PRESS RELEASE

Stockholm, Sweden 28 June 2025

FDA approves Gamifant® (emapalumab-lzsg) as first-ever treatment for adults and children with Macrophage Activation Syndrome in Still's disease

- *Approval based on the pooled analysis of our pivotal EMERALD and NI-0501-06 studies, showing 54% of patients treated with Gamifant achieved complete response at week 8.*

Sobi® (STO: SOBI) today announced that the U.S. Food and Drug Administration (FDA) approved Gamifant® (emapalumab-lzsg) for the treatment of adult and pediatric (newborn and older) patients with hemophagocytic lymphohistiocytosis (HLH)/macrophage activation syndrome (MAS) in known or suspected Still's disease, including systemic Juvenile Idiopathic Arthritis (sJIA), with an inadequate response or intolerance to glucocorticoids, or with recurrent MAS.

"With our expertise in primary hemophagocytic lymphohistiocytosis, we understand the urgency of managing MAS quickly to improve patient outcomes," said Guido Oelkers, Chief Executive Officer at Sobi. "Gamifant is already an established therapy making a meaningful difference for patients with primary HLH, and with this approval, we are excited about the opportunity to positively impact patients affected by MAS in Still's Disease".

The approval is based on results of the pooled data from two pivotal studies, the Phase 3 study (NCT05001737) and NI-0501-06 (NCT03311854). 54 percent (21/39) of patients had a complete response at Week 8, and 82% (32/39) achieved clinical MAS remission (VAS ≤1 cm) at Week 8. Safety and tolerability were consistent with previous clinical studies. In patients with HLH/MAS in Still's disease, the most common adverse events (≥20%) were viral infections, including cytomegalovirus infection or reactivation, and rash.

"MAS in Still's disease is a serious and potentially life-threatening complication, marked by severe hyperinflammation and, in some cases, multi-organ failure," said Alexei A. Grom, MD, Professor of Pediatrics, Research Director Division of Rheumatology, Cincinnati Children's Hospital Medical Center. "Many patients affected by MAS—both young children and adults—face significant unmet medical needs. With Gamifant now as the first FDA-approved treatment for MAS, we have a new therapeutic option that helps control hyperinflammation and reduce our reliance on high-dose glucocorticoids."

MAS, a form of HLH, is a severe complication of rheumatic diseases, occurring most frequently in Still's disease including systemic juvenile idiopathic arthritis and adult-onset Still's disease. HLH/MAS is a rare systemic disorder of interferon gamma (IFNγ) driven hyperinflammation with common clinical manifestations such as high persistent fever, elevated ferritin, cytopenias, coagulopathies, and hepatosplenomegaly.

Gamifant, an interferon gamma (IFNγ)–blocking antibody, is the first and only FDA approved treatment for adult and pediatric (newborn and older) patients with primary HLH with refractory, recurrent, or progressive disease or intolerance with conventional HLH therapy.

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U.S. Indication for Gamifant® (emapalumab-lzsg)

Please see the full Prescribing Information for Gamifant.

About macrophage activation syndrome (MAS)
Macrophage activation syndrome (MAS) is a severe complication of rheumatic diseases, most frequently in Still's disease including systemic juvenile idiopathic arthritis (sJIA) – a rare systemic disorder of auto-inflammatory nature with common clinical manifestations such as daily spiking fever, typical transient cutaneous rash, arthritis, lymphadenopathy, hepatosplenomegaly and serositis. MAS is characterized by fever, hepatosplenomegaly, liver dysfunction, cytopenias, coagulation abnormalities and hyperferritinaemia, possibly progressing to multiple organ failure and death. MAS is classified as a secondary form of haemophagocytic lymphohistiocytosis (HLH).

About Gamifant® (emapalumab-lzsg)
Gamifant® (emapalumab-lzsg) is the only approved anti-interferon gamma (IFNγ) monoclonal antibody. Gamifant works by binding to and neutralizing IFNγ. When IFNγ is secreted in an uncontrolled manner, hyperinflammation occurs within the body. Gamifant is indicated for administration through intravenous infusion over one hour.

Gamifant is approved in the US for the treatment of adult and pediatric (newborn and older) patients with primary hemophagocytic lymphohistiocytosis (HLH) with refractory, recurrent or progressive disease or intolerance with conventional HLH therapy.

Gamifant is also approved in the US for the treatment of adult and pediatric (newborn and older) patients with hemophagocytic lymphohistiocytosis (HLH)/macrophage activation syndrome (MAS) in known or suspected Still's disease with an inadequate response or intolerance to glucocorticoids, or with recurrent MAS.

About Sobi®
Sobi is a global biopharma company unlocking the potential of breakthrough innovations, transforming everyday life for people living with rare diseases. Sobi has approximately 1,900 employees across Europe, North America, the Middle East, Asia and Australia. In 2024, revenue amounted to SEK 26 billion. Sobi's share (STO:SOBI) is listed on Nasdaq Stockholm. More about Sobi at sobi.com and LinkedIn.

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

This information is information that Sobi is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out below, on 28 June 2025 at 01:00 CEST.

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