

## *FDA approves Enjaymo™ (sutimlimab-jome), first treatment for use in patients with cold agglutinin disease*

- \* Enjaymo is the only approved treatment to decrease the need for red blood cell transfusion due to hemolysis, the destruction of red blood cells, in adults with cold agglutinin disease (CAD)
- \* Enjaymo addresses a serious and chronic unmet medical need for adults living with CAD, a rare blood disorder

**Paris, February 4, 2022.** The U.S. Food and Drug Administration (FDA) has approved Enjaymo™ (sutimlimab-jome) to decrease the need for red blood cell transfusion due to hemolysis in adults with cold agglutinin disease (CAD). Enjaymo is the first and only approved treatment for people with CAD and works by inhibiting the destruction of red blood cells (hemolysis).

### ***Bill Sibold***

Executive Vice President, Head of Specialty Care

*“Until now, people living with cold agglutinin disease haven’t had an approved treatment option to manage the constant destruction of red blood cells. Without healthy, viable red blood cells, a chain reaction of debilitating signs and symptoms can be triggered, starting with severe anemia. Enjaymo is the only approved treatment to inhibit red blood cell destruction in CAD and help stop the chain reaction from the start.”*

CAD, a rare autoimmune hemolytic anemia, is caused by antibodies called cold agglutinins binding to the surface of red blood cells, which starts a process that causes the body’s immune system to mistakenly attack healthy red blood cells and cause their rupture (hemolysis). As red blood cells have the vital job of carrying oxygen throughout the body, patients with CAD may experience severe anemia, which can result in fatigue, weakness, shortness of breath, light-headedness, chest pain, irregular heartbeat, and other potential complications. CAD is a chronic and rare blood disorder that impacts the lives of an estimated 5,000 people in the U.S.

### *Enjaymo, targeting C1s in the classical complement pathway*

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 Phase 3 pivotal CARDINAL study results supporting approval*

The approval of Enjaymo in the U.S. is based on positive results from the 26-week open label, single arm pivotal Phase 3 study in patients with CAD (n=24) who have a recent history of blood transfusion, also known as the CARDINAL study.

### ***Catherine Broome, MD***

Associate professor of medicine at Georgetown University Lombardi Comprehensive Cancer Center, and a principal investigator in the CARDINAL study

*“For people living with cold agglutinin disease, it is as if their body’s immune system is waging a war on itself. The relentless destruction of healthy red blood cells is a daily, silent reality for people with CAD. For the first time, we have a treatment that targets complement-mediated hemolysis, which is the underlying cause of the red blood cell destruction in many CAD patients. In the pivotal study, patients*

*treated with sutimlimab had an improvement in anemia as measured by hemoglobin and bilirubin levels during the 26-week study.”*

In the study, Enjaymo met its primary efficacy endpoint, which was a composite endpoint defined as the proportion of patients who achieved normalization of hemoglobin (Hgb) level  $\geq 12$  g/dL or demonstrated an increase from baseline in Hgb level  $\geq 2$  g/dL at the treatment assessment time point (mean value from weeks 23, 25, and 26) and no blood transfusion from weeks 5 through 26 or medications prohibited per the protocol from weeks 5 through 26. Secondary endpoints were also met, including improvements in hemoglobin and normalization of bilirubin.

- The majority of patients (54%; n=13) met the composite primary endpoint criteria with 63% (n=15) of patients achieving a hemoglobin  $\geq 12$  g/dL or an increase of at least 2 g/dL; 71% (n=17) of patients remaining transfusion-free after week five; and 92% (n=22) of patients did not use other CAD-related treatments.
- For the secondary measures on disease process, patients enrolled experienced a mean increase in hemoglobin level of 2.29 g/dL (SE: 0.308) at week 3 and 3.18 g/dL (SE: 0.476) at the 26-week treatment assessment timepoint from the mean baseline level of 8.6 g/dL. The mean reduction in bilirubin levels (n=14) was by -2.23 mg/dL (95% CI: -2.49 to -1.98) from a mean baseline level of 3.23 mg/dL (2.7-fold ULN).

In the CARDINAL study, the most common adverse reactions occurring in 10 percent 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 percent (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). None of the adverse reactions led to discontinuation of Enjaymo in the study. Dosage interruptions due to an adverse reaction occurred in 17 percent (4/24) of patients who received Enjaymo.

Following the completion of the 26-week treatment period of CARDINAL (Part A), eligible patients continued to receive Enjaymo in an extension study.

The recommended dose of Enjaymo is based on body weight (6,500 mg for people 39-75 kg and 7,500 mg for people  $>75$  kg). Enjaymo is administered intravenously weekly for the first two weeks with administration every two weeks thereafter.

Enjaymo is expected to be available in the U.S. in the coming weeks. The U.S. list price, or wholesale acquisition cost, of Enjaymo is \$1,800 per vial. Actual costs to patients are generally anticipated to be lower as the list price does not reflect insurance coverage, co-pay support, or financial assistance from patient support programs. As part of our [commitment to ensure treatment access and affordability](#) for innovative therapies, Enjaymo Patient Solutions provides disease education, financial and co-pay assistance programs and other support services to eligible patients. For more information, please call 1-833-223-2428.

Enjaymo received FDA Breakthrough Therapy and Orphan Drug designation, and priority review, which is reserved for medicines that, if approved, would represent significant improvements in safety or efficacy in treating serious conditions. Outside of the U.S., sutimlimab has been submitted to regulatory authorities in Europe and Japan and reviews are ongoing.

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