Enjaymo™ (sutimlimab-jome) – Updated indication

- On January 25, 2023, the FDA approved a revised indication for Sanofi's Enjaymo (sutimlimab-jome), for the treatment of hemolysis in adults with cold agglutinin disease (CAD).
    - Enjaymo was previously approved to decrease the need for red blood cell transfusion due to hemolysis in adults with CAD.
- The approval of Enjaymo for the updated indication was based on CADENZA, a placebo-controlled study in 42 patients with CAD and no history of transfusion within 6 months, or more than one blood transfusion in the 12 months prior to enrollment in the trial. Efficacy was based on the proportion of patients (responders) who met the following criteria: an increase from baseline in hemoglobin level ≥ 1.5 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.
    - The responder rate was 72.7% with Enjaymo and 15% with placebo (treatment difference 58.78, 95% CI: 34.6, 82.96; p = 0.0004).
- The updated labeling for Enjaymo also includes long-term data from the previous CARDINAL study and the CADENZA study.
- The most common adverse reactions in the CADENZA study (≥ 18%) with Enjaymo use were rhinitis, headache, hypertension, acrocyanosis, and Raynaud's phenomenon.
- The recommended dosage of Enjaymo is based on body weight. For patients weighing 39 kg to less than 75 kg, the recommended dose is 6,500 mg and for patients weighing 75 kg or more, the recommended dose is 7,500 mg. Enjaymo should be administered intravenously weekly for the first two weeks, with administration every two weeks thereafter.