



NEWS — 15 OCTOBER 2012

European Commission awards EUR 6 million FP7 grant to support clinical development of NI-0501 to 'FIGHT HLH'

GENEVA — NovImmune announced that the European Commission has awarded a 6 million euro FP7 grant to the "FIGHT HLH" consortium of institutions to support clinical testing of NovImmune's anti-interferon gamma drug candidate, NI-0501.

Led by NovImmune, the FIGHT HLH Consortium includes leading institutions working to combat the impact of HLH, an orphan disease, on patients and their families. It includes Meyer University Children Hospital in Florence, Pediatric Hospital Bambino Gesù in Rome and Lonza Biologics Plc.

Cristina de Min, NovImmune Chief Medical Officer, noted, "Thanks to the excellent collaborative work of the FIGHT HLH Consortium members and support from the European Commission, we are poised to commence clinical study of NI-0501 in HLH patients. The program is designed to give a clear readout on the ability of the drug to affect disease course and benefit these high-need patients."

The Principal Investigator of the first clinical trial of the FIGHT HLH program, Prof. Maurizio Aricò, commented, "We are thrilled by the opportunity to collaborate with NovImmune to advance NI-0501 into clinical development as the evidence is compelling that interferon-gamma (IFN γ) is a primary driver of the disease and dramatic results in preclinical models have been demonstrated."

The development program for NI-0501 in HLH has been designed with the participation of key experts in both Europe and the USA.

"NovImmune is delighted to have been selected by the European Commission for such a prestigious grant, as NI-0501 holds the potential to become the first approved and targeted therapy to fight HLH," noted Jack Barbut, CEO of NovImmune.

About HLH

Hemophagocytic lymphohistiocytosis (HLH) is a severe immune system disorder, the genetic underpinnings of which are becoming clear. HLH is caused by a severe impairment of cytotoxic T cell function that triggers aberrant activation of the immune system. This is mediated to a large degree by dramatic increase in levels of IFN γ — the target of NI-0501. The primary form of the disease 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 NI-0501

NI-0501 is a fully human monoclonal antibody discovered and developed by NovImmune as a potent inhibitor of IFN γ . NovImmune advanced NI-0501 through Phase I clinical trials, in which the drug candidate was well tolerated at therapeutically relevant doses. In preclinical studies NovImmune has demonstrated that neutralizing IFN γ in animal models of HLH reversed organ pathology and normalized key clinical parameters to protect animals from death, whereas inhibition of other cytokines did not provide such protection.

About NovImmune

NovImmune is a leading drug discovery and development company focused on the creation of antibody-based drugs to benefit patients with inflammatory, auto-immune and other disorders. Thus far, NovImmune has advanced seven drug candidates to treat a range of conditions. The company's pipeline is a balance of preclinical and clinical candidates for validated and novel targets. NovImmune has established a next-generation antibody drug discovery platform that includes novel bispecific antibody drug capabilities — the simple, stable and smart *kappa-lambda*-body ($\kappa\lambda$ -body™). In 2009, NovImmune received the European Biotechnica Award. In 2010, NovImmune entered a partnership with Genentech to advance the company's anti-IL17 drug candidate. In addition to pursuing additional drug discovery, development and commercialization partnerships, the company plans to bring selected drugs to market for focused applications.

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