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Zymeworks Highlights 2019 Achievements and Announces Corporate Priorities

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VANCOUVER, British Columbia--(BUSINESS WIRE)-- Zymeworks Inc. (NYSE: ZYME), a clinical-stage biopharmaceutical company developing multifunctional biotherapeutics, today highlighted its key accomplishments in 2019 and updated its corporate priorities. Zymeworks also announced multiple clinical program advances for its lead candidates, ZW25 and ZW49.

Recent ZW25 and ZW49 Program Advances

- Zymeworks initiated a Phase 2 clinical trial evaluating ZW25 in combination with Ibrance® (palbociclib), an oral CDK4/6 inhibitor, and the hormone therapy fulvestrant with the goal of providing a chemotherapy-free treatment option to people with advanced HER2-positive, hormone receptor-positive breast cancer. Zymeworks entered into a clinical collaboration with Pfizer to advance the study.
- ZW25 achieved two additional regulatory milestones, recently being granted Fast Track and Orphan Drug Designations by the FDA in refractory biliary tract cancer (BTC). These were ZW25's second Fast Track and third Orphan Drug Designations. ZW25 already holds a Fast Track Designation for 1st line gastroesophageal adenocarcinoma (GEA) and Orphan Drug Designations for GEA and ovarian cancer.
- An interim update from the ongoing ZW49 Phase 1 dose-escalation study highlighted that there have been no dose-limiting toxicities observed and the maximum tolerated dose has not been reached. With over ten patients treated, the majority of treatment-related adverse events have been grade 1 or 2, and were reversible and manageable on an outpatient basis. Importantly, preliminary results from these initial dose cohorts include anti-tumor activity.

"Our significant achievements in 2019 demonstrate that we are executing on our vision to establish ZW25 as the foundational HER2 therapy across the spectrum of HER2-expressing cancers and lines of therapy," said Ali Tehrani, Ph.D., President and CEO at Zymeworks. "As our second therapeutic candidate, ZW49, continues to advance in the clinic, we are excited about its transformative potential for both patients with HER2-expressing cancers and for the development of future antibody-drug conjugate therapies. With a visionary leadership team, key hires company-wide, and a strong financial position, we are ready to deliver on our clinical programs and partnering priorities for 2020."

2019 Achievements

ZW25 Single Agent and Chemotherapy Combination Data Presented at Multiple Medical Meetings; Data Support Plans for Multiple Registration-Enabling Studies

- ZW25 demonstrated robust single agent anti-tumor activity and durable disease control across multiple HER2-expressing tumors that have progressed after standard-of-care (SOC) therapies, including HER2-targeted agents. These data support the initiation of a registration-enabling Phase 2 trial evaluating single agent ZW25 in refractory HER2-positive BTC followed by additional HER2-expressing tumor types.
- ZW25 plus chemotherapy showed durable anti-tumor activity for patients with heavily pretreated GEA, which supports the ongoing Phase 2 trial of ZW25 plus SOC chemotherapy and a planned registration-enabling trial in 1st line HER2-positive GEA vs Herceptin plus SOC chemotherapy.

ZW49 Enters Phase 1 Clinical Testing for HER2-Expressing Cancers

- ZW49 is a HER2-targeted bispecific antibody-drug conjugate (ADC) that capitalizes on the unique geometry and antibody framework of ZW25, and is armed with Zymeworks' proprietary ZymeLink™ cytotoxin. This design results in enhanced internalization and delivery of the cytotoxin to cancer cells. ZW49 is being evaluated in an ongoing Phase 1 clinical trial.

Partnerships Continue to Advance; Milestone Payments Received

- Zymeworks' pharmaceutical partner Lilly entered the clinic with a novel bispecific, Merck, Celgene, and Daiichi Sankyo advanced bispecific candidates toward clinical testing, GSK expanded its Azymetric™ partnership, and the first ZymeLink

ADC collaboration was signed with Iconic Therapeutics. These events resulted in multiple milestone payments and increased future potential milestone payments and royalties for Zymeworks.

Expertise Added to Leadership Team

- Extensive development and commercial experience was added to the executive management team and board of directors. In addition, a Chief People Officer was hired to strategically manage the growth of Zymeworks' human resources.

Balance Sheet Strengthened

- During the year, Zymeworks completed a public financing raising US \$201.3 million, and added additional non-dilutive capital from multiple pharmaceutical partners.

Updated Corporate Priorities

- Initiate ZW25 registration-enabling studies in 2nd line HER2-positive BTC and 1st line HER2-positive GEA
- Report ZW49 Phase 1 dose-escalation data and initiate expansion cohorts
- Expand ZW25 clinical development into additional HER2-expressing cancers
- Report ZW25 Phase 2 chemotherapy combination data from 1st line HER2-positive GEA
- Continue building a strong preclinical pipeline through internal R&D and external partnerships

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™ cytotoxic payload. 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 news release include statements that relate to Zymeworks' vision to establish ZW25 as the foundational HER2 therapy, Phase 2 clinical trial evaluating ZW25 in combination with palbociclib and clinical collaboration with Pfizer, strategies for the development of ZW25 and ZW49, anticipated achievement of corporate priorities, and expected clinical results and preclinical data, as well as the nature and progress of Zymeworks' current and projected corporate partnerships and other information that is not historical information. When used herein, words such as "believe", "may", "plan", "estimate", "continue", "anticipate", "expect", "goal", "vision", "potential", 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, including assumptions regarding anticipated reporting of additional clinical and preclinical data, the efficacy of ZW25, ZW49, and Zymeworks' therapeutic platforms, and Zymeworks' ability to enter into new partnership arrangements. 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, 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. 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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Investor Inquiries:
Ryan Dercho, Ph.D.
(604) 678-1388
[\[email protected\]](#)

Tiffany Tolmie
(604) 678-1388
[\[email protected\]](#)

Media Inquiries:
Kavita Shah, Ph.D.
(604) 678-1388
[\[email protected\]](#)

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