

Start of Phase I Study for Intranasal Pandemic Influenza Vaccine deltaFLU

AVIR Green Hills Biotechnology Inc. Vienna-Austria-Europe

Vienna (Austria), July 09, 2008 – Avir Green Hills Biotechnology starts a clinical phase I study with its intranasal vaccine deltaFLU against pandemic influenza. This novel generation of a live-attenuated vaccine based on the deletion of the NS1 gene has shown superior preclinical data. In taking this step, the Viennese biotech company sets yet another milestone in the development of effective and safe vaccines.

Aim of Phase I Study

The randomized, double-blind phase I study of the pandemic vaccine deltaFLU will be run at the Department of Clinical Pharmacology, Medical University of Vienna. The aim of phase I study is to analyze the safety and efficacy of the vaccine in healthy volunteers.

Preclinical Data, Pandemic Vaccine

“Our vaccine lacks the pathogenicity factor NS1. Due to this deletion, the vaccine is likely to show a superior safety profile. We are confident that the pandemic deltaFLU vaccine will be tolerated even at high doses,” comments Thomas Muster, founder and CEO/CSO of Avir Green Hills Biotechnology.

Outstanding preclinical data show an excellent immune response even against distantly related pandemic H5 strains (cross-protection). Moreover, a long lasting immune response - an important prerequisite for an effective vaccine - was observed.

“We are very pleased about the success of our vaccine in the preclinical studies. The data are superb and exceed our highest expectations,” reports Andrej Egorov, who is Vice President for Research at Avir Green Hills Biotechnology and one of the leading experts in the field of live attenuated influenza vaccines.

The novel influenza vaccine deltaFLU

differs from a conventional influenza vaccine in three major characteristics and in the method of production:

1. 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 virus entry.

2. Effective Immune Response

Though the vaccine looks like a pathogenic influenza virus to the body, it does not cause disease. However, after intranasal application, the vaccine stimulates a strong immune response, which offers protection against influenza. In other words, the vaccine “fakes” an infection that induces an immune response without causing illness.

3. Cross-Protection

The vaccine can induce an effective immune response against a wide range of influenza virus variants, which is only conditionally possible with conventional vaccines. This cross-reactivity can also provide protection against distantly related “drift variants” of pandemic influenza strains.

4. Cell-Based Production Method

The technology used by Avir Green Hills Biotechnology comprises a modern production method in cell cultures and does not rely on traditional egg-based manufacturing. In addition, Avir Green Hills Biotechnology has optimized the method of reverse genetics, which permits the generation of a vaccine against any potential influenza virus within a very short period of time. This might be essential for a timely response in pandemic situations.

Avir Green Hills Biotechnology Inc.

is a biopharmaceutical company based in Vienna, founded in 2002. Avir Green Hills Biotechnology's core competence is the development of innovative, therapeutic and prophylactic products against viral infections and cancer. "Our strength is our extensive know-how in virology and our network of renowned national and international partners in academia and industry," says Joachim Seipelt, Co-Founder and Vice President for Cooperation at Avir Green Hills Biotechnology.

After completion of phase I clinical trials, Avir Green Hills Biotechnology will start clinical phase II studies with the pandemic and the seasonal deltaFLU vaccines in 2009. Subsequently, Avir Green Hills Biotechnology plans to perform a phase III challenge trial against seasonal influenza, which will allow early proof of efficacy. These studies will provide the basis for phase III field trials leading to market authorization.

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