

Sutimlimab: Adis Evaluation

Key Points

- An IgG4 monoclonal antibody being developed by Sanofi for the treatment of CAD
- Received its first approval on 4 February 2022 in the USA
- Indicated to decrease the need for RBC transfusion due to haemolysis in adults with CAD

Summary

Sutimlimab (sutimlimab-jome; ENJAYMO™) is a humanized monoclonal antibody developed by Sanofi for the treatment of cold agglutinin disease (CAD).

Sutimlimab is an immunoglobulin G, subclass 4 (IgG4) monoclonal antibody that inhibits the classical complement pathway by binding to complement protein component 1, s subcomponent (C1s), a serine protease which cleaves C4 and C2 to form the C3 convertase. Inhibition of the classical complement pathway at the level of C1s prevents deposition of complement opsonins on the surface of red blood cell (RBCs), leading to inhibition of haemolysis in patients with CAD.

In February 2022, sutimlimab received its first approval in the USA to decrease the need for RBC transfusion due to haemolysis in adults with CAD. Sutimlimab is under regulatory review in Japan and the EU for CAD.

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