NOVARTIS AG
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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 October 22, 2010

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

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(Address of Principal Executive Offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F: x Form 40-F: o

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- Investor Relations Release -

Novartis Phase III study indicates MF59® adjuvanted influenza vaccine, Fluad®, is 75 percent more efficacious than studied non-adjuvanted vaccines in young children

- *Phase III results demonstrate 89 percent efficacy of Fluad (vs. 45 percent in non-adjuvanted vaccine group) in children between 6 months and 6 years of age against confirmed influenza illness(1a)*

- *Fluad, containing Novartis MF59 adjuvant, was generally well tolerated(1a), (1b)*

- *Study results support potential use of MF59 adjuvanted seasonal influenza vaccine in the pediatric population(1a)*

Basel, Oct. 22, 2010 New Phase III data demonstrate that MF59® adjuvanted influenza vaccine, Fluad®, was highly efficacious in protecting infants and young children against seasonal influenza(1a), (1b). This is the first efficacy study of an adjuvanted seasonal influenza vaccine in any pediatric population and the largest randomized, controlled efficacy study of influenza vaccination in children between 6 months and 6 years of age(1a). These data were presented at the 48th Annual Meeting of the Infectious Disease Society of America (IDSA) held in Vancouver, Canada. Fluad is not currently licensed for this age group.

The pivotal trial enrolling more than 4,700 children(1c) met its primary endpoints(1a), (1d). Fluad demonstrated 89 percent efficacy against vaccine-matched strains over two influenza seasons compared with 45 percent for the non-adjuvanted seasonal influenza vaccines group(1e). Results also showed that the MF59 adjuvanted vaccine has an acceptable tolerability profile, similar to the non-adjuvanted influenza vaccines used in the study(1a), (1f). These data have the potential to support the suitability of the MF59 adjuvanted vaccine for use in the pediatric population(1a), a population at high risk of influenza infection and transmission(2).

Additional analyses and data subsets are expected to be published in the coming months.

Infants and children are particularly susceptible to influenza, partially due to their still maturing immune systems, and they can transmit the virus easily to those around them. Immunization is a critical component of protecting our families and communities against the potentially devastating effects of influenza, said Andrin Oswald, Division Head of Novartis Vaccines and Diagnostics. As a leader in the field of influenza vaccines, Novartis is committed to developing next-generation vaccine technologies to combat the global threat of seasonal and pandemic influenza.

Severe influenza complications, such as pneumonia, are most common in children younger than 2 years of age, and may result in serious illness or death(3a), (4). Each year an average of 20,000 children under the age of 5 in the U.S. are hospitalized because of influenza complications(3b). The associated annual public health cost burden can reach up to 250 million US dollars(5), (6).

Clinical Trial Results and Design

The Phase III randomized, blinded, controlled study was conducted at trial sites in Germany and Finland(1g), (1h). The study aimed to assess the reactogenicity of the MF59 adjuvanted influenza vaccine compared with non-adjuvanted influenza vaccines, and the protective efficacy of the MF59 adjuvanted vaccine against confirmed influenza illness compared with non-adjuvanted influenza vaccine and non-influenza control vaccines(1d). During the 2007-08 and 2008-09 influenza seasons, children between 6 months and 6 years of age (n=4707) were randomized in three groups: two doses of the MF59 adjuvanted seasonal vaccine, a standard trivalent influenza vaccine or non-influenza control vaccines(1c), (1i). Antibody levels were measured on Days 1 (pre-vaccination), 29, 51 and 181(1h). Solicited and unsolicited adverse reactions were recorded for 7 and 28 days after each injection(1j). The non-adjuvanted vaccines studied in the trial were AgrippalS1® (Novartis Vaccines) and Influsplit SSW® (GSK Biologicals)(1k).

Fluad demonstrated 89 percent (95% CI: 78 - 95%) efficacy against disease caused by vaccine-matched strains and 86 percent (CI: 74 93%) efficacy against all circulating strains, versus 45 percent (CI: 16 64%) and 43 percent (CI: 15 61%) for the non-adjuvanted influenza vaccines, respectively(1e). Relative efficacy of the adjuvanted influenza vaccine was 75 percent (CI: 55 87%) versus non adjuvanted vaccines against all PCR-confirmed cases of influenza(1e).

Fluad was generally well tolerated(1a). Solicited local and systemic adverse events in the 6 to 36 month olds were similar for the vaccine groups(1f). Systemic reactions were slightly more frequent in older children receiving the MF59 adjuvanted vaccine(1f). The majority of adverse reactions were mild to moderate in severity, and frequencies of serious adverse events were similar in all vaccines groups(1f).

