



zymeworks

Zymeworks Receives FDA Acceptance of IND Application for ZW25, a Novel Bi-Specific Antibody, for the Treatment of HER2-Expressing Cancers

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VANCOUVER, British Columbia--(BUSINESS WIRE)-- Zymeworks Inc., a biopharmaceutical company discovering and developing innovative multi-functional protein-based therapeutics, including bi-specific antibodies and drug conjugates, for the treatment of cancer, announced today that the United States Food and Drug Administration (FDA) has accepted the Company's Investigational New Drug (IND) application for ZW25 for the treatment of certain HER2-expressing cancers. The Phase 1 clinical trial for ZW25 is anticipated to begin in late August of this year.

ZW25 is Zymeworks' lead therapeutics program. It is a novel bi-specific antibody, developed using the Company's industry-leading Azymetric™ platform, to target two different epitopes (bi-paratopic targeting) of the human epidermal growth factor receptor 2 (HER2) protein, which is over-expressed on the surface of many tumor types, including certain breast, gastric, lung, and ovarian cancers. ZW25 will be evaluated in the clinic for safety as well as efficacy in patients with tumors with low to moderate levels of HER2 expression. There are significant unmet medical needs for these patients as the current standard of care treatment approaches do not include HER2-targeted immunotherapies such as ZW25.

"We are proud and excited to advance ZW25 into clinical trials. We strongly believe ZW25 will address the needs of many HER2-expressing cancer patients, especially those who do not qualify for targeted HER2 therapies and other biologics," said Ali Tehrani, Ph.D., Zymeworks' President & CEO. "We remain committed to the research and development of protein based therapeutics to address unmet medical needs and that we believe will result in patients returning home to their loved ones, cancer free."

"We're pleased the FDA has cleared ZW25 for this first Phase 1 study in patients with locally advanced and/or metastatic HER2-expressing cancers and we look forward to initiating this clinical program in late August," said Diana Hausman, M.D., Zymeworks' Chief Medical Officer. "This is a significant milestone for Zymeworks and for the development of ZW25, and we are excited about its therapeutic potential in HER2-expressing cancers."

Previously, the FDA granted Orphan Drug Designation to Zymeworks' ZW25 for the treatment of ovarian cancer. Orphan designation qualifies Zymeworks for a number of development incentives, including tax credits for clinical testing and marketing exclusivity for a period of seven years if ZW25 is approved for this indication.

About ZW25

ZW25 is Zymeworks' lead therapeutics program based on the Azymetric™ platform. It is an engineered bi-specific antibody that targets two different epitopes (bi-paratopic targeting) of the HER2 protein and confers its efficacy via multiple mechanisms of action, including: (i) enhanced antibody-mediated effector function resulting from the increased decoration of the tumor cell surface; (ii) increased blockade of the HER2 cellular growth signal by the dual engagement of HER2 epitopes; and (iii) increased removal of surface-expressed HER2 protein due to enhanced HER2 internalization upon antibody engagement. ZW25 as a best-in-class HER2-targeting antibody for a variety of tumors characterized by HER2 overexpression, including breast, gastric, ovarian, colorectal and non-small cell lung cancers.

About Azymetric™ Platform

Bi-specific antibodies developed using the Azymetric™ platform resemble conventional mono-specific antibodies while being able to simultaneously bind to two different targets resulting in additive or synergistic therapeutic responses. Azymetric™ antibodies spontaneously assemble into a single molecule with two different Fab domains comprising of unique heavy and light chain pairings. Azymetric™ antibodies are manufactured using conventional monoclonal antibody processes and can be easily adapted to rapidly screen target and sequence combinations for bi-specific activity in the final therapeutic format, thereby significantly reducing drug development timelines.

About Zymeworks Inc.

Zymeworks is a privately held biotherapeutics company that is developing best-in-class Azymetric™ bi-specific antibodies and antibody drug conjugates for the treatment of cancer, autoimmune and inflammatory diseases. The company's novel Azymetric™, AlbuCORE™, and EFECT™ platforms, its Zymelink™ conjugation platform and cytotoxins, and its proprietary ZymeCAD™ structure-guided protein engineering technology, enable the development of highly potent bi-specific antibodies, multivalent protein therapeutics, and antibody drug conjugates across a range of indications. Zymeworks is focused on accelerating its biotherapeutics pipeline through in-house research and development programs and strategic collaborations. More information on Zymeworks can be found at www.zymeworks.com.



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