

Nasal spray against influenza: clinical phase I study started

The Viennese company Avir Green Hills Biotechnology developed a new intranasal influenza vaccine generation - The vaccine is based on the deletion of the NS1 gene - The first volunteers were vaccinated in Vienna this week

Vienna, 16 April 2007. This week, the Viennese company Avir Green Hills Biotechnology (GHB) started the first clinical phase I study for the novel influenza vaccine "Envax". In collaboration with the Department of Clinical Pharmacology at the Vienna General Hospital, headed by Dr. Volker Wachek, the first 4 volunteers were vaccinated. With this step Avir Green Hills Biotechnology accomplished an important milestone in the development of effective influenza vaccines.

The novel influenza vaccine differs from a conventional influenza vaccine in three major characteristics and in the method of production. It is administered intranasally with a spray device and promises a broader protection rate than currently available vaccines.

Nasal spray

The vaccine is administered intranasally with a spray device instead of being injected into a muscle. This approach offers the major advantage of stimulating the vaccine protection directly at the site of the virus entry.

Effective immune response

The vaccine can induce an effective immune response against a wide range of influenza virus variants, which is only conditionally possible with conventional vaccines.

Delta NS Technology

Though the vaccine looks like a pathogenic influenza virus to the body, it does not cause disease, because its pathogenicity factor NS1 was deleted. As a result, after intranasal application, the vaccine stimulates a strong immune response, which offers protection against influenza. We may say that the vaccine "fakes" an infection that induces an innate immune response without causing illness to the host.

Production method – Vero cells

The technology developed by GHB not only comprises the novel, more efficient vaccine but also an innovative production method in cell cultures (Vero cells) as well as a fast and efficient method (reverse genetics) of producing the vaccine viruses.

Vero cells

The conventional production in embryonated chicken eggs can only be automatized to a limited extent. Moreover, it requires the availability of pathogen-free, embryonated chicken eggs, which poses a problem, in particular in times of a pandemic. In addition, a vaccine produced in eggs cannot be administered to people suffering from egg allergy. GHB developed a production system in Vero cells that permits production in bio reactors, automatization and manufacture at any scale.

Phase I study to investigate tolerance

The phase I study investigates the proven pharmacological effect of the substance in the human organism. The main aim is to test the safety of this novel type of influenza vaccine administered as one single immunization in the form of a nasal spray.

In addition to safety, the study also serves to analyze the body's immune response to the influenza vaccination by detecting influenza-virus-specific antibodies in the blood and nasal secretion. The pertinent analyses will be carried out at the Institute of Virology at the Medical University of Vienna.

A total of 24 male volunteers participate in the clinical study. It is carried out by Dr. Volker Wachek from the Department of Clinical Pharmacology at the Vienna General Hospital, and managed by Mag. Franz Groiss and Mag. Andrea Pfeiffer, two experienced leaders of clinical studies at Avir Green Hills Biotechnology. The study is scheduled to end in summer 2007.

GHB leads EU research project “Fluvacc”

Containing influenza epidemics, and above all bird flu, is a priority in many countries' health policies. In this context, both the USA and the EU first and foremost bet on quickly developing an efficient human vaccine. The EU opted for the innovative vaccine development Delta NS Technology of the Vienna-based research company Avir Green Hills Biotechnology (GHB) as a future European pandemic preparedness strategy.

Avir Green Hills Biotechnology leads an international consortium comprising eight renowned national and international research partners. A total of eleven partners from eight different institutions participate in the project consortium, among them three academic institutions and five SMEs: Avir Green Hills Biotechnology (A), BIA Separations (Slo), Biotest (CZ), GPC Biotech AG (D), Weikom & Network (A), Medical University of Vienna (A), Robert Koch Institute (D), Institute for Influenza (Russia). EU funding amounts to a total of €9.2 million. The project started in September 2005, and research work will be supported for five years.

Avir Green Hills Biotechnology AG

Until now, GHB has been able to obtain around €25 million for product development. This amount comprises venture capital, atypical silent participation capital, grants and founders' own funds. The research company – founded in 2002 – intends to conclude phases I and II of the clinical studies for “Fluvacc” by early 2009. For carrying out the phase III studies, this will be followed by a strategic alliance with a partner from the pharmaceutical industry or another round of funding. The Viennese company plans to start the clinical phase I study for its pandemic H5N1 vaccine (avian influenza) in fall 2007. Upon the successful completion of the present study, it will embark on the clinical phase II study for “GHB01L1”, which is effective in preventing the annually recurring influenza.

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