NOVARTIS AG
Form 6-K
April 30, 2009

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 April 30, 2009

(Commission File No. 1-15024)

Novartis AG

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- Investor Relations Release -

Novartis investigational adjuvanted (MF59) pre-pandemic avian influenza vaccine Aflunov® shows long lasting, broadly cross-protective immune response

- *Aflunov® study published in PNAS demonstrated long-lasting immune memory of investigational MF59® adjuvanted pre-pandemic avian vaccine in adults up to seven years after vaccination*

- *Data suggests MF59 provides cross-protection for flu strain variations not contained in initial vaccine formulation*

- *Other Phase II studies reinforce safety and tolerability of the adjuvanted vaccine in children aged 6 months to 17 years*(1)

Basel, April 30 2009 A study published this week in the *Proceedings of the National Academy of Sciences of the United States of America* shows that Aflunov®, the Novartis investigational pre-pandemic avian influenza vaccine formulated with Novartis proprietary MF59® adjuvant, can elicit a broadly cross-reactive immune response covering all known H5N1 antigenic variants, even when that booster dose is administered six years after the initial priming dose.

The data show that the Novartis investigational adjuvanted vaccine elicited a long-lasting immune response that could be rapidly boosted following a single dose of the vaccine. This may provide public health officials additional flexibility to help protect citizens well in advance of an avian influenza pandemic. The study also showed that the adjuvanted vaccine created an immune memory not only against the H5N1 strain contained in the vaccine but also provided cross-protection against several other H5N1 strains.

These data reinforce the potentially broad applicability of the MF59 adjuvant and the role it can play in pandemic preparedness efforts around the world, said Andrin Oswald, CEO of Novartis Vaccines and Diagnostics. Cross-reactivity is an important element for a pre-pandemic vaccine given that variations are a common feature of emerging influenza strains. We will use these new insights, as well as our strong leadership position in cell based flu manufacturing, as part of our efforts to develop a vaccine against the current swine flu outbreak.

The findings published about the H5N1 vaccine suggest a way forward for the present swine flu outbreak, added Rino Rappuoli, Head of Research at Novartis Vaccines. We are working closely with the World Health Organization, U.S. Centers for Disease Control and Prevention (CDC), PAHO and other government agencies worldwide on developing a strong and effective response to the outbreak.

These data are part of several new studies presented this week at the Third International Conference on Influenza Vaccines for the World (IVW) in Cannes, France. Selected Aflunov data were previously presented in September 2008 at ESWI in Portugal, and announced at that time. Aflunov has not been tested on swine flu and has not been approved for sale in the U.S., Europe or other markets. A Phase II study has also demonstrated that Aflunov provided a protective immune response in children as young as 6 months to 17 years of age(1). It is the first and only pre-pandemic avian vaccine with a good safety profile and which is effective in building an immune response as early as 6 months of age(3).

To have a pre-pandemic vaccine that can produce a protective immune response in children as young as 6 months of age, as well as seniors is essential, said Timo Vesikari, M.D., Professor of virology and pediatrics and Director of the Vaccine Research Center at the University of Tampere, Finland. Children are not only at the biggest risk of complications from influenza, but they have been identified as the prime population for spreading the virus to all ages. We need to ensure that they are protected against a potential pandemic, which can strike at any time.

In a third study presented at IVW, Aflunov demonstrated that it could potentially be used to prime the general public against a potential influenza pandemic through a flexible dosing regimen, which would allow public health officials to immunize their citizens by administering the vaccine well in advance of a potential outbreak. The trial showed that a single priming dose of the vaccine was sufficient to develop immune memory in more than 90 percent of healthy adults, which could then be boosted one year later with either the same or a different strain of the avian influenza virus(2).

MF59 is the only flu adjuvant in a pre-pandemic program with an established safety profile, supported by more than 10 years of clinical safety data and more than 40 million doses of commercial use in Europe. The adjuvant has been studied in clinical trials involving more than 26,000 people, including children, and has been licensed for use in people 65 years of age and over in the seasonal influenza vaccine, Fluad®, since 1997 in the European Union(4). Fluad is not licensed for sale in the U.S.

Study details

The first study was a Phase II trial that involved 472 subjects aged 6 months to 17 years. The subjects were divided into three cohorts: toddlers 6-36 months of age, children 3-9 years of age and adolescents 9-17 years of age. Each age group was randomized in a 3-to-1 ratio to receive either the adjuvanted pre-pandemic vaccine (Aflunov) or Fluad, a seasonal influenza vaccine. Participants in the adjuvanted pre-pandemic vaccine arm received two 0.5 mL doses. Those in the Fluad arm received two 0.25 mL doses if they were younger than 3 years of age and one 0.5 mL dose if they were 3 years of age or older. Antibody responses were measured using standard hemagglutination inhibition (HI), single radial hemolysis (SRH) and microneutralization antibody response (MN) methods.

