

MEDIA INFORMATION

Novimmune Receives Rare Pediatric Disease Designation from the FDA for its Lead Drug emapalumab

Providing eligibility is confirmed at the time of approval of emapalumab for the treatment of primary Hemophagocytic Lymphohistiocytosis (HLH), Novimmune would qualify for a rare pediatric disease priority review voucher

Geneva, Switzerland – 5th September, 2017 – Novimmune SA, a privately held Swiss biopharmaceutical company, announced today that the Food and Drug Administration of the US (FDA) has granted Rare Pediatric Disease Designation to its lead compound emapalumab for the treatment of primary HLH as a drug for a “rare pediatric disease”. Priority review vouchers are awarded upon the FDA approval of an eligible drug for a rare pediatric disease. In addition to the Rare Pediatric Disease designation, emapalumab has Orphan Drug designation in both the US and Europe, has received FDA’s Breakthrough Therapy designation, and has been granted eligibility for the European Medicines Agency’s PRIME scheme.

“We are delighted to have been granted this special designation for our emapalumab program,” said Chairman and Chief Executive Eduard Holdener. “We are looking forward to working with the regulatory authorities to make this medicine available to patients with this devastating disease as soon as possible. This priority review voucher is also precious as it can be used to secure the priority review of another program with the FDA and may be transferred between companies.”

About HLH and emapalumab

HLH is a hyperinflammatory syndrome characterized by uncontrolled and aberrant activation of the immune system and a life-threatening cytokine storm presenting with non-remitting fever, reduction in the number of blood cells and impaired coagulation potentially leading to death. Two forms of HLH are described: primary HLH is genetically determined and is typically diagnosed in infants and young children, while secondary HLH occurs on a background of a rheumatic/inflammatory disease, a malignancy or an infection.

Mortality in patients with primary and secondary HLH remains high, despite the use of aggressive immune-chemotherapy.

Emapalumab is a fully human, anti-interferon-gamma (IFN γ) monoclonal antibody discovered and developed by Novimmune. The biological activity of IFN γ , which is considered to have a pivotal pathogenic role in HLH, is neutralized by emapalumab, the first targeted therapy for this disease

About Novimmune

Novimmune SA is a privately held, Swiss biopharmaceutical company focused on the discovery and development of antibody-based drugs for the targeted treatment of inflammatory diseases, immune-related disorders, and cancer. The company is headquartered in Geneva and runs a Clinical and Commercial Development Center in Basel. The company currently employs 130 people. More information is available on the company website at www.novimmune.com.

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