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Focetria[®], the Novartis pandemic influenza vaccine, receives European Union approval

- *Focetria to allow for more rapid response in the event of an influenza pandemic, to be adapted with identified viral strain after WHO pandemic declaration*
- *Focetria includes MF59 adjuvant – boosts the body's immune system and enhances protection with a lower dose of a viral antigen than other vaccines*

Basel, May 8, 2007 – Focetria[®], a new human vaccine designed for use following the declaration of an influenza pandemic, has received European Union approval in all 27 member states as well as Iceland and Norway.

Focetria will be manufactured to contain the influenza strain declared at the time of a pandemic by the World Health Organization (WHO). It will also include the proprietary adjuvant MF59, which was developed by Novartis and could extend the vaccine supply by allowing for smaller amounts of viral antigens to be used in each dose compared to vaccines without this additive.

“Novartis is pleased with this positive decision by the European Commission for Focetria,” said Dr. Jörg Reinhardt, CEO of Novartis Vaccines and Diagnostics, a division of Novartis. “The approval of this vaccine, which incorporates our proprietary MF59 adjuvant, marks an important milestone in preparations to combat a potential pandemic threat.”

Once the WHO declares a pandemic, Novartis will submit a revised application to the European Medicines Agency (EMA) to incorporate the identified viral strain. The Focetria mock-up file submitted for EU approval in early 2006 was based on clinical studies involving the MF59 adjuvant and different influenza strains with pandemic potential, including H5N1 and H9N2.

Separately, Novartis has submitted for European Union approval a pre-pandemic H5N1 influenza vaccine incorporating the MF59 adjuvant and based on the same technology as Focetria. This vaccine is intended for use prior to the declaration of a pandemic to help bolster the immune system of those receiving it to better defend against infections from a H5N1 virus.

Novartis commitment to pandemic preparedness

Novartis is working closely with government and regulatory officials worldwide to support pandemic preparedness efforts. Novartis has engaged in discussions with several governments concerning pandemic influenza vaccine supply and has received contracts to provide H5N1 vaccines for stockpiling.

Novartis is committed to supporting leadership initiatives by the WHO to ensure public safety in case of a pandemic, including the development of a global pandemic vaccine stockpile for developing countries. Novartis is also supportive of the WHO's leadership role in global pandemic planning. The WHO is a key global hub for pandemic preparedness, ensuring cohesion and coordination amongst all players involved, including the industry, governments of both developed or developing countries and their populations.

In January 2007, the US Department of Health and Human Services (HHS) awarded Novartis a USD 55 million contract to further develop the MF59 adjuvant technology for use in potentially extending vaccine supplies in case of a pandemic outbreak. An adjuvant is a substance added to a vaccine to enhance the body's immune response to the vaccine's active constituent, called the antigen.

Novartis has also developed a new influenza vaccine manufacturing process that utilizes a proprietary cell line, rather than chicken eggs, for antigen production. The Novartis proprietary cell culture technology may reduce production time to meet demands of influenza outbreaks and may also help to develop antigens for a wider range of viral strains that are difficult to grow in eggs. These are two important production advantages in the event of an influenza pandemic.

About H5N1 avian influenza

Global health authorities have identified H5N1 avian influenza as an aggressive viral strain with pandemic potential. While researchers have not quantified the likelihood of an outbreak, to date H5N1 has caused serious illness in Southeast Asia in more than 250 people. The mortality rate of patients investigated has been over 50%¹.

An influenza pandemic outbreak is expected to spread quickly globally, so the licensing and production of sufficient quantities of pandemic vaccines is considered an enormous challenge. The WHO has recommended early development of vaccines and their use to reduce disease severity and mortality in the event of an outbreak. The WHO has further stressed the need to work collaboratively with researchers and vaccine manufacturers to ensure that the largest possible amount of vaccines and antiviral drugs are available at the outbreak of a pandemic².

References

1 WHO Cumulative Number of Confirmed Human Cases of Avian Influenza, WHO Web site
http://www.who.int/csr/disease/avian_influenza/country/cases_table_2006_10_31/en/index.html, accessed February 6, 2007

2 WHO Strategic Action Plan for Pandemic Influenza 2006-2007, WHO website
http://www.who.int/csr/resources/publications/influenza/WHO_CDS_EPR_GIP_2006_2c.pdf, accessed February 6, 2007

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About Novartis

Novartis Vaccines and Diagnostics is a division of Novartis focused on the development of preventive treatments and tools. Novartis Vaccines is the world's fifth-largest manufacturer and second-largest supplier of influenza vaccines in the US. The division's products also include 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 that protect the world's blood supply.

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.novartisvaccines.com>.

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Media materials

For images and video related to the Novartis Vaccines influenza products, please visit www.thenewsmarket.com/novartisvaccines. Journalists may register and download print-quality images and broadcast-standard video from this site at no charge.

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