Zymeworks Submits Investigational New Drug (IND) Application for ZW49 and Presents IND-Enabling Studies at the San Antonio Breast Cancer Symposium

December 8, 2018

- *ZW49 combines Azymetric™ and ZymeLink™ technologies to broaden the therapeutic window of antibody-drug conjugates (ADCs)*
- *Complete tumor regressions observed in high and low HER2-expressing models*
- *Superior preclinical efficacy compared to approved HER2 ADCs*
- *Toxicology results support clinical dosing well above predicted efficacy levels*
- *Potential to address unmet need in high and low HER2-expressing cancers, including brain metastases*

VANCOUVER, Canada--(BUSINESS WIRE)-- Zymeworks Inc. (NYSE/TSX: ZYME), a clinical-stage biopharmaceutical company developing multifunctional therapeutics, presented IND-enabling data for ZW49, a novel biparatopic HER2-targeted ADC, at the San Antonio Breast Cancer Symposium in San Antonio, TX.

“These data highlight the potential efficacy of ZW49 versus leading HER2 ADCs and demonstrate the power of combining our therapeutic platforms to achieve greater efficacy and tolerability, thereby increasing the therapeutic window,” said Ali Tehrani, Ph.D., President and CEO of Zymeworks. “With the recent submission of our IND for ZW49 we are pleased with the speed and trajectory of ZW49’s development and look forward to starting clinical trials in early 2019.”

ZW49 is a HER2-targeted bispecific ADC that capitalizes on the unique geometry and antibody framework of Zymeworks’ lead clinical candidate, ZW25, and is armed with the Company’s proprietary ZymeLink-cytotoxic payload. This design results in enhanced internalization and delivery of the cytotoxin to cancer cells. In preclinical studies, ZW49 demonstrated complete tumor regressions in a panel of high and low HER2-expressing patient derived xenografts and promising efficacy in a model of breast cancer brain metastases. These results compared favorably when benchmarked against approved and leading HER2 ADCs in clinical development. Importantly, efficacy was observed at exposures that were well tolerated in preclinical studies suggesting a broad therapeutic window.

The poster is available through the conference website or through Zymeworks’ website at http://ir.zymeworks.com/events-and-presentations.

About the Azymetric™ Platform

The Azymetric platform enables the transformation of monospecific antibodies into bispecific antibodies, giving the antibodies the ability to simultaneously bind two different targets. This unique technology enables the development of multifunctional biotherapeutics that can block multiple signaling pathways, recruit immune cells to tumors, enhance receptor clustering degradation, and increase tumor-specific targeting. These features are intended to enhance efficacy while reducing toxicities and the potential for drug resistance. Azymetric bispecifics have been engineered to retain the desirable drug-like qualities of naturally occurring antibodies, including low immunogenicity, long half-life and high stability. In addition, they are compatible with standard manufacturing processes with high yields and purity, potentially significantly reducing drug development costs and timelines.

About the ZymeLink™ Platform

The ZymeLink platform is a modular suite of site-specific conjugation technologies, customizable linkers, and proprietary cytotoxic payloads designed for the targeted delivery of therapeutics with optimal tolerability and efficacy. The ZymeLink platform is compatible with traditional antibodies and with the Azymetric platform and is intended to facilitate the development of next-generation antibody-drug conjugates with broad therapeutic windows.

About Zymeworks Inc.

Zymeworks is a clinical-stage biopharmaceutical company dedicated to the discovery, development, and commercialization of next-generation multifunctional biotherapeutics. Zymeworks’ suite of complementary therapeutic platforms and its fully-integrated drug development engine provide the flexibility and compatibility to precisely engineer and develop highly-differentiated product candidates. Zymeworks’ lead product candidate, ZW25, is a novel bispecific antibody currently being evaluated in an adaptive Phase 1 clinical trial. An Investigational New Drug (IND) application was recently submitted to the Food and Drug Administration (FDA) for its second product candidate, ZW49, a novel bispecific antibody drug conjugate (ADC). Zymeworks is also advancing a deep pipeline of preclinical product candidates and discovery-stage programs in immuno-oncology and other therapeutic areas. In addition to Zymeworks’ wholly-owned pipeline, its therapeutic platforms have been further leveraged through multiple strategic partnerships with global biopharmaceutical companies.

Cautionary Note Regarding Zymeworks’ 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 news release include statements that relate to ZW49 and its potential as an anti-cancer treatment, Zymeworks’ clinical plans and future results including the anticipated timing of clinical trials for ZW49, Zymeworks’ technology platform, and other information that is not historical information. When used herein, words such as “believe”, “may”, “plan”, “will”, “estimate”, “continue”, “anticipate”, “intend”, “expect”, 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 fiscal quarter ended September 30, 2018 (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. You 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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Source: Zymeworks Inc.