Enjaymo™ (sutimlimab-jome) – New orphan drug approval

- On February 4, 2022, the FDA announced the approval of Sanofi's Enjaymo (sutimlimab-jome), to decrease the need for red blood cell (RBC) transfusion due to hemolysis in adults with cold agglutinin disease (CAD).

- CAD is an autoimmune disorder characterized by RBC destruction, which leads to anemia and cold-induced circulatory symptoms, such as pain and discoloration of fingers or toes.

    — The disease is rare, affecting about one person per million annually, and mostly develops in individuals between ages 40 and 80 years.

- Enjaymo is an immunoglobulin G monoclonal antibody that inhibits the classical complement pathway, resulting in inhibition of hemolysis in patients with CAD.

- The efficacy of Enjaymo was demonstrated in CARDINAL, an open-label, single-arm study in 24 patients with CAD. Patients were treated with Enjaymo for 6 months. Efficacy was based on the proportion of patients who met the following criteria: an increase from baseline in hemoglobin (Hgb) level ≥ 2 g/dL or a Hgb level ≥ 12 g/dL at the treatment assessment time point (mean value from weeks 23, 25, and 26), no blood transfusion from week 5 through week 26, and no treatment for CAD beyond what was permitted per protocol from week 5 through week 26.

    — A total of 13 patients (54%) were responders based on the efficacy criteria.

- Warnings and precautions for Enjaymo include serious infections, infusion-related reactions, risk of autoimmune disease, and recurrent hemolysis after Enjaymo discontinuation.

- The most common adverse reactions (≥ 10%) with Enjaymo use were respiratory tract infection, viral infection, diarrhea, dyspepsia, cough, arthralgia, arthritis, and peripheral edema.

- The recommended dose of Enjaymo is based on body weight. For patients weighing 39 kg to less than 75 kg, the recommended dose is 6,500 mg intravenously (IV) and for patients weighing 75 kg or more, the recommended dose is 7,500 mg. Administer Enjaymo IV weekly for the first two weeks, with administration every two weeks thereafter.

- Sanofi's launch plans for Enjaymo are pending. Enjaymo will be available as an 1,100 mg/22 mL (50 mg/mL) intravenous solution in a single-dose vial.