Zymeworks Announces Expansion of Zanidatamab Pivotal Trial in Asia in Collaboration with BeiGene and Associated Milestone Payment

December 9, 2021

- *First patient dosed in South Korea under Zymeworks and BeiGene collaboration agreement*
- *HERIZON-GEA-01 enrollment progresses with multiple active sites and continued global recruitment*
- *Zymeworks to receive US$8MM development milestone payment from BeiGene*

VANCOUVER, British Columbia--(BUSINESS WIRE)--Dec. 9, 2021-- Zymeworks Inc. (NYSE: ZYME), a clinical-stage biopharmaceutical company developing multifunctional biotherapeutics, today announced that its collaborator, BeiGene, Ltd., has dosed the first patient in South Korea in the HERIZON-GEA-01 trial. As a result of this development milestone, Zymeworks will receive a US$8 million payment under its zanidatamab collaboration agreement with BeiGene.

Zymeworks and BeiGene continue to work to expedite the opening of approximately 300 clinical trial sites across 38 countries in support of the global Phase 3 pivotal trial. With a 24-month projected enrollment period, this study may enable the submission of a supplemental Biologics License Application by Zymeworks in the United States as early as 2024.

About the HERIZON-GEA-01 Clinical Trial

HERIZON-GEA-01 is a global, randomized, Phase 3 clinical trial [NCT05152147] designed to evaluate the efficacy and safety of zanidatamab in combination with physician's choice chemotherapy [CAPOX (capecitabine/oxaliplatin) or FP (5FU/cisplatin)] with or without the PD-1 inhibitor, tislelizumab, compared to trastuzumab plus physician's choice chemotherapy for first-line treatment in subjects with advanced or metastatic HER2-positive gastroesophageal adenocarcinomas. Primary endpoints are progression-free survival per RECIST 1.1 criteria, as assessed by blinded independent central review, and overall survival. The trial is expected to enroll approximately 700 patients at approximately 300 sites across 38 countries. Zymeworks' collaborator, BeiGene, will oversee trial sites in Asia (excluding Japan), Australia and New Zealand, and Zymeworks will oversee trial sites in the rest of the world, including North and South America, Japan, Europe, Middle East and Africa.

About the Zymeworks-BeiGene Collaboration

In November 2018, Zymeworks and BeiGene entered into license and collaboration agreements in which BeiGene was granted an exclusive license for the research, development, and commercialization of zanidatamab 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 zanidatamab and ZW49 worldwide across multiple HER2-expressing cancers and lines of therapy.

About Zanidatamab

Zanidatamab is a bispecific antibody, based on Zymeworks' Azymetric™ platform, that can simultaneously bind two non-overlapping epitopes of HER2, known as biparatopic binding. Zanidatamab's unique binding properties result in multiple mechanisms of action including HER2-receptor clustering, internalization, and downregulation; inhibition of growth factor-dependent and -independent tumor cell proliferation; antibody-dependent cellular cytotoxicity and phagocytosis; and complement-dependent cytotoxicity. Zanidatamab is currently being evaluated in two pivotal clinical trials, one for the first-line treatment of advanced or metastatic HER2-positive gastroesophageal adenocarcinoma (HERIZON-GEA-01) and one for previously treated HER2-amplified biliary tract cancer (HERIZON-BTC-01). Zanidatamab is also being evaluated in several Phase 2 clinical trials for HER2-expressing gastroesophageal, colorectal, and breast cancers. The FDA has granted zanidatamab with Breakthrough Therapy designation for patients with previously treated HER2 gene-amplified biliary tract cancer, as well as two Fast Track designations, one as monotherapy for refractory biliary tract cancer and one in combination with standard of care chemotherapy for first-line gastroesophageal adenocarcinoma. These designations mean zanidatamab is eligible for Accelerated Approval, Priority Review and Rolling Review, as well as intensive FDA guidance on an efficient drug development program. Zanidatamab has also received Orphan Drug designations from the FDA as well as the European Medicines Agency for the treatment of biliary tract and gastric cancers.

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, zanidatamab, is a novel Azymetric™ HER2-targeted bispecific antibody currently being evaluated in multiple Phase 1, Phase 2, and pivotal clinical trials globally as a targeted treatment option for patients with solid tumors that express HER2. Zymeworks' second clinical candidate, ZW49, is a novel bispecific HER2 -targeted antibody-drug conjugate currently in Phase 1 clinical development and combines the unique design and antibody framework of zanidatamab with Zymeworks' proprietary ZymeLink™ linker and 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 additional information about Zymeworks, visit www.zymeworks.com and follow @ZymeworksInc on Twitter.

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’ expectations regarding: the receipt of a payment under its collaboration agreement with BeiGene; the projected enrollment period and number of patients, sites and countries for the HERIZON-GEA-01 trial; the potential submission of a supplemental Biologics License Application by Zymeworks in the United States; Zymeworks’ clinical development of its product candidates and related clinical trials; the potential therapeutic effects of zanidatamab;Zymeworks’ preclinical pipeline; and other information that is not historical information. When used herein, words such as “will”, “continue”, “may”, “expected”, “is eligible for” 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’ Quarterly Report on Form 10-Q for its quarter ended September 30, 2021 (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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Zymeworks Inc.

Investor Inquiries:
Ryan Dercho, Ph.D.
(604) 678-1388
ir@zymeworks.com

Jack Spinks
(604) 678-1388
ir@zymeworks.com

Media Inquiries:
Mary Klem
(604) 678-1388
media@zymeworks.com

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