About MF59

Novartis MF59 adjuvant has been designed to improve immune response to vaccine antigens(7a), (7b). It is the only oil-in-water adjuvant supported by more than 13 years of post-marketing clinical safety data and more than 158 million doses distributed for use in elderly, adults and children as young as 6 months of age(8).

About Fluad

Fluad is the only commercially-available, inactivated, subunit seasonal influenza vaccine containing the Novartis MF59 adjuvant. Fluad is indicated for active immunization against seasonal influenza in individuals 65 years of age and older(8). Fluad has been available in Europe since 1997(7c) and is currently licensed by 13 European Health Authorities and more than 10 other countries in Asia-Pacific and Latin America(8). Fluad is not currently licensed in the United States or Canada(8). Currently, Novartis Vaccines seasonal influenza vaccines licensed in the United States and Canada are indicated for persons aged four and above(8).

Important Safety Information

Fluad is indicated for active immunization against seasonal influenza in individuals 65 years of age and older, and especially for those with an increased risk of associated complications due to underlying chronic conditions, including diabetes, cardiovascular and respiratory diseases. In China, Fluad is indicated for active immunization against seasonal influenza in individuals 60 years of age and older.

Fluad should not be administered to individuals with known hypersensitivity to any component of Fluad or to eggs, chicken proteins, kanamycin and neomycin sulfate, formaldehyde and cetyltrimethy lammonium bromide. Fluad should not be administered to people who have febrile illness or an acute infection.

The most common local adverse reactions to Fluad include injection site pain, redness, swelling, ecchymosis and induration. The most common systemic reactions include fever, malaise, shivering, fatigue, headache, sweating, myalgia and arthralgia.

Vaccination with Fluad may not protect all individuals. Patients with endogenous or iatrogenic immunosuppression or are undergoing immunosuppressant treatment may have an inadequate response to vaccination.

Before administering Fluad, please see full Prescribing Information.

About Novartis Vaccines

Novartis Vaccines and Diagnostics is a division of Novartis, focused on the development of preventive treatments. The division has two businesses: Novartis Vaccines and Novartis Diagnostics. 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. Novartis Diagnostics, the blood testing 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 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 2009, the Group s continuing operations achieved net sales of USD 44.3 billion, while approximately USD 7.5 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 102,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit http://www.novartis.com.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as potential, expected, potentially, committed, may, can, designed, or similar expressions, or by express or implied discussions regarding potential new indications or labeling for Fluad, or potential approvals to sell Fluad in additional markets, or regarding potential future revenues from Fluad or MF59. 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 with Fluad to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Fluad will be submitted or approved for any additional indications or labeling in any market. Nor can there be any guarantee that Fluad will be submitted or approved for sale in any additional markets. Neither can there be any guarantee that Fluad or MF59 will achieve any particular levels of revenue in the future. In particular, management s expectations regarding Fluad 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.

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References

(1) Vesikari T, Knuf M, Wutzler P, et al. Efficacy of an MF59-adjuvanted seasonal influenza vaccine versus non-adjuvanted influenza vaccine and control vaccine in 6 <72 month old children. Presented at the 48th Annual Meeting of the Infectious Disease Society of America. October 21-24, 2010 Vancouver, British Columbia ,Canada.

(2) Centers for Disease Control and Prevention. 2010 Yellow Book. Chapter 2: The Pre-Travel Consultation Routine Vaccine-Preventable Diseases. Influenza (Seasonal, Avian, and Pandemic). Available at: http://wwwnc.cdc.gov/travel/yellowbook/2010/chapter-2/influenza-seasonal-avian-pandemic.aspx. Accessed on October 18, 2010.

(3) Centers for Disease Control and Prevention. Children, the Flu, and the Flu Vaccine. Available at: http://www.cdc.gov/flu/protect/children.htm. Accessed on October 18, 2010.

(4) Centers for Disease Control and Prevention. Flu Symptoms & Severity. Available at: http://www.cdc.gov/flu/about/disease/symptoms.htm. Accessed on October 18, 2010.

(5) Keren et al: Direct Medical Cost of Influenza-Related Hospitalizations in Children, Pediatrics 2006;118;e1321-e1327.

(6) Thompson et al: Influenza-Associated Hospitalizations in the United States, JAMA. 2004;292(11):1333-1340 (doi:10.1001/jama.292.11.1333).

(7) Podda, A., Del Giudice, G., O Hagan, D. MF59: A Safe and Potent Adjuvant for Human use. Immunopotentiators in Modern Vaccines.149-159.

(8) Novartis 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: October 22, 2010

By: /s/ MALCOLM B. CHEETHAM

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