NOVARTIS AG
Form 6-K
September 22, 2008

# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# FORM 6-K

**REPORT OF FOREIGN PRIVATE ISSUER**

**PURSUANT TO RULE 13a-16 or 15d-16 OF**

**THE SECURITIES EXCHANGE ACT OF 1934**

**Report on Form 6-K dated September 19, 2008**

**(Commission File No. 1-15024)**

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# Novartis AG

**(Name of Registrant)**

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(Address of Principal Executive Offices)

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**- Investor Relations Release -**

## Novartis MF59®-adjuvanted vaccine rapidly induces protective antibody levels against diverse strains of avian flu

- *Study shows the investigational pre-pandemic vaccine AFLUNOV® provides rapid immune response in individuals primed with MF59-adjuvanted H5 vaccine up to six years earlier(1)*

- *Individuals primed with MF59 adjuvant developed immunity seven days after receiving the AFLUNOV booster*

- *Study supports notion of pre-pandemic vaccination to ensure protective antibody levels in population with one additional immunization in the event of a pandemic*

**Basel, September 19, 2008** A new study shows that individuals immunized six years earlier with an MF59 adjuvanted H5N3 (clade 0) vaccine mounted a protective immune response seven days after a single immunization with an H5N1 (clade 1) vaccine containing the Novartis proprietary adjuvant MF59. The immune response was broadly cross reactive and covered all H5N1 clades known to date. These data were presented at the Third European Influenza Conference in Vilamoura, Portugal.

Responses were seen even against viral strains not included in either vaccine(1) suggesting proactive priming strategies with an MF59 adjuvanted-H5 vaccine may have the potential to help save lives in an avian influenza pandemic situation.

These data highlight the potential for priming the public against an avian influenza of pandemic proportion with the MF59 adjuvant. The results indicate that regardless of which avian strain individuals are originally primed with, they are quickly protected against a broad range of avian strains following their MF59-adjuvanted booster vaccine, even strains they were not initially inoculated against, said study investigator Iain Stephenson M.R.C.P., Infectious Diseases Unit, University Hospitals Leicester and Department of Inflammation, Infection and Immunity, University of Leicester, UK.

These results potentially provide a rationale to prevent pandemic influenza by proactively immunizing the public with stockpiled pre-pandemic vaccines containing MF59, Dr Stephenson added.

According to the trial results, healthy adults primed with an MF59-adjuvanted H5 vaccine at least 6 years ago, and boosted with the Novartis pre-pandemic vaccine AFLUNOV (7.5µg MF59-adjuvanted A/Vietnam/1194/2004 clade 1 H5N1), showed a protective cross-reacting antibody response to diverse H5N1 virus variants. Response was seen within 7 days and results were significantly higher ($P < 0.05$) at 14 days than those primed with a un-adjuvanted vaccine(1). In addition, these study

results suggest primed individuals would only need one dose of an MF59-adjuvanted vaccine in a pandemic situation to elicit initial protection reducing overall response time, and potentially the spread of the virus(1).

These findings show that priming subjects with the Novartis proprietary adjuvant MF59 included in AFLUNOV can induce long-lasting immune-memory and further supports a proactive priming strategy as part of pandemic preparedness efforts said Dr. Joerg Reinhardt, CEO of Novartis Vaccines and Diagnostics, a division of Novartis. Novartis Vaccines is committed to putting forth the most effective vaccine possible to help protect the global public against a possible pandemic situation.

An influenza pandemic occurs when a new influenza strain emerges (one to which humans have no immunity), mutates and spreads globally as a virus. Although it is not possible to predict the actual pandemic influenza strain, global health authorities have identified H5N1 avian influenza as a strain with the greatest pandemic potential in humans(3). H5N1 is currently circulating in birds and has caused serious illness in more than 380 people worldwide with a mortality rate, among people known to have been infected, of greater than 60 percent(4).

The purpose of pre-pandemic vaccination is to prime the immune system to better defend against infections from an H5N1 influenza virus and is intended for use before the World Health Organization (WHO) declares an influenza pandemic. AFLUNOV is the only pre-pandemic vaccine in development with an extensively-studied adjuvant, MF59, that is supported by more than 10 years of clinical safety data and commercial use.

