

# FOR IMMEDIATE RELEASE:

## Vacc-C5 to Move from Lab to Phase I/II Clinical Trial

# New Path to Therapeutic HIV Vaccine Discovered by Studying Immunologic Profile of Rare HIV Controllers

(Oslo, March 17) Based on encouraging results from pre-clinical research, Bionor Immuno AS, today announced intentions to take the therapeutic and potentially preventative HIV-vaccine candidate Vacc-C5 into a Phase I/II clinical trial. The research results indicate that Vacc-C5 may induce a protective antibody response in HIV patients similar to that found in patients with slow or non-progressing disease.

"The very slow or non-progressing HIV infection observed in a small minority of patients, often referred to as 'controllers' because of their ability to live symptom-free with HIV, has been the subject of academic interest for years. The discovery of these antibodies in such patients could lead to a significant shift in the approach to treating HIV. The results have been presented to the Company's Clinical Advisory Board and with very encouraging feedback," said Birger Sørensen, CEO of Bionor Immuno.

Vacc-C5 is the second vaccine in Bionor's pipeline. Vacc-4x, acting by a different mechanism (cell mediated immunity), has undergone a multi-centre placebo-controlled Phase IIB trial with 134 HIV-patients who have temporarily stopped taking daily ART. Results from the study are expected in October 2010.

## Researchers Discover Vacc-C5 after Studying Immune Response of HIV Controllers

From research on blood donated by patients with a slow or non-progressing HIV disease, the Company has identified a specific part of the virus, C5, which is believed to induce hyperactivation of the immune system. Researchers believe that the antibodies to C5 are likely to be protective and cause a slow disease progression. Using its proprietary platform technology, the Company has developed Vacc-C5, which is designed to induce a similar antibody response to the one discovered in patients with slow disease progression. Vacc-C5 has passed pre-clinical research tests showing that it has the potential to induce the desired antibodies.

Disease progression from HIV to AIDS is triggered by the hyper-activation of the immune system. This hyper-activation overwhelms the immune system and gradually causes a collapse in the immune system, leading to AIDS. Researchers hope that Vacc-C5 will have the ability to stop or greatly slow this progression.

The antibodies induced by Vacc-C5 are expected to be beneficial at all stages of HIV disease and can be used for both treatment and prevention. Vacc-C5 works by halting the hyper-activation of the immune system, producing a dual effect; i) slowing down or halting the disease progression and ii) significantly reducing the production of the virus. These properties, in combination with the properties of the Company's most advanced vaccine candidate, Vacc-4x, may form a potent preventative HIV vaccine.



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### **Clinical Trial Program Strategy**

As part of the preparations for a Phase I/II clinical trial to be initiated in Q2, 2011, the Company will carry out routine toxicity tests, to ensure the safety of the Vacc-C5 components. The toxicology program is planned to be completed by early 2011.

Following the decision to move Vacc-C5 forward towards clinical testing the Company has placed an order with Bachem for the production of pharmaceutical-grade vaccine components to be used in the upcoming trial.

#### The HIV-market

In 2008 the United Nations estimated 33.4 million people are living with HIV globally, of which 2.14 million have access to highly effective treatment. The latter have access to antiretroviral therapy at a cost of between US\$12,000 to \$15,000 per year, per patient. Data monitor estimates the value of antiretroviral sales in the seven major markets (France, Germany, Italy, Japan, Spain, UK and USA) at US\$11.7 billion. The antiretroviral therapy must be administered at precise intervals during the day and often cause adverse side effects.

#### **About Bionor Immuno**

Bionor Immuno is an innovative biotech company developing synthetic peptide vaccines that stimulate cell-mediated immunity. Previous efforts made to use T-cell stimulation for vaccines have been notoriously unsuccessful and this is the reason they are not on the market today. Bionor Immuno carefully designs synthetic (modified) peptides with improved efficacy and safety profiles. Among the diseases targeted are chronic infections such as HIV, Hepatitis C (HCV), Human Papilloma Virus (HPV) and Influenza. Bionor Immuno's platform technology is broadly applicable and makes it possible to extend the range of projects to include vaccines targeting cancer. More information is available at <a href="https://www.bionorimmuno.com">www.bionorimmuno.com</a>. Bionor Immuno AS is a wholly owned subsidiary of Nutri Pharma ASA. Nutri Pharma ASA is listed on the Oslo Stock Exchange under the ticker symbol "NUT." More information is available at <a href="https://www.nutripharma.com">www.nutripharma.com</a>.

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