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**PRESS RELEASE**  
**For immediate distribution**

## **“EuroVacc 02” HIV Vaccine trial begins in February 2005**

Lausanne, Switzerland and London, United Kingdom, February 16, 2005 -- The European Vaccine Effort against HIV/AIDS, today announced that a phase I clinical trial of novel investigational vaccines comprising DNA-HIV-C and NYVAC-HIV-C for the prevention of HIV infection has started in Lausanne and London in February 2005. These vaccines are based on HIV subtype C, which is prevalent in China, India and sub-Saharan Africa, and constitutes more than 50 percent of the new HIV infections worldwide.

The phase I clinical trial, with the EuroVacc Foundation as the sponsor, will evaluate the safety of DNA-HIV-C alone and of the prime-boost regimen of DNA-HIV-C+NYVAC-HIV-C, and to compare the immunogenicity of the prime-boost regimen to NYVAC-HIV-C alone in healthy volunteers at low risk of acquiring HIV infection. The study will recruit 40 healthy volunteers: 20 at the Centre Hospitalier Universitaire Vaudois (CHUV) in Lausanne, and 20 at St Mary's Hospital, Imperial College London. All volunteers, male or female, should be between 18 and 55 yrs, HIV-negative and at low risk of infection.

The trial will carefully evaluate the safety and immunogenicity of the combination of the vaccines, in particular their ability to generate HIV-specific cell-mediated immune response to HIV, which is considered to be a key determinant of protection against infection. According to the principal clinical investigators Prof. Giuseppe Pantaleo of CHUV in Lausanne and Prof. Jonathan Weber of Imperial College London for the clinical studies, “if this study generates promising results, EuroVacc intends to further evaluate the vaccines in larger clinical trials.”

### **Development background**

The vaccine candidates for the trial - DNA-HIV-C and NYVAC-HIV-C - were developed within the network European Vaccine Effort against HIV/AIDS. NYVAC-HIV-C (a vaccine candidate based on poxvirus) was manufactured by sanofi pasteur - the vaccine division of Sanofi-Aventis - and has already been evaluated in a phase I study (EuroVacc 01) at the same clinical centres in Lausanne and London. The completed phase I study showed that the NYVAC-HIV-C is safe and immunogenic. The DNA-HIV-C vaccine was developed by Professors Hans Wolf and Ralf Wagner at the University of Regensburg based on a representative Chinese subtype C isolate CN54 jointly developed with Professor Yiming Shao from the CDC Beijing. The plasmid was constructed in collaboration with Genart GmbH - a biotech company in Regensburg Germany, and the vaccine was manufactured by Cobra Biomanufacturing Plc.

## About EuroVacc

The European Vaccine Effort against HIV/AIDS network, funded by the European Union under the 5<sup>th</sup> Framework Programme, involves 21 leading research laboratories as well as pharmaceutical companies and biotech companies in France, Germany, Italy, the Netherlands, Spain, Sweden, Switzerland and the United Kingdom. The goal of this network is to develop safe and effective preventive vaccines against HIV/AIDS. This group has been working together for more than five years, and has developed a pipeline of potential vaccines.

The EuroVacc Foundation, a non profit organization, was created in 2002 as an evolution of the network. The EuroVacc Foundation aims at facilitating European collaboration in vaccine development, coordinating European efforts and raising funds for fundamental and clinical research so as to accelerate the development of a safe and effective vaccine against HIV infection. The Foundation also promotes educational and training programmes relevant to vaccine development worldwide.

## Editors' notes

Contrary to classical vaccine boosters, one strategy being developed for a preventive HIV vaccine comprises two different "antigen transporters" (vectors). A first dose of antigen A in vector X is administered, followed by a booster using the same antigen A in vector Y this time. In this way, immune reactions to, and the consequent inhibition of the transporter are reduced. The first injections prime the immune system whereas the second injections further enhance (boost) the immune response. Therefore this combined vaccine strategy is expected to strengthen stimulation of the immune response

While there is a need to identify the best candidates for the "prime" and the most efficient for the "boost", results from recent pre-clinical studies in non-human primates conducted by EuroVacc suggest that the use of the DNA as prime followed by a boost based on poxvirus (NYVAC in this trial) induces stronger immune responses than either vaccine alone.

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