Press Release

European Commission approves Enjaymo® (sutimlimab) for treatment of hemolytic anemia in adult patients with cold agglutinin disease

- Enjaymo is the first-and-only approved therapeutic option approved for hemolytic anemia in adult patients with cold agglutinin disease

Paris, November 17, 2022. The European Commission (EC) has granted marketing authorization for Enjaymo® (sutimlimab) for the treatment of hemolytic anemia in adult patients with cold agglutinin disease (CAD), a rare, serious, and chronic autoimmune hemolytic anemia, where the body's immune system mistakenly attacks healthy red blood cells and causes their rupture, known as hemolysis.

> ***Dietmar Berger, MD, PhD***
> Chief Medical Officer, Global Head of Development at Sanofi
> *"This approval highlights our ambition to develop first- and best-in-class medicines that transform people's lives. Up until now, patients in Europe had to rely on a combination of cold avoidance, blood transfusions and off-label treatments to manage their disease. The approval of Enjaymo by the European Commission provides patients, for the first time, with access to a therapy that can make a meaningful difference in the treatment and daily experience of living with CAD."*

Enjaymo is currently the only approved treatment for CAD and is a first-in-class humanized monoclonal antibody that is designed to selectively target and inhibit the classical complement pathway specific serine protease, C1s. It will be available as a 50mg/mL solution for infusion.

> ***Alexander Röth, MD***
> Department of Hematology and Stem Cell Transplantation, University Hospital, University of Duisburg-Essen, Germany
> *"Coupled with diagnostic journeys that can last years, the impact of fatigue on quality of life in CAD is often debilitating and is comparable to conditions such as cancer-related anemia and other autoimmune disorders. Clinicians now have a much-needed therapeutic option to offer to their patients."*

About the CADENZA and CARDINAL Clinical Trials

The EC approval 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 Part A trial, eligible patients were randomized 1:1 to receive a fixed weight-based dose (6.5g or 7.5g) of Enjaymo or placebo via intravenous infusion on Day 0, Day 7, and then once every other week up to Week 26. The open-label Part B of the study assessed long-term safety as well as durability of response to Enjaymo in patients with CAD. In the CADENZA Part A study, Enjaymo met its primary composite endpoint and all secondary endpoints and demonstrated inhibition of hemolysis, increase in hemoglobin levels, and clinically meaningful improvement in The Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue scores. Enjaymo demonstrated an acceptable safety profile and was generally well-tolerated. 96% of patients in the Enjaymo group and 100% of patients in the placebo group experienced at least one treatment emergent adverse event (TEAE). Headache (22.7% vs 10.0%), hypertension (22.7% vs 0%), rhinitis (18.2% vs 0%), Raynaud phenomenon (18.2% vs 0%), and acrocyanosis (13.6% vs 0%) were reported more frequently in Enajymo-treated patients compared with placebo.

In the CARDINAL Part A trial, patients received a fixed weight-based dose (6.5g or 7.5g) of Enjaymo via intravenous infusion on Day 0, Day 7, and then once every other week up to Week 26. Part B of the study evaluated the long-term safety as well as durability of response to Enjaymo in patients with CAD over a 2-year follow up. In the CARDINAL Part A study, the efficacy of Enjaymo was assessed based on the achievement of a primary composite endpoint (Hb≥12 g/dL or an increase of at least 2 g/dL; no blood transfusion or prohibited medications from Weeks 5 through 26) and different secondary endpoints, including improvements in hemoglobin, normalization of bilirubin, and FACIT-fatigue score. The most common adverse reactions occurring in 10% or more of patients were respiratory tract infection, viral infection, diarrhea, dyspepsia, cough, arthralgia, arthritis, and peripheral edema. Serious adverse reactions were reported in 13% (3/24) of patients who received Enjaymo. These serious adverse reactions were streptococcal sepsis and staphylococcal wound infection (n=1), arthralgia (n=1), and respiratory tract infection (n=1).

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. Enjaymo was approved by the US Food and Drug Administration (FDA) 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. The Japanese Ministry of Health, Labor and Welfare approved Enjaymo in June 2022. The European Medicines Agency (EMA) also made the decision to maintain orphan designation.

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 US, 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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