

Camrelizumab Biosimilar, PD-1 Monoclonal Antibody

Catalog No.: YR0095

Basic Information

Molecular Weight

150 kDa

Endotoxin

<1EU/mg (<0.001EU/μg) Determined by LAL gel clotting assay

Sterility

0.2 μm filtration

Aggregation

<5% Determined by SECP

Purity

>95% Determined by SDS-PAGE

Background

Camrelizumab Biosimilar uses the same protein sequences as the therapeutic antibody camrelizumab. Camrelizumab is an IgG4κ humanized monoclonal antibody being investigated for hepatocellular carcinoma. It targets programmed cell death protein 1 (PD-1), a protein on the surface of cells, also known as CD279 (cluster of differentiation 279). Camrelizumab is being evaluated in the Phase 2/3 (NCT02989922) of patients with advanced hepatocellular carcinoma (HCC) in second-line after failure or intolerance to prior systemic treatment. The study has 2 arms in which patients will be intravenous administered 3 mg/kg SHR-1210 on day 1 every 2 weeks or every 3 weeks. The primary outcome measures are the overall response rate (ORR) and overall survival (OS) rates at 6 months with duration of response and OS at 2 years as secondary endpoints. The estimated enrollment is 220 patients, and the estimated primary completion date is December 2018. A randomized, open-label Phase 3 study (NCT03099382) is evaluating the efficacy of camrelizumab treatment compared to standard-of-care treatment (docetaxel or irinotecan) in patients with esophageal carcinoma. Patients are randomly assigned to receive either SHR-1210 (200 mg every 2 weeks) or the standard of care (docetaxel 75 mg/m² on day 1 every 3 weeks or irinotecan 180 mg/m² on day 1 every 2 weeks). This Phase 3 study has an estimated enrollment of 438 and an estimated primary completion date of June 2018.

Reported Applications

ELISA, neutralization, functional assays such as bioanalytical PK and ADA assays, and those assays for studying biological pathways

Immunogen Information

Clone

Camrelizumab

Isotype

human IgG4 kappa

Immunogen

Human PD-1

Recommended Isotype Control(s)

In Vivo Grade Recombinant Human IgG4-S228P Kappa Isotype Control Antibody

Recommended Dilution Buffer

1×PBS pH 7.0

Contact

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Product Information

Production

Purified from cell culture supernatant in an animal-free facility

Purification

Protein A or G purification

Storage

2 - 8°C for up to 4 weeks and -80°C for long term storage (Avoid repeated freezing and thawing)