

MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG**Focetria® pandemic influenza vaccine receives positive European Union regulatory agency opinion supporting approval**

- *Approval of Focetria, an immune enhancing pandemic influenza vaccine, would allow for more rapid response in the event of influenza pandemic*

Basel, February 23, 2007 – Novartis announced today that it has received a positive opinion supporting European Union regulatory approval of the human vaccine Focetria® for use in the event of an pandemic influenza outbreak, such as one that could be caused by the H5N1 virus.

The Committee for Medicinal Products for Human Use (CHMP), which reviews applications for all 27 countries in the European Union as well as Iceland and Norway, has recommended approval of this new vaccine. The European Commission generally follows the recommendations of the CHMP and delivers its final decision within two to three months.

The EU submission for Focetria was considered a “mock-up” since it lays the groundwork for a more rapid approval and availability of a specific vaccine once a pandemic has been declared.

Focetria would be manufactured to contain the pandemic influenza strain declared at the time of a pandemic along with the proprietary adjuvant MF59 developed by Novartis. Studies have shown that MF59 could boost the body’s immune response to the vaccine’s active constituent and extend vaccine supplies by allowing for smaller amounts of viral antigens to be used in each dose compared to vaccines without this additive.

“The availability of a pandemic influenza vaccine soon after the declaration of a pandemic is essential to reduce disease burden and deaths. This positive recommendation for our proprietary MF59-adjuvanted pandemic vaccine brings us one step closer to achieving public health and pandemic preparedness goals,” said Dr. Jörg Reinhardt, CEO of Novartis Vaccines and Diagnostics, a division of Novartis.

“We are committed to working with governments and international organizations to reduce the impact of an influenza pandemic through ongoing research and development projects for pre-pandemic and pandemic influenza vaccines,” Reinhardt said.

Novartis submitted the Focetria mock-up file for EU approval in early 2006. Once the World Health Organization (WHO) declares a pandemic, Novartis will submit a revised application to the European Medicines Agency (EMA) to incorporate the identified viral strain. This revised application can be approved more quickly than a totally new application. The filing for the Novartis mock-up vaccine was based on clinical studies involving the MF59 adjuvant and different H5N1 strains with pandemic potential.

Separately, Novartis has submitted an MF59-adjuvanted H5N1 pre-pandemic influenza vaccine for EU approval based on the same technology as Focetria. This vaccine is intended for use prior to a pandemic declaration to help prime and boost the immune system of those receiving the vaccine 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 provided H5N1 vaccines for stockpiling, notably in the US and UK.

In January 2007, the US Department of Health and Human Services awarded Novartis a USD 55 million contract to further develop the adjuvant technology of MF59 in the US to potentially extend 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. Research supporting the use of the MF59 adjuvant includes:

- Clinical trial data presented at the Second International Conference on Influenza Vaccines for the World (IVW 2006) confirming that the addition of the MF59 adjuvant can augment antibody response and increase protection of subjects against circulating influenza strains not included in the vaccines
- Clinical research published in *The Lancet* in 2001 demonstrating that an MF59-adjuvanted vaccine, based on the non-pathogenic H5N3 virus strain, induced antibodies against H5N1 influenza virus at lower antigen levels
- A study published in the *Journal of Infectious Diseases* in 2005 showing that an MF59-adjuvanted vaccine induced broadly cross-reactive antibodies capable of neutralizing H5N1 viruses isolated from a number of Southeast Asian countries between 1997 and 2004
- Clinical trial data, supported by the US National Institutes of Health (NIH), of an MF59-adjuvanted vaccine against an H9N2 avian influenza virus that were published in 2006 in the online edition of *Clinical Infectious Diseases*; in this study, an MF59-adjuvanted vaccine induced antibody levels believed to offer protection using one quarter of the dose level used against a seasonal flu strain

Additionally, Novartis has developed a new vaccine manufacturing process that uses cell cultures rather than chicken eggs for antigen production. The new technology may reduce production time to meet demands of influenza outbreaks and to combat evolving strains of the virus, including avian influenza strains that are difficult to grow in eggs. The cell culture-based vaccine Optaflu[®] was submitted for EU regulatory approval in July 2006 and is currently in clinical studies in the US.

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 percent.¹

An influenza pandemic would be expected to spread quickly globally; licensing and production of sufficient quantities of pandemic vaccines is therefore an enormous challenge. The WHO recommends early vaccine development and use to reduce disease severity and mortality and stresses the need to work collaboratively with researchers and manufacturers towards ensuring that as much as possible, vaccines and antiviral drugs are available at the start of a pandemic².

Disclaimer

This release contains certain forward-looking statements, relating to the Novartis Group's business, which can be identified by the use of forward-looking terminology such as "supporting approval," "would," "could", "committed", "will," "can be," "may reduce" or similar expressions, or by express or implied discussions regarding potential marketing approvals or future sales of Focetria or other vaccines. Such statements reflect current views with respect to future events and are subject to certain risks, uncertainties and assumptions. There can be no guarantee that Focetria or other vaccines will be approved for any indications in any market or that Focetria or any vaccines will reach any particular sales levels. In particular, management's expectations regarding Focetria and other vaccines could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including additional analysis of existing clinical data and new clinical data; competition in general; the ability of Novartis to obtain or maintain patent or other proprietary intellectual property protection; increased government, industry, and general public pricing pressures; and other risks and factors referred to in the Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

About Novartis

Novartis Vaccines and Diagnostics is a new 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 101,000 associates and operate in over 140 countries around the world.

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