



## **PRESS RELEASE**

### **FOR IMMEDIATE RELEASE**

#### **NOVIMMUNE initiates Phase I/IIa trials proof-of-concept study with NI-0401, a novel fully human anti-CD3 monoclonal antibody in Crohn's Disease**

**Geneva, Switzerland, June 26, 2006.** NovImmune SA ("NovImmune") announced today that it has initiated a Phase I/IIa proof-of-concept clinical trial of its novel fully human anti-CD3 monoclonal antibody, NI-0401, a product of its own research. The study is designed to assess the safety, tolerability and pharmacokinetics of NI-0401 when administered intravenously at several dose levels. This is a placebo-controlled multiple ascending dose study conducted in the Netherlands in up to 60 patients who are suffering from moderate to severe Crohn's Disease.

Anti-CD3 antibodies are known to induce a specific and potent immunosuppressive effect. In addition, the modulation of the CD3 complex may also induce long-term immunological tolerance. Therefore, intermittent injections of NI-0401 can potentially lead to clinical benefits over an extended period of time. NI-0401 targets the CD3 antigen on the surface of T lymphocytes, which are involved in many immune-related diseases. Since the CD3 antigen is a key regulator of T lymphocytes, the clinical benefits expected from NI-0401 potentially extend beyond Crohn's Disease, to a number of other autoimmune diseases, including insulin-dependent diabetes, multiple sclerosis, rheumatoid arthritis and to provide protection from organ transplantation rejection.

Recent advances in generating "fully human" monoclonal antibodies, applied by NovImmune in the development of NI-0401, resulted in an antibody that contains exclusively human sequences and is thus less likely to be immunogenic in humans. In addition, NovImmune has engineered NI-0401 to abolish Fc binding in order to potentially present a better clinical safety profile.

"The in-house generation of a fully human anti-CD3 monoclonal antibody and the commencement of clinical trials in patients in less than three years demonstrates NovImmune's ability to execute a streamlined process from bench to bedside" said Jack Barbut, CEO of NovImmune.

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#### **About NI-0401**

NI-0401 is a fully human monoclonal antibody, which may have therapeutic potential in a broad range of autoimmune diseases. It targets the CD3 antigen, a key regulator in the activation of T-lymphocytes. The proliferation of activated T-cells is a hallmark of many autoimmune diseases, including insulin-dependent diabetes, Crohn's disease, multiple sclerosis and rheumatoid arthritis, and of organ transplant rejection. In May 2005, Serono and NovImmune have signed an exclusive agreement under which NovImmune has granted Serono exclusive worldwide rights to develop and commercialize two of NovImmune's fully human monoclonal antibodies, NI-0401 and NI-0501. NovImmune is responsible for the development of the two products until completion of Phase IIa clinical trials, after which Serono will consider further development.

## **About Crohn's Disease**

Crohn's disease is a chronic inflammatory bowel disease that can affect all parts of the intestinal tract as well as extra intestinal organs. At present no curative treatment is available, with the exception of bone marrow transplantation. The incidence of this disease varies by region and is increasing, with a current worldwide prevalence ranging from 10 to 70 cases per 100,000. The disease affects slightly more females than males and has a peak incidence at about 30 years of age.

Patients with Crohn's Disease present acute symptoms such as abdominal abscess, but many also have an underlying, chronic disease, and symptoms for one to two years before the diagnosis is established. The clinical symptoms of Crohn's disease include diarrhoea, abdominal pain, anorexia, anaemia, anal lesions including fistulas and extra intestinal symptoms such as fatigue, low-grade fever, arthritis, dermatological efflorescence and abnormalities of the liver function.

Due to the chronic inflammation, Crohn's disease frequently leads to complications, such as the formation of intestinal strictures and more than 70% of patients will require surgery at least once during the course of their disease.

## **About NovImmune**

NovImmune is a Geneva-based drug development company focusing on immune mechanisms in order to clinically impact Immune Related Diseases, Inflammation and Organ transplantation. NovImmune has a portfolio of fully human therapeutic monoclonal antibodies at various stages of development, including NI-0501 in final stage of GMP production at Lonza Biologics. These fully human antibodies are generated by NovImmune in house, using technologies licensed from Medarex or Cambridge Antibody Technology.

For further information, please contact:

Jack Barbut, CEO  
NovImmune SA  
Tel. +41 22 593 51 14