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MEDIA INFORMATION

FDA Accepts emapalumab Biologics License Application with Priority Review

Geneva, 28th May, 2018 — Swiss biotech company Novimmune today announced that the U.S. Food and Drug Administration (FDA) has accepted for filing with Priority Review, its Biologics License Application (BLA) for its lead compound, emapalumab (NI-0501). Emapalumab is the first medicine specifically developed to treat patients with primary Hemophagocytic Lymphohistiocytosis (HLH), a rare, lethal disease affecting babies and children.

The granting of the Priority Review for the BLA accelerates the timing of the FDA review compared to standard procedure. The PDUFA (Prescription Drug User Fee Act) goal date for completion of the FDA review of the emapalumab BLA is November 20, 2018.

Novimmune Chairman and Chief Executive Officer, Eduard Holdener, said: "We are delighted that the FDA considers the medicine worthy of a Priority Review." Cristina de Min, Novimmune's Chief Medical Officer, added: "We look forward to working with the FDA during the review and feel honored to put forward emapalumab for consideration as a new potential drug for children affected by this serious, life threatening disease."

On 11th March 2016, the FDA granted Breakthrough Therapy Designation to emapalumab. Three months later, the compound was declared eligible for PRIME (PRIority MEdicine) by the European Medicines Agency (EMA) for the treatment of primary Hemophagocytic Lymphohistiocytosis. In addition, on 25th August 2017, a Rare Pediatric Disease designation was granted by the FDA for emapalumab for the treatment of primary HLH.

Novimmune is also preparing a Marketing Authorization Application (MAA) for submission to the EMA later this year.

About Hemophagocytic lymphohistiocytosis

Hemophagocytic Lymphohistiocytosis (HLH) is a clinical syndrome of hyperinflammation, driven by high interferon gamma (IFNγ) production, characterized by severe hyperferritinemia, fever, severe cytopenia, coagulation defects and organomegaly.

HLH occurs as a familial autosomal recessive disorder (primary HLH) or as an acquired, reactive condition (secondary HLH). Primary HLH typically arises in pediatric patients, is lethal if untreated, and has a 40% mortality rate with current best available care. The secondary form of the disease typically arises later in life, and is also associated with significant mortality. HLH is an orphan disease for which no drugs have been approved, representing a high unmet need.

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. More than 140 employees operate from two sites, Geneva and Basel, Switzerland. More information is available on the company website at www.novimmune.com.

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