INNOGENETICS
BIOTECHNOLOGY FOR HEALTHCARE

Innogenetics announces positive results in pivotal preclinical study in sepsis

Gent, Belgium – May 6, 2003 – Innogenetics today reported the results of its pivotal preclinical evaluation of a proprietary anti-inflammatory monoclonal antibody, INNO 202, for the treatment of severe sepsis. The very positive results achieved in a clinically relevant animal model open the prospects for clinical trials in humans in the near future.

Sepsis is a common, frequently fatal clinical condition of which the incidence has increased dramatically over the last two decades to become the tenth leading cause of death in many developed countries. Sepsis is the primary cause of death in intensive care units (ICU), and is associated with very high healthcare costs. Recent estimates indicate a figure of approximately $17 billion/year in the USA alone. Unfortunately, despite some advances in therapy and supportive care, the condition remains a major cause of illness and death, with a pressing need for new and more effective treatments.

According to Professor Lyle L. Moldawer of the University of Florida College of Medicine (Gainesville, Florida, USA), a recognized expert in the sepsis field who actively participated in the study: “Within the context of previous anti-inflammatory sepsis trials, the present results offer a strong indication that INNO 202 could represent a potentially effective mode of intervention in sepsis.”

Responding to the challenge of sepsis

After previous encouraging results in pilot preclinical studies, followed by the in-house humanization of its candidate monoclonal antibody INNO 202, Innogenetics proceeded to carry out a pivotal trial in a highly relevant animal model for sepsis. This model was chosen together with leading American and European experts in the sepsis field as being especially relevant from a clinical standpoint. This is because treatment in this model is only given once clear acute symptoms of sepsis have appeared following bacterial (*Escherichia coli*) challenge. By contrast, in many other sepsis models, treatment is administered prior to challenge or at a fixed time thereafter, irrespective of whether symptoms have appeared or not. The approach adopted by Innogenetics is closer to the real time situation encountered in intensive care units.

In addition, to ensure objectivity, the study was placebo-controlled and conducted in a blinded, paired fashion so that the investigators did not know beforehand which animal received treatment and which received placebo.

Positive preclinical results

Results of the preclinical trial were very positive: all six control animals not receiving the monoclonal antibody developed symptoms of severe bacterial sepsis and died early. By contrast, no less than six out of the eight animals given the candidate drug survived for 7 days or more, i.e., considered by experts as being ‘long-term survivors’

in this model. The difference in survival curves between the two groups was statistically significant.

Next steps for INNO 202

Another leading expert on sepsis and pulmonary inflammatory responses, Professor Edward Abraham of the University of Colorado Health Sciences Center (Denver, Colorado, USA), was also encouraged by the outcome: “The strong results on survival achieved with INNO 202 in a clinically relevant animal model now open the perspectives for the evaluation of this molecule in clinical trials.”

Innogenetics now plans to pursue the further development of its proprietary humanized anti-inflammatory monoclonal antibody INNO 202 in clinical trials together with possible interested parties.

Notes to the Editor

Sepsis: The body’s response gone haywire

Sepsis is the body’s response to an infection by microorganisms. Uncomplicated infection occurs very commonly (e.g., dental abscess, gastroenteritis, or a viral flu) and can be easily managed and cleared by the body’s immune system. However, when more severe infection occurs, the body’s defense system may be unable to cope with the invading microorganisms. The immune response may then become dangerously amplified, dysregulated, and finally immunosuppressed. Moreover, it is also believed that sepsis involves a series of interactions between inflammation, coagulation, and fibrinolysis that may get out of hand and become lethal.

In severe sepsis, the function of one or more vital organs (e.g., lungs, kidney, heart, liver) fails, resulting in an approximate 30% mortality rate. Finally, in septic shock, the most severe condition, which is associated with no longer treatable low blood pressure, mortality rates may reach as high as 50%.

Sepsis: A major and growing healthcare threat

In recent years, sepsis has emerged as a major threat to public health. In the United States alone, annually some 750,000 persons develop its symptoms, and no less than 200,000 die as a consequence of its two most serious forms: severe sepsis and septic shock. It is now the tenth leading cause of death overall in many developed countries. The incidence of sepsis has risen dramatically over recent years and is expected to reach 1 million in the US alone by the end of the decade.

This increase is due to several factors such as the rising numbers of elderly or debilitated persons; increasing use of invasive procedures; more patients needing transplantation or with diseases such as cancer requiring strong treatment (e.g., chemotherapy) that weakens their immune response; and the widespread use of antibiotics favoring the emergence of drug-resistant microorganisms (especially in hospitals).

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About Innogenetics

Innogenetics, a Belgium-based, international biotechnology company, is pursuing a challenging twofold growth strategy, encompassing both diagnostics and therapeutics.

The Company is committed to becoming a worldwide leader in high value-added diagnostics (especially "theranostics") focusing on infectious diseases, neurodegeneration, and genetic testing. With its vertically integrated diagnostics activities, Innogenetics is leveraging its intellectual property, know-how, and product offerings through strategic partnerships with leading in vitro diagnostic players such as Bayer, Roche, and Abbott. By running a profitable diagnostic business, Innogenetics can therefore finance the development of new therapeutics.

At present, the Company's therapeutics portfolio consists of innovative candidates in the fields of hepatitis C, immune disorders, and wound care (the latter through its wholly owned subsidiary XCELLentis). Its clinical development program for a hepatitis C therapeutic vaccine is currently in phase II. Pre-clinical programs are also ongoing for the treatment of pulmonary edema and sepsis, as well as for a hepatitis C prophylactic vaccine. Finally, phase II clinical trials are ongoing in the field of wound care.

Founded in 1985, Innogenetics has been listed on NASDAQ Europe since November 1996 and on Euronext Brussels since December 2002. The Company has its headquarters in Gent, Belgium, with sales affiliates located in France, Germany, Italy, the Netherlands, Spain, and the USA. It employs 600 people worldwide.

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SPECIAL NOTE REGARDING FORWARD-LOOKING INFORMATION

This press release contains forward-looking statements that involve risks and uncertainties, including but not limited to projections of future revenues, operating income, and other risks. Prospective investors should be aware that these statements are estimates, reflecting only the judgment of our management, and they should not place undue reliance on any forward-looking statements.