PRESS RELEASE

Stockholm, Sweden, 25 February 2022

Gamifant (emapalumab) recommended for approval in China for treatment of primary haemophagocytic lymphohistiocytosis (HLH)

Sobi® today announces that the Center for Drug Evaluation (CDE) has recommended approval of Gamifant® to the National Medical Products Administration of China (NMPA). 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.

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 treatment option for patients with progressive disease through a targeted mode of action[1].

"We are gratified that CDE has recommended Gamifant as potentially the first approved treatment for primary HLH in China," said Norbert Oppitz, Head of International at Sobi. "If approved by the NMPA, this will be welcome news for those impacted by primary HLH across China."

About primary haemophagocytic lymphohistiocytosis (HLH)

Primary haemophagocytic lymphohistiocytosis (HLH) is an ultra-rare, rapidly progressive, often-fatal syndrome of hyperinflammation in which hyperproduction of interferon gamma (IFNγ) 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® (emapalumab)

Emapalumab is a monoclonal antibody (mAb) that binds to and neutralises interferon gamma (IFNγ). 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. Visit www.gamifant.com for more information.

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, LinkedIn and YouTube.

Thomas Kudsk Larsen
Head of Communication and Investor Relations
thomas.kudsklarsen@sobi.com
+44 7443 191 773

Paula Treutiger
Global Head of Communication
paula.treutiger@sobi.com
+46 73 366 65 99

Contacts
For details on how to contact the Sobi Investor Relations Team, please click here. For Sobi Media contacts, click here