

## PRESS RELEASE

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### **Gamifant approved in China for the treatment of primary haemophagocytic lymphohistiocytosis**

Sobi® today announced that the National Medical Products Administration of China (NMPA) has approved Gamifant® (emapalumab) for use in China. The indication is for treatment of adult and paediatric (newborn and older) patients with primary haemophagocytic lymphohistiocytosis (HLH) with refractory, recurrent or progressive disease or intolerance to conventional HLH therapy. The approval followed the recommendation announced in February 2022.

Primary HLH is an ultra-rare, life-threatening, hyperinflammatory disorder, characterised by uncontrolled activation of the immune system. Morbidity and mortality are high due to lack of detection and non-specific symptoms, but if diagnosed early and appropriately treated, the inflammation and damage can be reduced. Gamifant represents a new treatment option for patients with progressive disease through a targeted mode of action<sup>1</sup>.

"We are very pleased to announce the approval by the NMPA of this important treatment for patients with primary HLH in China. We look forward to serving those affected by this very serious and severe condition in China," said Norbert Oppitz, Head of International at Sobi.

#### **About primary haemophagocytic lymphohistiocytosis**

Primary haemophagocytic lymphohistiocytosis (HLH) is an ultra-rare, rapidly progressive, often-fatal syndrome of hyperinflammation in which hyperproduction of interferon gamma (IFN $\gamma$ ) is thought to drive immune system hyperactivation, ultimately leading to organ failures. Diagnosis is challenging due to the variability in signs and symptoms, which may include fevers, swelling of the liver and spleen, severe low red and white blood cell counts, bleeding disorders, infections, neurological symptoms, organ dysfunction and organ failure. Primary HLH can rapidly become fatal if left untreated, with median survival of less than two months. The immediate goal of treatment is to quickly control the hyperinflammation and to prepare for haematopoietic stem-cell transplant. The current conventional treatment prior to transplant includes steroids and chemotherapy and are not specifically approved to treat primary HLH.

#### **About Gamifant®**

Gamifant (emapalumab) is a monoclonal antibody that binds to and neutralises interferon gamma. Gamifant is the first and only medicine approved in the US and UAE for primary HLH, an ultra-rare syndrome of hyperinflammation that usually occurs within the first year of life and can rapidly become fatal unless diagnosed and treated.

#### **References**

1. Merli P, Algeri M, Gaspari S, Locatelli F. Novel Therapeutic Approaches to Familial HLH (Emapalumab in FHL). Front Immunol. 2020 Dec 2;11:608492. doi: 10.3389/fimmu.2020.608492. PMID: 33424859; PMCID: PMC7793976.

#### **Sobi®**

Sobi is a specialised international biopharmaceutical company transforming the lives of people with rare diseases. Providing sustainable access to innovative medicines in the areas of haematology, immunology and specialty care, Sobi has approximately 1,600 employees across Europe, North America, the Middle East and Asia. In 2021, revenue amounted to SEK 15.5 billion. Sobi's share (STO:Sobi) is listed on Nasdaq Stockholm. More about Sobi at [sobi.com](https://sobi.com), LinkedIn and YouTube.

#### **Contacts**

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