Orphan Drug Designations for the treatment of biliary tract, gastric, and ovarian cancers.

About the Zymeworks-BeiGene Collaboration

In November 2018, Zymeworks and BeiGene entered into license and collaboration agreement in which BeiGene was granted an exclusive license for the research, development and commercialization of ZW25 and ZW49 in Asia (excluding Japan), Australia, and New Zealand. The companies are collaborating on joint global development for selected indications, with the goal of developing ZW25 and ZW49 worldwide across multiple HER2-expressing cancers and lines of therapy.

About Zymeworks Inc.

Zymeworks is a clinical-stage biopharmaceutical company dedicated to the development of next-generation multifunctional biotherapeutics. Zymeworks' suite of therapeutic platforms and its fully integrated drug development engine enable precise engineering of highly differentiated product candidates. Zymeworks' lead clinical candidate, ZW25, is a novel Azymetric™ bispecific antibody currently in Phase 2 clinical development. Zymeworks' second clinical candidate, ZW49, is a bispecific antibody-drug conjugate currently in Phase 1 clinical development and combines the unique design and antibody framework of ZW25 with Zymeworks' proprietary ZymeLink™ linker-cytotoxin. Zymeworks is also advancing a deep preclinical pipeline in oncology (including immuno-oncology agents) and other therapeutic areas. In addition, its therapeutic platforms are being leveraged through strategic partnerships with nine biopharmaceutical companies. For more information, visit www.zymeworks.com.

Cautionary Note Regarding Forward-Looking Statements

This press release includes “forward-looking statements” within the meaning of the U.S. Private Securities Litigation Reform Act of 1995 and “forward-looking information” within the meaning of Canadian securities laws, or collectively, forward-looking statements. Forward-looking statements in this press release include, but are not limited to, statements that relate to Zymeworks’ clinical and preclinical development of its product candidates, payment as a result of BeiGene’s achievement of a development milestone, and other information that is not historical information. When used herein, words such as “will”, “may”, “plan”, 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, market conditions and the factors described under “Risk Factors” in Zymeworks’ Annual Report on Form 10-K for its fiscal year ended December 31, 2019 (a copy of which may be obtained at www.sec.gov and www.sedar.com). Consequently, forward-looking statements should be regarded solely as Zymeworks’ current plans, estimates and beliefs. Investors should not place undue reliance on forward-looking statements. Zymeworks cannot guarantee future results, events, levels of activity, performance or achievements. Zymeworks does not undertake and specifically declines any 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, except as may be required by law.

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