Anti-erbB-2 (Her-2/neu) (Margetuximab)

IVMB0478

Product Information

Product SKU:	IVMB0478	**Clone**:	MGAH22	**Target**:	erbB-2
Size:	100 mg, 5.0 mg, 25 mg, 50 mg, 1.0 mg			**Isotype**:	Human IgG1κ

Additional Information

Reactivity:	Human	**Host Species**:	Human
Antibody Type:	Biosimilar Recombinant Human Monoclonal Antibody	**Expression Host**:	HEK-293 Cells

Immunogen Information

Background:

erbB-2 encodes a member of the epidermal growth factor (EGF) receptor family of receptor tyrosine kinases[1]. erbB-2 enhances kinase-mediated activation of downstream signaling pathways by forming a heterodimer with other ligand-bound EGF receptor family members. Dysregulation of erbB-2 contributes to tumorigenesis in breast, ovarian, gastric, and other cancers.

Margetuximab is a human/mouse chimeric anti-erbB-2 monoclonal IgG1 antibody derived from mouse clone 4D5, the precursor of trastuzumab[2]. Margetuximab has an Fc domain (MGFc0264) engineered for increased binding to both alleles of human activating Fcγ receptor IIIA (CD16A) and for reduced binding to CD32B. Compared with WT Fc domain, the optimized MGFc0264 domain demonstrates increased affinity for both alleles of human CD16A as well as human C1q but decreased binding to human CD32B (inhibitory FcγR) and the 131R allele of CD32A (human activating FcγR). Binding to the 131H allele is not substantially modified. The optimized Fc domain also confers improved antibody-dependent cell cytotoxicity against erbB-2-positive tumor cells, including low ERBB2 expressors, independent of the FcγR variant for the effector cells.

The MGFc0264 Fc domain was generated by mutating five sites: L235V, F243L, R292P, Y300L, and P396L[2]. The L235V mutation was inserted to reduce CD32B binding. The Fc domain

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modifications do not influence antigen recognition or anti-proliferative activity in the absence of effector cells.

In clinical trials, Margetuximab binds to erbB-2 with high affinity and produces direct growth suppression of erbB-2-expressing tumor cell lines[3]. Positive data from clinical trials led to US Food and Drug Administration approval for Margetuximab in the treatment of metastatic HER2-positive breast cancer in 2020[4].

Endotoxin Level: < 1.0 EU/mg as determined by the LAL method

Applications: ELISA

Synonyms: Anti erbB-2, erbB2, HER2, CD340

Antigen Distribution: erbB-2 is an overexpressed cell-surface oncoprotein.

Immunogen: Human erbB2/EGFR2/CD340

Formulation: This biosimilar antibody is aseptically packaged and formulated in 0.01 M phosphate buffered saline (150 mM NaCl) PBS pH 7.2 - 7.4 with no carrier protein, potassium, calcium or preservatives added. Due to inherent biochemical properties of antibodies, certain products may be prone to precipitation over time. Precipitation may be removed by aseptic centrifugation and/or filtration.

Specificity: This non-therapeutic biosimilar antibody uses the same variable region sequence as the therapeutic antibody Margetuximab. This product is for research use only. Margetuximab activity is directed against Human erb-b2 receptor tyrosine kinase 2 (ERBB2; HER-2/neu).

Product Preparation: Recombinant biosimilar antibodies are manufactured in an animal free facility using onlyin vitroprotein free cell culture techniques and are purified by a multi-step process including the use of protein A or G to assure extremely low levels of endotoxins, leachable protein A or aggregates.

Storage & Handling: Functional grade biosimilar antibodies may be stored sterile as received at 2-8°C for up to one month. For longer term storage, aseptically aliquot in working volumes without diluting and store at -80°C. Avoid Repeated Freeze Thaw Cycles.