Zymeworks Highlights 2020 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 2020 and updated its corporate priorities.

“2020 was a leap forward for our lead clinical program in terms of a potential first approval and future approvals,” said Ali Tehrani, Ph.D., President and CEO at Zymeworks. “The launch of our first pivotal trial and achievement of Breakthrough Therapy designation for zanidatamab mark important milestones towards our accelerated commercialization strategy, and our new clinical partnerships further strengthen zanidatamab’s broad therapeutic profile. 2021 promises to be a data-rich year for both zanidatamab and ZW49 as we continue to demonstrate their potential to become foundational therapies in the treatment of HER2-expressing cancers.”

2020 Achievements

Zanidatamab Enters Late-Stage Clinical Development with Accelerated Strategy

- Zymeworks initiated a global pivotal trial (HERIZON-BTC-01) for zanidatamab monotherapy in patients with previously treated HER2 gene-amplified biliary tract cancer (BTC). This single arm trial is designed to support accelerated approval based on a primary endpoint of objective response rate and may enable submission of a Biologics License Application (BLA) as early as 2022.
- Zanidatamab received additional drug review special designations in the U.S. and the European Union. The U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy designation for BTC and the European Commission (EC) granted Orphan Drug designation for gastroesophageal adenocarcinoma (GEA), expediting potential commercialization. Previously the FDA granted two Fast Track designations to zanidatamab, in BTC and GEA, in addition to Orphan Drug designations for BTC, GEA, and ovarian cancer.

Zanidatamab Data and Partnerships Continue to Support Broad Therapeutic Potential

- **Gastric Cancer:** Clinical data from patients with refractory GEA treated with zanidatamab monotherapy as well as zanidatamab in combination with chemotherapy were updated and support plans to launch a second pivotal trial as 1st line treatment for advanced HER2-positive GEA in mid-2021 with partner BeiGene. These data will be updated as part of an oral presentation at the upcoming American Society of Clinical Oncology (ASCO) Gastrointestinal Cancers Symposium, January 15, 2021.
- **Breast Cancer:** Clinical collaborations were initiated to evaluate zanidatamab in combination with a CD47 blocker (ALX Oncology’s ALX148) in patients with advanced HER2-expressing breast cancer and with a CDK4/6 inhibitor (Pfizer’s Ibrance) in patients with HER2-positive, HR-positive breast cancer.
- **Endometrial Cancer:** Zymeworks’ first investigator-led trial was initiated by Dr. Vicky Makker at Memorial Sloan Kettering Cancer Center. The Phase 2 trial will evaluate zanidatamab monotherapy in HER2-overexpressed advanced endometrial cancers and carcinosarcomas.

Clinical Advancement of HER2 Bispecific ADC, ZW49, for HER2 Expressing Cancers

- ZW49 is being evaluated in a Phase 1 clinical trial as a treatment for patients with locally advanced or metastatic HER2-expressing cancers that have progressed following treatment with existing approved therapies, including HER2-targeted agents. Clinical studies continued in 2020 with dose escalation to determine the safety and efficacy profile of ZW49. Zymeworks will be providing a clinical progress update for ZW49 by webcast on Wednesday, January 27, 2021 at 4:30 pm ET.

Commercial, Clinical and Scientific Competencies Added to Leadership Team

- Zymeworks welcomed key commercial, scientific and clinical development talent to the leadership team with the additions of Guowei Fang, Ph.D., as Senior Vice President, Research, James Priour as Senior Vice President, Commercial, Manny Duenas as Vice President, Global Value and Access, and Pamela Farmer, MD, as Vice President, Global Patient Safety.

Partnerships Advance: Milestone Payments Received and Deal Values Increase

- Our partnerships continued to advance in 2020 with Iconic/Exelixis achieving a milestone for ZymeLink™ together with new and expanded Azymetric™ and EFECT™ collaborations with Merck and BMS. Zymeworks has nine active collaborations

that could result in up to US$8.6 billion in potential milestone payments in addition to royalties on potential product sales.

Balance Sheet Strengthened and Cash Runway Extended

- In early 2020, Zymeworks completed an oversubscribed public financing raising US$320.8 million, extending its runway into 2022 and potentially beyond. The Company also received non-dilutive capital from several of its pharmaceutical partners.

Updated Corporate Priorities

- Complete enrolment of zanidatamab pivotal trial in HER2+ biliary tract cancer
- Launch pivotal trial in 1st line HER2+ GEA and present supporting Phase 2 clinical data
- Present data to support zanidatamab breast cancer development strategy
- Advance ZW49 into and complete cohort expansion
- Present data from new therapeutic programs and technology platforms

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 (ZW25), is a novel Azymetric™ bispecific antibody which has been granted Breakthrough Therapy designation by the FDA and is currently enrolling in a pivotal clinical trial for refractory HER2+ biliary tract cancer (HERIZON-BTC-01) as well as several Phase 2 clinical trials for HER2+ gastroesophageal and breast cancers. 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 zanidatamab 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 additional information about Zymeworks, visit www.zymeworks.com and follow @ZymeworksInc on Twitter.

Zymeworks 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 Zymeworks' global pivotal trial for zanidatamab in BTC (including the potential submission of a BLA), commercialization strategy, anticipated updates for zanidatamab and ZW49 and their potential to become foundational therapies in the treatment of HER2-expressing cancers, plans to launch a second pivotal trial with BeiGene, potential milestone payments and royalties on potential product sales, anticipated cash runway, and other information that is not historical information. When used herein, words such as "may", "will", "plan", "continue", "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, 2020 (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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