Novartis gains European approval for its innovative flu vaccine Optaflu®

- Novartis proprietary cell culture technology offers independence from chicken eggs for vaccine production and enables flexible, faster start-up of manufacturing
- New technology provides possibility to obtain a better matched vaccine with circulating viruses than currently available technologies

Basel, June 13, 2007 – Optaflu®, the first influenza vaccine to utilize a Novartis proprietary cell line for the production of viral antigen components rather than the traditional chicken eggs, has received European Union approval in all 27 member states, as well as Iceland and Norway.

Optaflu, has been approved for use in vaccination against seasonal influenza and contributes to meeting the growing demand for seasonal influenza vaccines. The use of a Novartis proprietary cell culture technology enables a faster and more flexible start-up of vaccine manufacturing, offering the potential to more quickly respond to a potential pandemic influenza threat.

“Optaflu marks the first major innovation in influenza vaccine manufacturing in over 50 years. This vaccine, which is based on our proprietary cell culture technology, would provide for a more flexible and reliable production process, so as to contribute to meeting the ongoing need for seasonal influenza vaccines and the potential need for influenza vaccines in the event of a pandemic," said Dr. Jörg Reinhardt, CEO of Novartis Vaccines and Diagnostics.

This new vaccine is expected to be available in Germany and Austria for the 2007/2008 influenza season and to be available in the remaining EU countries for the 2008/2009 influenza season. A submission for US regulatory approval is anticipated for 2008.

Influenza can cause mild to severe illness and may also lead to death. Influenza epidemics result in approximately 250,000 to 500,000 deaths each year worldwide¹. Influenza-related complications can include pneumonia and dehydration and worsening of chronic conditions, such as congestive heart failure, asthma, or diabetes². The World Health Organization (WHO) and its Global Influenza Surveillance Network recommend vaccination as the principal method for preventing influenza¹.

Increased circulation of avian influenza A/H5N1 virus has been documented in Asia and Europe. On a pandemic threat scale of one to six, WHO currently ranks the H5N1 risk at phase three. This virus is highly contagious in chickens, adding the possibility that a pandemic strain could emerge at a time when egg supplies are lower than usual due to a previous epidemic in chickens. Novartis proprietary cell culture line offers an alternative to traditional egg-derived vaccines.
More than 3,400 people received Optaflu during the clinical development program evaluating the vaccine's safety and immunogenicity. This data showed Optaflu fulfilled all of the European Union’s immunogenicity and safety criteria.

The results further showed this cell culture-derived vaccine was comparable to conventional egg-based vaccines in stimulating an immune response and tolerability. Additives, such as antibiotics and thiomersal, are avoided in the Optaflu production process. Additionally, people allergic to eggs and egg products can benefit from this vaccine since it is created without egg proteins.

Optaflu is administered via intramuscular injection like established, conventional egg-based vaccines. Data from the Phase III clinical program were presented at the Influenza Vaccines for the World Congress (IVW) meeting in October 2006. Additional data was also presented at Options for the Control of Influenza VI Conference (Options VI) in Toronto in June 2007.

**Cell culture technology first new innovation for influenza vaccines in 50 years**

Cell culture manufacturing is the first major innovation in influenza vaccine manufacturing in more than 50 years. It represents a new approach to vaccine production whereby influenza virus is propagated in readily available mammalian cell lines rather than in chicken eggs.

Virus cultivation utilizing the Novartis proprietary cell line as an exclusive host, offers the possibility of more robust virus proliferation, since most circulating viral strains are unable to replicate in chicken eggs. As a next generation of products, it also offers the possibility for vaccine seed strain development that more closely matches the original "wild" virus because cell culture technology eliminates the need for passage through eggs where the virus may be forced to adapt in order to replicate. As a result, the antigen included in the vaccine may express more authentically the surface of the wild type virus, potentially translating into a better immunogenic and effective response.

The Novartis proprietary cell culture technology enables flexible, faster start-up of vaccine manufacturing. With the advent of this technology, Novartis Vaccines is contributing to meet the growing need for seasonal influenza vaccines and quickly respond to potential pandemic influenza threats.

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Novartis Vaccines and Diagnostics is a division of Novartis focused on the development of preventive treatments and tools. The division is comprised of two activities: Novartis Vaccines and Chiron. Novartis Vaccines is the world’s fifth-largest manufacturer and second-largest supplier of influenza vaccines in the US. The division’s products include influenza, meningococcal, pediatric and travel vaccines. Chiron, the blood testing and molecular diagnostics business, is dedicated to preventing the spread of infectious diseases through the development of novel blood-screening tools. For more information, please visit http://www.novartisvaccines.com.

Novartis AG (NYSE: NVS) is a world leader in offering medicines to protect health, cure disease and improve well-being. Our goal is to discover, develop and successfully market innovative-products to treat patients, ease suffering and enhance the quality of life. We are strengthening our medicine-based portfolio, which is focused on strategic growth platforms in innovation driven pharmaceuticals, high-quality and low-cost generics, human vaccines and leading self-medication OTC brands. Novartis is the only company with leadership positions in these areas. In 2006, the Group’s businesses achieved net sales of USD 37.0 billion and net income of USD 7.2 billion. Approximately USD 5.4 billion was invested in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 100,000 associates and operate in over 140 countries around the world.

For more information, please visit http://www.novartis.com.

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