Leinco Technologies, Inc.
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Anti-Human IFNy (Emapalumab)

Biosimilar Recombinant Human Monoclonal Antibody

Product Information

Product No.:	LT2900
Clone:	NI-0501
Isotype:	Human Human IgG1 L2

Product Description

Specificity:
This non-therapeutic biosimilar antibody uses the same variable region sequence as the therapeutic antibody Emapalumab. This product is for research use only. Emapalumab activity is directed against human IFNγ.

Antigen Distribution:
IFNγ is produced by natural killer and natural killer T cells, T-helper 1 (Th1) CD4 + T cells, and CD8 + and cytotoxic T-lymphocytes.

Background:
IFNγ plays roles in Th1 differentiation, macrophage function, leukocyte migration to sites of infection, and increasing major histocompatibility complex expression to improve T-cell recognition of infected or malignant cells [1]. Hemophagocytic lymphohistiocytosis (HLH) is a rare but severe dysregulation of the immune system characterized by increased IFNγ production, macrophage and lymphocyte hyperactivity with tissue infiltration, hypersecretion of pro-inflammatory cytokines (CXCL9), hemophagocytosis, tissue damage, and multi-organ failure [2]. IFNγ plays a central role in the pathophysiology of HLH, and blocking IFNγ leads to clinical improvement.

Emapalumab was developed by Novimmune and Swedish Orphan Biovitrum as an immunotherapeutic treatment for HLH [2]. Emapalumab is a fully human IgG1 monoclonal antibody that targets and binds to IFNγ with high affinity. Emapalumab neutralizes IFNγ activity and inhibits interaction with its receptor by acting as a non-competitive inhibitor binding to free IFNγ and IFNγ-Receptor-1(IFNγR1)-bound IFNγ. Emapalumab inhibits receptor dimerization and transduction of interferon-γ signaling, impairing the interaction induced by IFNγ at the cell surface with IFNγR1 and IFNγ R2 and thereby neutralizing IFNγ biologic activity [2,3,4]. Emapalumab prevents recruitment of IFNγR2 but has no effect on IFNγR1 endocytosis and internalization into lysosomes [2,4]. In HLH patients, emapalumab reduces the plasma concentrations of the cytokine CXCL9.

Emapalumab is composed of anti-(human IFNγ) human monoclonal NI-0501 heavy chain, disulfide

with human monoclonal NI-0501 light chain, dimer [2]. Emapalumab is produced by recombinant DNA technology and is approximately 148 kDa [5].

Known Reactivity Species:
Human

Expression Host:
HEK-293 Cells

Format:
Purified No Carrier Protein

Immunogen:
Human IFNγ

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.
Other Applications Reported in Literature:

ELISA
WB
IP
FA
FC
N
IF Microscopy

Country of Origin
USA

References
1. Mah AY, Cooper MA. Crit Rev Immunol. 36(2):131-147. 2016.
2. Al-Salama ZT. Drugs. 79(1):99-103. 2019.
3. Locatelli F, Jordan MB, Allen C, et al. N Engl J Med. 382(19):1811-1822. 2020.
4. Hatterer E, Richard F, Malinge P, et al. Cytokine. 59(3):570. 2012.
5. https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/761107lbl.pdf

410 Axminister Dr, St. Louis, MO 63026 (800) 538-1145 leincoglobal@leinco.com