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MEDIA INFORMATION

Novimmune submits Biologics License Application in the US for its lead drug emapalumab

Geneva, 29th March, 2018 — Novimmune, a Swiss biotech company focused on the discovery and development of antibody-based drugs, today announced that it has successfully submitted a Biologics License Application (BLA) to the US Food and Drug Administration (FDA) seeking marketing approval for its lead compound, emapalumab (NI-0501), for the treatment of patients with primary Hemophagocytic Lymphohistiocytosis (HLH).

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

Novimmune Chairman and Chief Executive Officer Eduard Holdener said: "This is a very special moment in the history of our company as emapalumab is Novimmune's first medicine to be submitted for regulatory approval." Cristina de Min, Novimmune's Chief Medical Officer, added, "The emapalumab research and development program has made significant progress in the understanding, diagnosis and management of this life threatening disease in children. We look forward to working with the FDA during the review process for the first targeted therapy for primary HLH."

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 EMA for the treatment of primary Hemophagocytic Lymphohistiocytosis. In addition, on August 25th, 2017, a rare pediatric disease designation was granted by the FDA for emapalumab for the treatment of primary HLH.

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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