

## **Sobi and Novimmune selected as Honourees for 2019 National Organization for Rare Disorders (NORD) Rare Impact Award in Industry Innovation for Gamifant® (emapalumab)**

Sobi™ and Novimmune SA have both been selected as honourees by the National Organization for Rare Disorders (NORD) for the 2019 Rare Impact Awards. The companies were nominated in the category of Industry Innovation in recognition of the US Food and Drug Administration (FDA) approval in November 2018 of Gamifant® (emapalumab-lzsg) for the treatment of paediatric (newborn and older) and adult patients with primary haemophagocytic lymphohistiocytosis (HLH) with refractory, recurrent or progressive disease or intolerance to conventional HLH therapy.

The Rare Impact Awards recognise individuals, organisations and industry innovators for outstanding work in support of the rare disease community. The 2019 Rare Impact Awards ceremony will take place on Saturday, 22 June, as part of NORD's [2019 Living Rare, Living Stronger NORD Patient and Family Forum](#) in Houston.

"We are honoured to be recognised by NORD for the work we have done to bring Gamifant to primary HLH patients. Primary HLH is often fatal, and we are grateful to be able to contribute to helping these very sick patients," said Rami Levin, President of Sobi in North America.

"Novimmune is proud that our research and development activities have led to a new drug that can make a difference in the lives of primary HLH patients," said Cristina de Min, Chief Medical Officer at Novimmune. "We share this award with the patients, families and the healthcare providers who participated in the emapalumab clinical study and whose efforts helped make the FDA approval possible."

Primary HLH is an ultra-rare syndrome of hyperinflammation with high morbidity and mortality for which there was previously no approved drug. The goal of HLH therapy is to control the severe inflammation and to prepare for haematopoietic stem-cell transplantation, which is the only cure. A combination of chemotherapy and high doses of steroids has been so far the conventional approach to treat HLH. Gamifant represents a major advance in the treatment of these patients through a targeted mode of action.

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### **About primary haemophagocytic lymphohistiocytosis (HLH)**

Primary haemophagocytic lymphohistiocytosis (HLH) is an ultra-rare, rapidly progressive, often-fatal syndrome of hyperinflammation in which massive hyperproduction of interferon gamma (IFN $\gamma$ ) is thought to drive immune system hyperactivation, ultimately leading to organ failures. It is estimated that fewer than 100 cases of primary HLH are diagnosed each year in the US, but this is believed to represent underdiagnosis. 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 is not specifically approved to treat primary HLH.

### **About emapalumab**

Emapalumab is a monoclonal antibody (mAb) that binds to and neutralises interferon gamma (IFN $\gamma$ ). In the US, emapalumab is indicated for paediatric (newborn and older) and adult primary haemophagocytic lymphohistiocytosis (HLH) patients with refractory, recurrent or progressive disease, or intolerance to conventional HLH therapy. Emapalumab is the first and only medicine approved in the US for primary HLH, a rare syndrome of hyperinflammation that usually occurs within the first year of life and can rapidly become fatal unless diagnosed and treated. The FDA approval is based on data from the phase 2/3 studies (NCT01818492 and NCT02069899). Emapalumab is indicated to be administered through intravenous (IV) infusion over one hour twice per week until haematopoietic stem cell transplant (HSCT). Visit [www.gamifant.com](http://www.gamifant.com) for more information, including full US prescribing Information.

Emapalumab was developed and submitted for approval to the FDA by Novimmune. Sobi acquired the global rights to emapalumab from Novimmune through an exclusive licensing agreement announced in July 2018.

### **About Sobi™**

At Sobi, we are transforming the lives of people affected by rare diseases. As a specialised international

biopharmaceutical company, we provide sustainable access to innovative therapies in the areas of haematology, immunology and specialty care. We bring something rare to rare diseases – a belief in the strength of focus, the power of agility and the potential of the people we are dedicated to serving. The hard work and dedication of our approximately 1050 employees around the globe has been instrumental in our success across Europe, North America, the Middle East, Russia and North Africa, leading to total revenues of SEK 9.1 billion in 2018. Sobi's share (STO:SOBI) is listed on Nasdaq Stockholm. You can find more information about Sobi at [www.sobi.com](http://www.sobi.com).

### **About Novimmune SA**

Novimmune SA is a privately held, Swiss biopharmaceutical company focused on discovering and developing antibody-based drugs targeted for the treatment of inflammatory diseases, immune-related disorders and cancer. Founded in 1998 by the renowned immunologist Professor Bernard Mach, Novimmune has more than 150 employees and operates in two sites in Geneva and Basel (Switzerland). Since its foundation, Novimmune has built a significant R&D pipeline of drug candidates, of which emapalumab is the most advanced. The development program of Gamifant was supported by a FP7 grant from the European Commission (FIGHT HLH). Novimmune has also developed a bispecific antibody generation platform designed to streamline the identification, production and characterisation of fully-human bispecific antibodies. More information is available at [www.novimmune.com](http://www.novimmune.com).

### **For more information please contact**

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