Zymeworks Inc.

Fact Sheet

ZYME

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ZYMEWORKS

QUICK REFERENCE

Zymeworks, Inc.
NYSE: ZYME
Outstanding Shares: **50,903,633**
Website: **www.ZYMEWORKS.com**

BUSINESS SUMMARY

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™ bispecific antibody currently which has been granted Breakthrough Therapy designation by the FDA and is in a registration-enabling clinical trial for refractory HER2-positive biliary tract cancer as well as several Phase 2 clinical trials for HER2-positive 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.

TECHNOLOGY

- Azymetric™ is the best-in-class platform for therapeutic antibodies that can simultaneously bind to multiple distinct locations on a target or to multiple targets, resulting in unique mechanisms of action not accessible through typical monospecific antibodies. Azymetric™ bispecific antibodies can block multiple signaling pathways, recruit immune cells to tumors, enhance receptor clustering and internalization, and increase tumor-specific targeting.

- ZymeLink™, a next-generation antibody drug conjugate (ADC) platform, is a suite of proprietary cytotoxins (cell-killing compounds), stable linkers, and conjugation technologies. ZymeLink™ is compatible with traditional antibodies, proteins, and the Azymetric™ bispecific antibody platform, creating multifunctional therapeutics designed to overcome the limitations of existing ADCs.

- The EFECT™ (Effector Function Enhancement and Control Technology's) library includes proprietary mutations to the CH2 domain of the antibody's Fc region to selectively modulate an antibody's interactions with the Fc-gamma receptors (FcgR) expressed on the surface of immune cells and with a component of the complement pathway (i.e. C1q).

CONTACT INFORMATION

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Recent Press Releases *(Headlines and Excerpts)*

Zymeworks Announces Expansion of Zanidatamab Pivotal Trial in HER2-Amplified Biliary Tract Cancer in Asia in Collaboration With BeiGene

Zymeworks to receive US$10 million milestone payment from BeiGene

Multiple sites active and recruiting globally in North America, Europe, and Asia

Dec 1, 2020 -- Zymeworks Inc. announced that its partner, BeiGene, Ltd., has dosed the first patient in South Korea in a pivotal, single-arm clinical trial of zanidatamab (formerly ZW25) monotherapy in patients with advanced or metastatic HER2-amplified biliary tract cancer (BTC). Zymeworks will receive a US$10 million payment under its collaboration with BeiGene as a result of the achievement of this development milestone.

Zymeworks and BeiGene are progressing the opening of multiple clinical trial sites in support of the global registration-enabling Phase 2b clinical trial of zanidatamab in patients with HER2-amplified BTC. In the Asia region, multiple sites are open for enrollment in South Korea, and in China all sites have been selected with enrollment anticipated to begin in the first quarter of 2021.

Zymeworks Receives FDA Breakthrough Therapy Designation for HER2-Targeted Bispecific Antibody Zanidatamab in Patients with Biliary Tract Cancer

Nov 30, 2020 -- Zymeworks Inc. announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation for zanidatamab in patients with previously-treated HER2 gene-amplified biliary tract cancer (BTC).

The FDA grants Breakthrough Therapy designation to new medicines that are intended to treat a serious condition and where clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint. Zanidatamab will now be eligible for Accelerated Approval, Priority Review and Rolling Review, as well as intensive FDA guidance on an efficient drug development program.

Zymeworks Receives Orphan Drug Designation From the European Commission for HER2-Targeted Bispecific Antibody Zanidatamab in Patients With Gastric Cancer

Nov 19, 2020 -- Zymeworks Inc. announced that the European Commission (EC) has granted Orphan Drug designation for zanidatamab, the company's investigational HER2-targeted bispecific antibody, in patients with gastric cancer.

The EC grants Orphan Drug designation to therapies that represent a significant benefit over existing treatments, are intended for the treatment, prevention or diagnosis of a life-threatening or chronically debilitating disease, and where prevalence of the condition in the European Union (EU) is less than 5 in 10,000 persons. Orphan drug designation gives companies certain benefits, including 10 years of market exclusivity following regulatory approval, reduced regulatory fees, clinical protocol assistance, and access to research grants.

Zymeworks and ALX Oncology Announce Clinical Collaboration Evaluating Zanidatamab with the CD47 Blocker ALX148 in Patients with Advanced HER2-Expressing Breast Cancer

Nov 16, 2020 -- Zymeworks Inc. (NYSE: ZYME), a clinical-stage biopharmaceutical company developing multifunctional biotherapeutics, and ALX Oncology Holdings Inc. (NASDAQ: ALXO), a clinical-stage immuno-oncology company developing therapies that block the CD47 checkpoint pathway, today announced they have entered into a clinical collaboration to evaluate the combination of Zymeworks' zanidatamab (formerly ZW25), a HER2-targeted bispecific antibody, and ALX148, a next-generation CD47 blocker, for the treatment of patients with advanced HER2-expressing breast cancer and other solid tumors.

Under the terms of the agreement, Zymeworks will conduct an open label, multi-center Phase 1b study to assess the safety and efficacy of the combination of zanidatamab and ALX148 in a two-part study. The first part of the trial will evaluate the safety of the combination treatment. The second part of the trial will evaluate the safety, tolerability and anti-tumor activity of the combination in separate cohorts of subjects with HER2-positive breast cancer, HER2-low breast cancer, and non-breast HER2-expressing solid tumors.

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