Media Update

CHMP recommends approval of Enjaymo™ (sutimlimab), first and only approved treatment for hemolytic anemia in adult patients with cold agglutinin disease

Paris, September 16, 2022. The European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion for Enjaymo™ (sutimlimab), recommending that the C1 protein (C1s) inhibitor be approved in the European Union (EU) for treatment of hemolytic anemia in adult patients with cold agglutinin disease (CAD). CAD is a rare, serious, and chronic autoimmune hemolytic anemia.

The positive CHMP opinion is based on data from two Phase 3 clinical trials: CADENZA, a double-blind, placebo-controlled clinical trial of adults with CAD without a recent history of blood transfusion (within the past 6 months), and CARDINAL, a 26-week open label, single-arm pivotal study in patients with CAD who have had a recent blood transfusion.

In the CADENZA trial, eligible patients were randomized 1:1 to receive a fixed weight-based dose (6.5g or 7.5g) of sutimlimab or placebo via intravenous infusion on Day 0, Day 7 and then once every other week up to Week 26. The positive results of the study were presented at the European Hematology Association (EHA) 2021 Congress. The open-label Part B of the study assessed long-term safety as well as durability of response to sutimlimab in patients with CAD.

In the CARDINAL trial, patients received a fixed weight-based dose (6.5g or 7.5g) of sutimlimab via intravenous infusion on Day 0, Day 7 and then once every other week up to Week 26. The positive results were presented at the Late-Breaking Abstracts Session of the 61st Annual Meeting of the American Society of Hematology in 2019. Part B of the study evaluated the long-term safety as well as durability of response to sutimlimab in patients with CAD over a 2-year follow up and the positive results were presented at EHA 2022.

The European Commission will review the CHMP recommendation, and Sanofi expects a decision by the end of 2022.

Enjaymo was approved by the U.S. Food and Drug Administration in February 2022 as the first and only treatment indicated to decrease the need for red blood cell transfusion due to hemolysis in adults with CAD.

About Enjaymo™ (sutimlimab)

Enjaymo is a humanized monoclonal antibody that is designed to selectively target and inhibit C1s in the classical complement pathway, which is part of the innate immune system. By blocking C1s, Enjaymo inhibits the activation of the complement cascade in the immune system and inhibits C1-activated hemolysis in CAD to prevent the abnormal destruction of healthy red blood cells. Enjaymo does not inhibit the lectin and alternative pathways.

About cold agglutinin disease

Cold agglutinin disease (CAD) is a rare type of autoimmune hemolytic anemia, where part of the body's immune system mistakenly destroys healthy red blood cells (hemolysis). CAD impacts the lives of an estimated 12,000 people in the U.S., Europe, and Japan and is associated with profound fatigue and increased risk of thromboembolic events and mortality.

About Sanofi

We are an innovative global healthcare company, driven by one purpose: we chase the miracles of science to improve people's lives. Our team, across some 100 countries, is dedicated to transforming the practice of medicine by working to turn the impossible into the possible. We provide potentially life-changing treatment options and life-saving vaccine protection to millions of people globally, while putting sustainability and social responsibility at the center of our ambitions.
Sanofi is listed on EURONEXT: SAN and NASDAQ: SNY

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