



zymeworks

Zymeworks' ZW25 and ZW33 Granted Orphan Drug Designation for Ovarian Cancer by U.S. Food and Drug Administration

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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 granted Orphan Drug Designation to Zymeworks' lead investigational products ZW25 and ZW33 for the treatment of ovarian cancer. Orphan drug 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 or ZW33 is approved for this indication.

ZW25 is Zymeworks' lead therapeutics program and is due to begin Phase 1 clinical development in the U.S. in late August. 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 a subset of breast, gastric, lung, and ovarian cancers. ZW33 is a drug-conjugated version of ZW25 currently in development in preparation for an IND filing in early 2017.

"We are very excited with the potential of our novel engineered bispecific antibody ZW25 and its drug conjugate ZW33, as new treatment options for patients with ovarian cancer," said Gordon Ng, Ph.D., Chief Scientific Officer of Zymeworks. "We believe ZW25's and ZW33's multiple differentiated mechanisms of action can be significantly more efficacious than current HER2-directed treatments for HER2 expressing cancers and can enhance the range of current treatments available to these patients."

"We're pleased that the FDA has recognized the significant need for new and better therapies for women with ovarian cancer, which remains the leading cause of death due to gynecological malignancies," said Diana Hausman, M.D., Chief Medical Officer of Zymeworks. "The granted orphan drug designations underscore the potential of both ZW25 and ZW33 in addressing this important unmet medical need. We are looking forward to initiating clinical development for this indication in the very near future."

Each year, more than 22,000 women in the U.S. are diagnosed with ovarian cancer and it is responsible for more than 14,000 deaths. There are currently no HER2-targeted treatments approved for ovarian cancer and poses a significant unmet medical need for patients.

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 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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