**Study details**

In an open-label study, 54 healthy adults (age 23-60 years) received two doses of AFLUNOV (7.5µg MF59-adjuvanted A/Vietnam/1194/2004 clade 1 H5N1) vaccine 21 days apart. Twenty-four subjects were primed with either MF59-adjuvanted or an un-adjuvanted H5N3 (A/duck/Singapore/1997 clade 0-like) vaccine at least 6 years earlier and 30 subjects were unprimed(1). Some subjects also received a booster dose, 16 months after primary immunization. Pre and post-vaccination antibody to antigenically diverse H5 viruses were measured by hemagglutination-inhibition (HAI), neutralizing antibody (MN) and single radial hemolysis (SRH).

Among primed subjects, protective cross-reacting antibody titers to diverse H5N1 virus variants were seen by day 7 after a single vaccine dose(1). In subjects primed with an MF59-adjuvanted vaccine responses were statistically significantly higher ($P < 0.05$) than those primed with un-adjuvanted vaccine. By day 7, after one dose of AFLUNOV, ≥80% of MF59-H5 primed recipients achieved sero-protective HAI titers of ≥1:40 to all clade 1, 2.1, 2.2, and 2.3 avian H5 virus variants tested as well as the original antigen. In MF59-H5N3 primed subjects, responses were greatest at day 14 with geometric mean antibody titers of 1:378, 1:1754 and 73mm2 to the clade 1 A/Vietnam/2004 vaccine strain and 1:347, 1:2128 and 72mm2 to a clade 2 A/Turkey/2005 variant by HAI, MN and SRH respectively(1).

**Novartis Vaccines commitment to pandemic preparedness**

The immune-enhancing Novartis Vaccines proprietary adjuvant MF59 may enhance the body s immune response to the vaccine s active constituent (antigen) and offer varying degrees of cross-protection to better defend against the potentially dangerous disease causing infections from an H5N1 virus. In the seasonal influenza vaccine Fluad®, MF59 has been shown to better enhance the antibody response to vaccination when compared to non-adjuvanted vaccines, to increase protection in the elderly, and to provide protection even against influenza strains not included in the vaccine(5), (6). Fluad has a history of proven safety and tolerability, with more than 40 million doses distributed worldwide since 1997(7).

Novartis Vaccines is working closely with government and regulatory officials worldwide to support pandemic preparedness efforts, including engaging in government contracts to provide H5N1 vaccines for stockpiling. The Company has also been involved in discussions to educate government agencies about the benefits of proactive use of pre-pandemic vaccination in pandemic preparedness planning efforts.

Novartis Vaccines is supportive of the WHO s leadership role in global pandemic planning as discussed in the organization s THE WORLD HEALTH REPORT 2007: Global Public Health Security in the 21st Century. The WHO is a key global hub for pandemic preparedness, ensuring cohesion and coordination among all players involved, including the industry, governments of both developed or developing countries and their populations.

The Company also recognizes the importance of pandemic influenza preparedness planning within the business community in an effort to protect the global economy. With this commitment, Novartis Vaccines is working with business leaders to support their continuity planning for pandemic preparedness.

**Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as may , potential , potentially , suggest , would , can , committed , possible , intended , or similar expressions, or by express or implied discussions regarding the potential that AFLUNOV® or an MF59 adjuvanted vaccine will be approved for sale in any market, or regarding potential future revenues from such products. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of the Company regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results with to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that AFLUNOV® or an MF59 adjuvanted vaccine will be approved for sale in any market. Nor can there be any guarantee that such products will achieve any particular levels of revenue in the future. In particular, management s expectations could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; the Company s ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry and general public pricing pressures; the impact that the foregoing factors could have on the values attributed to the Novartis Group s assets and liabilities as recorded in the Group s consolidated balance sheet, and other risks and factors referred to in 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 AG provides healthcare solutions that address the evolving needs of patients and societies. Focused solely on healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic pharmaceuticals, preventive vaccines, diagnostic tools and consumer health products. Novartis is the only company with leading positions in these areas. In 2007, the Group s continuing operations (excluding divestments in 2007) achieved net sales of USD 38.1 billion and net income of USD 6.5 billion. Approximately USD 6.4 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 98,000 full-time associates and operate in over 140 countries around the world. For more information, please visit http://www.novartis.com

**References**


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(7) Company data on file.


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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**Novartis AG**

Date: September 19, 2008

By: /s/ MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham
Title: Head Group Financial Reporting and Accounting