After the first dose of adjuvanted pre-pandemic vaccine, HI results demonstrated that two Committee for Medicinal Products for Human Use (CHMP) criteria were reached by the adolescent group and one was reached by the toddler and children groups. SRH results showed that all three cohorts fulfilled CHMP for geometric mean ratio and seroconversion. Following the second vaccination with the adjuvanted pre-pandemic vaccine, all three CHMP immunogenicity criteria were met in all three age groups as measured by HI and SRH. Further, 94 percent of toddlers, 92 percent of children and 72 percent of adolescents achieved at least a fourfold increase in MN titer over baseline and 99 percent of all three groups achieved an MN titer of ≥ 40 common measures of seroprotection(1).

The second study was a Phase II open-label trial that involved participants from 18 to 40 years of age. A subset of 99 subjects received one dose of adjuvanted pre-pandemic

vaccine (H5N1 clade 1 [Vietnam]) either three weeks before or after one dose of Agrippal (2007 season). A heterologous (H5N1 clade 2 [Turkey]) adjuvanted pre-pandemic vaccine booster dose, mixed with Agrippal, was administered one year later.

Antibody responses were measured one, two and three weeks later to assess cross-reactivity by HI, MN and SRH and measure seroconversion and seroprotection. After priming, the vaccine gave similar seroconversion (>40 percent) and seroprotection (>40 percent) rates against homologous virus as seen in previous studies three weeks post-vaccination. All three EMEA licensure criteria were met using both HI and SRH assays(2).

Heterologous boosting produced memory immune responses, evident within one week, in more than 90 percent of the subjects. Seroconversion and seroprotection rates were equivalent to those seen after homologous priming(2).

Novartis Vaccines commitment to pandemic preparedness

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.

Novartis Vaccines is working closely with government and regulatory officials worldwide to support pandemic preparedness efforts, including providing 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. 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.

Novartis is the only vaccines manufacturer that has an established, licensed FCC (Flu cell culture) facility which is operating in Marburg, Germany. A second facility, a collaboration with HHS, Department of Health and Humans Services, U.S, is under construction in Holly Springs, North Carolina.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as suggests, can , could, may, potentially will, expect, suggest, potential, could, would, commitment, preparedness, planning, or similar expressions, or by express or impl regarding potential marketing approvals for Aflunov or regarding potential future revenues from Aflunov or from other pandemic preparedness efforts. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of management regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Aflunov will be approved for any sale in any market. Nor can there be any guarantee that Aflunov or our pandemic preparedness efforts will achieve any particular levels of revenue in the future. In particular, management s expectations could be affected by, among other things, unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; competition in general; government, industry and general public pricing pressures; the company s ability to obtain or maintain patent or other proprietary intellectual property protection; 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 Vaccines and Diagnostics is a Novartis division 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 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 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 2008, the Group s continuing operations achieved net sales of USD 41.5 billion and net income of USD 8.2 billion. Approximately USD 7.2 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 98,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit http://www.novartis.com.

References

(1) Anke Hilbert, Elena Fragapane Nicola Groth, Sandrine Tilman, Timo Vesikari. A Phase II, randomized, controlled, observer-blind, single-center study to evaluate the immunogenicity, safety and tolerability of two doses of MF59®-adjuvanted H5N1 influenza vaccine, AFLUNOV®, in subjects aged 6 months to 17 years. Accessed March 24, 2009.

(2) Angelika Banzhoff, Elena Fragapane, Volker Brauer, Emanuele Montomoli, Chiara Gentile, Anke Hilbert, Sandrine Tilman, Pio Lopez; Novartis AG. M459-Adjuvanted H5N1 Prepandemic Influenza Vaccine Demonstrates Flexible Prime Boosting. Accessed March 23, 2009.

(3) Timo Vesikari. Aphase II randomized, controlled, observer-blind, single center study to evaluate the immunogenicity, safety and tolerability of two doses of MF59-adjuvanted HF5N1 influenza vaccine, AFLUNOV, in subjects aged 6 months to 17 years. University of Tampere Medical School, Finland. Accessed March 23, 2009

(4) Ott Gary et al. The Adjuvant MF59: A 10-Year Perspective, Methods in Molecular Medicine., Vol 42: Vaccine Adjuvants: Preparation Methods and Research Protocols

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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: April 30, 2009

By: /s/ MALCOLM B. CHEETHAM

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