



zymeworks

Zymeworks Receives Second Orphan Drug Designation for ZW25 in Gastric Cancer

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VANCOUVER, Canada--(BUSINESS WIRE)-- Zymeworks Inc. ("Zymeworks"), a clinical-stage biopharmaceutical company dedicated to the discovery, development and commercialization of next-generation multifunctional biotherapeutics, initially focused on the treatment of cancer, today announced that its lead product candidate, ZW25, has been granted orphan drug designation from the U.S. Food and Drug Administration (the "FDA") in the treatment of gastric cancer, including cancer of the gastroesophageal junction ("GEJ").

"Gastric Cancer represents ZW25's second orphan drug designation, in addition to ovarian cancer, which was granted last year," said Ali Tehrani, Ph.D., Zymeworks' President & CEO. "Gastric cancer is the fifth most common cancer in the world, and we believe ZW25 has the potential to address the significant unmet medical need that exists for patients with this disease."

Dr. Diana Hausman, Zymeworks' Chief Medical Officer, added, "ZW25 demonstrated encouraging anti-tumor activity in preclinical models of gastric cancer. We are excited about the opportunity to advance the development of ZW25, which is currently being evaluated in a first in human Phase 1 clinical trial in the US in patients with advanced HER2 expressing cancers, including gastric/GEJ tumors."

The FDA grants orphan drug designation to biological products that are intended to treat a rare disease or condition, which is generally defined as affecting a patient population of fewer than 200,000 people in the United States. Orphan drug designation provides the sponsor certain financial incentives, including tax credits, the waiver of associated application fees, and a period of marketing exclusivity if the product candidate receives the first marketing approval for the indication for which it has such designation.

About ZW25

ZW25 is Zymeworks' lead product candidate currently being evaluated in an adaptive Phase 1 clinical trial in the United States, based on our Azymetric platform. It is a bispecific antibody that can simultaneously bind two non-overlapping epitopes, known as biparatopic binding, of HER2 resulting in dual HER2 signal blockade, increased binding and removal of HER2 protein from the cell surface, and enhanced effector function. These combined mechanisms of action have led to significant anti-tumor activity in preclinical models. We are developing ZW25 as a best-in-class HER2-targeting antibody intended as a treatment option for patients with any solid tumor that expresses HER2.

About Zymeworks Inc.

Zymeworks is a clinical-stage biopharmaceutical company dedicated to the discovery, development and commercialization of next-generation multifunctional biotherapeutics, initially focused on the treatment of cancer. 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. 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.



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