Leinco Technologies, Inc.
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Anti-Human CD38 (Isatuximab) [Clone SAR-650984]

Biosimilar Recombinant Human Monoclonal Antibody

Product Information

Product No.:	C3140
Clone:	SAR-650984
Isotype:	Human Human IgG1κ

Product Description

Specificity:
This non-therapeutic biosimilar antibody uses the same variable region sequence as the therapeutic antibody Isatuximab. Isatuximab (SAR-650984) specifically targets a specific extracellular epitope (R45-I300) of CD38 (Met110 to Cys119).

Antigen Distribution:
CD38 is expressed on plasma cells, other lymphoid and myeloid cell populations, natural killer cells, B cells, activated T cells, some peripheral regulatory T cells, monocytes, lymph node germinal center lymphoblasts, intrafollicular cells, dendritic cells, erythrocytes, platelets, committed stem cells, Purkinje cells, neurofibrillary tangles in the brain, epithelial cells in the prostate, β-cells in the pancreas, retinal cells in the eye, and sarcolemma of smooth and striated muscle. CD38 can also be detected on early osteoclast progenitors but not on osteoblasts and mature osteoclasts. CD38 expression is very high and uniform on all malignant cells in multiple myeloma. While generally found on the plasma membrane, CD38 has also been detected in the cytosol or nucleus in the brain, pancreatic acinar cells, smooth muscle, and osteoclasts.

Background:
CD38 is a multifunctional cell surface protein with key roles in calcium signaling and nicotinamide adenine dinucleotide (NAD+) metabolism. It is expressed at low levels in various tissues but is highly expressed in plasma cells and plasma cell-derived neoplasms like multiple myeloma. CD38 has become an important therapeutic target, especially in multiple myeloma, where monoclonal antibodies such as daratumumab and isatuximab have shown significant efficacy. These antibodies work by inducing cell death through mechanisms like complement-dependent cytotoxicity and antibody-dependent cell-mediated cytotoxicity. Given its diverse functions, CD38 is also being explored as a therapeutic target in conditions beyond hematological malignancies, including autoimmune diseases and infections[1-3].

Isatuximab (SAR-650984) is an anti-CD38 monoclonal antibody that was generated by immunizing mice with 300-19 cells transfected to express the full-length human CD38 antigen followed by humanization by variable domain resurfacing[6]. It has demonstrated significant efficacy in treating multiple myeloma. It induces tumor cell death through antibody-dependent cellular cytotoxicity and complement-dependent cytotoxicity. Clinical trials have shown its effectiveness in improving rates of

minimal residual disease negativity in patients with newly diagnosed, transplantation-eligible multiple myeloma, as well as in those with relapsed or refractory disease. Isatuximab is generally well-tolerated, with the most common side effects being manageable infusion reactions[4,5].

Known Reactivity Species:
Human

Expression Host:
HEK-293 Cells

Format:
Purified No Carrier Protein

Immunogen:
Murine 300-19 cells transfected to express the full-length human CD38 antigen

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.

Purity
≥95% by SDS Page, ≥95% monomer by analytical SEC

Endotoxin
≤ 1.0 EU/mg as determined by the LAL method

Storage and Stability
Functional grade preclinical 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 ≤ -70°C. **Avoid Repeated Freeze Thaw Cycles.**

Product Preparation
Recombinant biosimilar antibodies are manufactured in an animal free facility using only *in vitro* protein 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.

Pathogen Testing
To protect mouse colonies from infection by pathogens and to assure that experimental preclinical data is not affected by such pathogens, all of Leinco's recombinant biosimilar antibodies are tested and guaranteed to be negative for all pathogens in the IDEXX IMPACT I Mouse Profile.
Other Applications Reported in Literature:

B,
FA,
FC

Country of Origin
USA

References
1. Morandi F, Airoldi I, Marimpietri D, Bracci C, Faini AC, Gramignoli R. Cells. 2019;8(12):1527.
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3. van de Donk NWCJ, Janmaat ML, Mutis T, et al. Immunol Rev. 2016;270(1):95-112.
4. Richardson PG, Beksaç M, Špička I, Mikhael J. Expert Opin Biol Ther. 2020;20(12):1395-1404.
5. Shen F, Shen W. Technol Cancer Res Treat. 2022;21:15330338221106563.
6. Deckert J, Wetzel MC, Bartle LM, et al. Clin Cancer Res. 2014 Sep 1;20(17):4574-83.

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