NOVARTIS AG
Form 6-K
April 23, 2010

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 23, 2010

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

Lichtstrasse 35

4056 Basel

Switzerland

(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

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Yes: o **No**: x

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Yes: o **No**: x

Indicate by check mark whether the registrant by furnishing the information contained in this form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes: o **No**: x

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- Investor Relations Release -

Novartis gains new indication for Diovan®* for the treatment of children and adolescents with high blood pressure in the EU

- *New indication brings the world s number one selling high blood pressure medication to patients 6-18 years, for whom treatment options have been limited*

- *Pediatric high blood pressure is increasingly recognized as a cause for concern, particularly as it is becoming more common*

- *Occurrence in childhood and adolescence increases the risk of developing the condition as an adult, underlining the importance of early blood pressure control*

Basel, April 23, 2010 The European Commission (EC) has granted Diovan® (valsartan) a new pediatric indication for the treatment of hypertension in children and adolescents 6-18 years of age. Following the Commission s decision, the pediatric indication needs to be implemented through EU National Competent Authorities before Diovan will be available for pediatric use across the European Union (EU), both in the existing tablet formulations as well as a newly developed oral solution.

Following national implementation across the EU, Novartis intends to apply for a six-month exclusivity extension of the protection for valsartan (the active ingredient in Diovan), in line with the European Pediatric Regulation.

Evidence suggests that there are in fact more cases of pediatric high blood pressure in the EU than previously thought(1). While the total number of children with high blood pressure in the EU is unknown, data from various EU countries suggest an average prevalence rate of up to 11%(2). European Society of Hypertension (ESH) guidelines emphasize that high blood pressure in childhood and adolescence increases the risk of developing the condition in adulthood(3), which can subsequently lead to an increased risk of cardiovascular disease and damage to vital organs such as the heart and kidney(4).

We are seeing an increasing number of children and adolescents being diagnosed with high blood pressure, a trend largely the result of the growing number of young people who are overweight or obese, said Franz Schaefer, MD, Professor of Pediatrics and Chief of the Pediatric Nephrology Division, Heidelberg University Hospital, Germany. The only way to help reduce the impact of this condition in this patient group is to improve the identification and treatment of it.

Diovan was also approved for pediatric use in the United States by the Food and Drug Administration (FDA) in December 2008, for the treatment of children aged 6-16 years with high blood pressure(5).

Diovan is the world s number one selling high blood pressure medication(6). It provides the flexibility of a wide range of single-pill combinations and dosing options, all with the convenience of a once-daily treatment schedule. These include Co-Diovan® (valsartan/hydrochlorothiazide), Exforge® (valsartan/amlodipine) and Exforge HCT® (valsartan/amlodipine/hydrochlorothiazide).

In addition to the valsartan family of products, the Novartis portfolio of cardiovascular and metabolic medications for the treatment of high blood pressure and diabetes includes the first and only approved direct renin inhibitor, Rasilez® (aliskiren), and its single-pill combination formulations, Rasilez HCT® (aliskiren/hydrochlorothiazide) and Valturna® (aliskiren/valsartan); and Galvus® (vildagliptin) and Eucreas® (vildagliptin/metformin) for the treatment of type 2 diabetes.

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*Diovan is marketed under several trade names in EU countries

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as risk, will, intends, can, or similar expressions, or by express or implied discussions regarding a potential exclusivity extension for Diovan or regarding potential future revenues from Diovan. 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 Diovan will be granted an exclusivity extension. Nor can there be any guarantee that Diovan will achieve any particular levels of revenue in the future. In particular, management s expectations regarding Diovan could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; the ability of the company and its competitors to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry and general public pricing pressures; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; 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 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 100,000 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) Lurbe E, et al. Management of high blood pressure in children and adolescents: recommendations of the European Society of Hypertension. J Hypertens 2009;27:1719-42.

(2) Gilardini L. Sympathoadrenergic and metabolic factors are involved in ambulatory blood pressure rise in childhood obesity. J Hum Hypertens 2008;22:75-82.

(3) Flynn JT. Hypertension in the young: epidemiology, sequelae and therapy. Nephrol Dial Transplant 2009;24:370-5.

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(5) Diovan® US Prescribing Information.

(6) IMS Midas Worldwide Sales Data. December 2009.

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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 23, 2010

By: /s/ MALCOLM B. CHEETHAM

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