

Novartis submits first regulatory file for H5N1 adjuvanted influenza vaccine with European regulators for pre-pandemic avian influenza prevention

- *Pre-pandemic MF59-adjuvanted H5N1 vaccines could protect against a broader range of viruses in case of a avian flu pandemic situation*
- *Regulatory agencies evaluating the use of adjuvants such as MF59 for lessening the severity of a pandemic*

Basel, November 28, 2006 - Novartis announced today that the European Medicines Agency (EMA) has accepted for review the company's application for an MF59-adjuvanted pre-pandemic H5N1 influenza vaccine. Novartis' adjuvanted H5N1 vaccine is the first vaccine being evaluated for the prevention of infections from avian influenza (also known as "bird flu") in four clinical studies. It could be used prior to a pandemic outbreak, boosting the immune system's ability to defend against infections from a H5N1 virus strain.

"Novartis is committed to the development and supply of vaccines to protect against the possibility of a pandemic influenza outbreak. In addition, the use of our proprietary adjuvant MF59 has shown to be dose sparing and provide protection against a broader range of viral strains, while using lower amounts of viral antigens for the vaccine," said Dr. Joerg Reinhardt, CEO of Novartis Vaccines and Diagnostics. "Global public health advocates recognize avian influenza as a major worldwide health concern, we are preparing to develop and produce a vaccine that will help protect people before and during a pandemic."

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 those infected has been 50 percent.i

Because a viral pandemic would be expected to spread quickly, it is unlikely that manufacturers would be able to license and produce sufficient quantities of vaccines within the recommended prevention period. The World Health Organization (WHO) recommends early vaccination to control an outbreak and reduce mortality and stresses the need to work collaboratively with researchers and manufacturers to ensure that vaccines and antiretroviral drugs are available at the start of a pandemic.ii

More about Novartis' MF59 adjuvant

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. Recently presented data from a clinical trial using an MF59-adjuvanted vaccine compared to a non-adjuvanted egg-based vaccine reconfirmed that the addition of the MF59 adjuvant to a conventional seasonal influenza vaccine can augment the antibody response to the vaccination and increase protection of subjects against circulating influenza strains not included in the vaccines which may have undergone changes (heterovariants) from the strains recommended by WHO for the composition of seasonal vaccines. These findings were presented at the Second International Conference on Influenza Vaccines for the World (IVW 2006) in Vienna, Austria last month.

FLUAD is currently the only seasonal adjuvanted influenza vaccine licensed for use in Europe for use in those 65 years and older. FLUAD uses MF59 as adjuvant and has been demonstrated to be a well-tolerated vaccine which induces a stronger and broader protection than conventional non-adjuvanted

subunit vaccines, through induction of higher antibody levels and demonstrated improved clinical effectiveness. To date, more than 25 million doses of FLUAD have been distributed, and post-marketing surveillance data indicate that FLUAD is a well-tolerated and potent vaccine against influenza.

Novartis has developed a new production process known as cell culture-derived influenza vaccine technology, or "flu cell culture", which 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 flu cell culture based vaccine Optaflu was submitted to the EMEA in July and currently is in clinical studies in the United States.

Better protection shown with H5N1 vaccine containing MF59-adjuvant

Clinical research published in the Lancet in 2001 demonstrated that MF59-adjuvanted vaccine, based on the non-pathogenic H5N3 virus strain, induced antibodies against H5N1 influenza virus at lower antigen levels. In fact, the MF59-adjuvanted vaccine achieved these results using half the seasonal influenza dose. A follow-up study published in 2003 in the journal Vaccine explored the potential of longer-term protection following a booster dose of the vaccine administered 16 months after the original study. The clinical trial demonstrated that antibodies persisted for 16 months in the majority of the subjects who had received the MF59-adjuvanted vaccine and that a dose of the MF59-adjuvanted vaccine administered 16 months after the original study boosted antibodies back to protective levels.

A study published in the Journal of Infectious Diseases in 2005 showed that the 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. Seroconversion rates in this study, the percentage of subjects reaching protective antibody titers, were significantly higher than those achieved with non-adjuvanted vaccines, ranging from 43 percent up to 100 percent.

Data from a clinical study supported by the NIH of an MF59-adjuvanted vaccine against an H9N2 avian influenza virus were published in September in the online edition of Clinical Infectious Diseases. In this study, MF59-adjuvanted vaccine induced antibody levels believed to offer protection using one quarter of the dose level used against a seasonal flu strain. Novartis has provided the NIH with MF59-adjuvanted H5N1 vaccines for similar clinical testing.

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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 "could protect", "preparing to develop", "may reduce" or similar expressions, or by express or implied discussions regarding potential marketing approvals or future sales of influenza virus vaccines or other candidate 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 vaccine candidates will be approved for any indications in any market or that any candidate vaccines will reach any particular sales levels. In particular, management's expectations regarding commercialization of vaccine candidates could be affected by, among other things, additional analysis of clinical data; new clinical data; unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; the ability of Novartis to obtain or maintain patent or other proprietary intellectual property protection; competition in general; 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 U.S. 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. The division has two businesses: Novartis Vaccines and Chiron. Novartis Vaccines is the world's fifth-largest vaccines manufacturer and second-largest supplier of flu vaccines in the United States. Leading 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, treat 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. Novartis is the only company with leadership positions in both patented and generic pharmaceuticals. 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. In 2005, the Group's businesses achieved net sales of USD 32.2 billion and net income of USD 6.1 billion. Approximately USD 4.8 billion was invested in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 99,000 people and operate in over 140 countries around the world. For more information, please visit <http://www.novartis.com>.

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