

Ontamalimab ELISA Kit

SKU: GXEL00208 | Assay: Quantitative ELISA (Colorimetric)

The Ontamalimab ELISA Kit (SKU: GXEL00208) is a high-sensitivity quantitative ELISA for the quantitative measurement of Ontamalimab in Plasma, Serum. The assay covers a detection range of 0.31-5 µg/mL with a sensitivity of 0.156 µg/ml and is read colorimetrically at 450 nm.

Background: Ontamalimab (SHP647) is a fully human, immunoglobulin G2 , antihuman mucosal addressin cell adhesion molecule-1 (MAdCAM-1) monoclonal antibody being developed for the treatment of ulcerative colitis (UC) and Crohn's disease (CD). A population pharmacokinetic/pharmacodynamic (PK/PD) analysis was conducted using clinical phase 2 study data to evaluate the PK and PD of ontamalimab following subcutaneous administrations of 7.5, 22.5, 75, and 225 mg every 4 weeks in patients with moderate to severe UC or CD. A total of 440 patients with UC (n = 249; 56.6%) or CD (n = 191; 43.4%) were included in the analysis. A 2-compartment model with parallel linear and nonlinear elimination adequately characterized concentration-time profiles of ontamalimab. The apparent clearance and volume of distribution were 0.0127 L/h (0.305 L/day) and 6.53 L, respectively. Apparent clearance and volume of distribution were mainly dependent on baseline albumin and body weight, respectively. No differences in the PK properties of ontamalimab were observed between patients with UC or CD. The presence of antidrug antibodies did not impact the PK of ontamalimab. Nonlinear elimination occurred at very low concentrations and was unlikely to contribute to the elimination half-life under steady-state conditions. A linear PK/PD model described the relationship between ontamalimab and free MAdCAM-1. Minimum concentrations of ontamalimab at steady state following 75 mg every 4 weeks were associated with >95% suppression of circulating free MAdCAM-1. The PK/PD properties characterized support phase 3 testing in UC and CD.

Specifications

Product Name	Ontamalimab ELISA Kit
SKU	GXEL00208
Accession	Q13477
Alternative Names	PF-00547659, PF-547659, SHP647, 2098790-40-8
Assay Type	Quantitative
Detection Method	Colorimetric
Sensitivity	0.156 µg/ml
Detection Range	0.31-5 µg/mL
Recovery	80-120%
Sample Types	Plasma, Serum
Storage	2-8°C. See Storage & Stability.
Note	For Research Use Only. Not for diagnostic procedures.

Storage & Stability

The stability of ELISA kit is determined by the loss rate of activity. The loss rate of this kit is less than 10% prior to the expiration date under appropriate storage condition. Store at 2-8°C on receipt; avoid repeated freeze-thaw cycles.

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