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.

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Sanofi Forward-Looking Statements
This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words “expects”, “anticipates”, “believes”, “intends”, “estimates”, “plans” and similar expressions. Although Sanofi’s management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the fact that product candidates if approved may not be commercially successful, the future approval and commercial success of therapeutic alternatives, Sanofi’s ability to benefit from external growth opportunities, to complete related transactions and/or obtain regulatory clearances, risks associated with intellectual property and any related pending or future litigation and the ultimate outcome of such litigation, trends in exchange rates and prevailing interest rates, volatile economic and market conditions, cost containment initiatives and subsequent changes thereto, and the impact that COVID-19 will have on us, our customers, suppliers, vendors, and other business partners, and the financial condition of any one of them, as well as on our employees and on the global economy as a whole. Any material effect of COVID-19 on any of the foregoing could also adversely impact us. This situation is changing rapidly and additional impacts may arise of which we are not currently aware and may exacerbate other previously identified risks. The risks and uncertainties also include the uncertainties discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under “Risk Factors” and “Cautionary Statement Regarding Forward-Looking Statements” in Sanofi’s annual report on Form 20-F for the year ended December 31, 2021. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.