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Media release – For immediate release

NovImmune initiates a Proof-of-Concept study in Primary Biliary Cirrhosis (PBC).

The PIANO study: Primary biliary cirrhosis: Investigating A New treatment Option using NI-0801, a fully human anti-CXCL10 monoclonal antibody

Plan-Les-Ouates/Geneva/Switzerland. NovImmune announced today that a Proof-of-Concept (PoC) study with NI-0801, a fully human monoclonal antibody neutralizing the CXCL10/Interferon-gamma-inducible protein-10 (IP-10) chemokine, was initiated in patients with PBC. This is a chronic inflammatory, debilitating condition of the bile ducts that leads to liver cirrhosis and eventually to liver failure, and which represents a high unmet medical need.

Preclinical models and human data strongly associate CXCL10/IP-10 to the etiology of PBC.

Two previous Phase I trials in healthy volunteers have demonstrated that the administration of NI-0801 is safe and well tolerated.

PBC is an orphan, autoimmune, progressive liver disorder that primarily affects females. Typically, the disease becomes apparent during middle age (between 30 and 65). Inflammation, developing around the small bile ducts, progressively induces an obstruction and accumulation of bile leading to damage of liver cells. As damage worsens, scarring (cirrhosis) gradually occurs and may ultimately cause liver failure, for which transplantation is the only therapeutic option. Common early symptoms of PBC are itching and fatigue. Currently, only symptomatic treatments are available and the need for disease modifier drugs is extremely high.

CXCL10/IP-10 is secreted by several cell types in response to inflammation and contributes significantly to the entry of immune cells into the liver. These cells are responsible for the destruction of the biliary tract in PBC and, with time, provoke the dysregulated scarring process which characterizes the late stages of the disease. The neutralization of CXCL10/IP-10 with NI-0801 offers the possibility to interfere with one of the key inflammatory processes that leads to PBC.

David Adams, Professor of Hepatology, Director of the NIHR BRU Centre for Liver Research at the University of Birmingham, and Principal Investigator of the PoC study, commented that "the therapeutic approach of neutralizing CXCL10/IP-10 with NI-0801 will potentially offer for the first time great benefits to the large and therapeutically ill-served PBC patient population".

PBC, an orphan disease

An orphan disease is any disease that affects a small percentage of the population. PBC affects approx. 4 in 10'000 people and therefore is considered as an Orphan disease. Worldwide approx. 300'000 people suffer from this disease.

NovImmune SA

NovImmune SA ('NovImmune') is a drug discovery and development company with a focus on therapeutic mAbs for inflammatory diseases and immune-related disorders. NovImmune has generated to date seven proprietary mAbs. The pipeline is a balance of preclinical and clinical compounds with a mix of both clinically validated as well as novel targets. Each of these portfolio products has the potential to become a medicine for multiple medical conditions due to the overlapping mechanism of action underlying these types of diseases. Four compounds are at this time in clinical development, with the most advanced in Phase II.

In addition, NovImmune has developed a proprietary platform for the generation of fully human mono-, bi- and panspecific antibodies.

For more information please visit our website: www.novimmune.com

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