

NOVARTIS AG  
Form 6-K  
May 04, 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)

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**Novartis AG**

(Name of Registrant)

Lichtstrasse 35

4056 Basel

Switzerland

(Address of Principal Executive Offices)

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

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**Form 20-F:**  **Form 40-F:**

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:  **No:**

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Yes:  **No:**

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:  **No:**

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**Novartis International AG**  
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**- Investor Relations Release -**

**FDA approves Exforge HCT® - the only high blood pressure treatment to combine three medications in a single pill**

- *Exforge HCT combines in one pill a calcium channel blocker, angiotensin receptor blocker and diuretic (amlodipine, valsartan, hydrochlorothiazide)*
- *In a clinical trial, Exforge HCT demonstrated significantly greater reductions in systolic and diastolic BP, compared to all dual combinations of its components(1)*
- *Up to 85% of patients may need multiple medications to help control their blood pressure(2) and many need three or more(1)*
- *Exforge HCT can help appropriate patients reach BP goals; offers convenience and potential cost savings by reducing up to three co-payments to one*

**Basel, 30 April, 2009** The US Food and Drug Administration (FDA) has approved Exforge HCT, the only single pill to combine the three most prescribed high blood pressure treatments in their classes in the US(3): the calcium channel blocker amlodipine, the angiotensin receptor blocker valsartan, and the diuretic hydrochlorothiazide. Exforge HCT is an important new option for patients who have tried taking dual combinations of these classes of blood pressure medications without success.

The majority of people with hypertension will require more than one medication to control their blood pressure and it is not uncommon for patients with severe hypertension and/or patients requiring stricter blood pressure control to need three or more medications, said David A. Calhoun, MD, Professor of Medicine, Vascular Biology and Hypertension Program, University of Alabama at Birmingham. With a triple combination option, appropriate patients may experience a simpler routine of a convenient, once-daily pill to help them control their high blood pressure.

Exforge HCT provides proven efficacy in patients with moderate to severe hypertension (MSDBP 100 mmHg and <120 mmHg, MSSBP 145 mmHg and <200 mmHg)(1). In a clinical trial, the maximum dose of Exforge HCT (amlodipine/valsartan/hydrochlorothiazide 10 mg/320 mg/25 mg) demonstrated additional reductions of 18-29% in systolic blood pressure and 19-32% in diastolic blood pressure when compared to all dual combinations of its components at the same doses(1),(4). The reductions in systolic/diastolic blood pressure with Exforge HCT were 7.6/5.0 mmHg greater than with valsartan/hydrochlorothiazide 320 mg/25 mg; 6.2/3.3 mmHg greater than with amlodipine/valsartan 10mg/320 mg; and 8.2/5.3 mmHg greater than with amlodipine/hydrochlorothiazide 10 mg/25 mg(4). These results also include a placebo effect of unknown size. Ambulatory blood pressure monitoring showed that the blood pressure lowering effect of Exforge HCT was maintained throughout the 24-hour period(4).



High blood pressure affects approximately 74 million adults in the US and one in four adults worldwide<sup>(5)</sup>. If high blood pressure is not treated, it can lead to heart attack and stroke<sup>(6)</sup>. Exforge HCT is not indicated for the treatment or prevention of heart attack or stroke.

Research suggests that up to 85% of patients may need multiple medications<sup>(2)</sup> and many need three or more<sup>(1)</sup> to help control their blood pressure. Patients may find treatment more convenient with one single pill rather than separate pills.

Exforge HCT contains three effective medicines that work in three different ways<sup>(1)</sup>. A patient may be switched to the single pill combination Exforge HCT if blood pressure is not adequately controlled on any two of the following anti-hypertensive classes: calcium channel blockers, angiotensin receptor blockers, and diuretics<sup>(4)</sup>. The full blood pressure lowering effect was achieved two weeks after being on the maximal dose of Exforge HCT<sup>(4)</sup>.

This approval of Exforge HCT as the only single blood pressure pill combining the efficacy of three of the most-prescribed treatments in their classes represents a significant milestone toward reducing the burden of unmet need in hypertension, said Trevor Mundel, MD, Global Head of Development at Novartis Pharma AG. Novartis remains confident in the important role of single pill combination medications to help appropriate patients achieve their blood pressure targets, while providing physicians with a range of powerful yet flexible combinations of doses to effectively manage high blood pressure in different patients.

Exforge and Exforge HCT will be offered at the same price in the US on a dose equivalent basis, essentially providing the added diuretic in Exforge HCT at no additional cost. Since Exforge HCT combines three medications in a single pill, patients may benefit from reduced insurance co-payments.

This FDA approval was based on a clinical trial of Exforge HCT of over 2,000 patients<sup>(1)</sup>. Exforge HCT is currently under review in the EU.

#### **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as may, can, potential, will, suggests, confident, or similar expressions, or by express or implied discussions regarding potential additional approvals for Exforge HCT or regarding potential future revenues from Exforge HCT. 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 Exforge HCT to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Exforge HCT will be approved for any sale in any additional market. Nor can there be any guarantee that Exforge HCT will achieve any particular levels of revenue in the future. In particular, management's expectations regarding Exforge HCT 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; 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 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>.

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## References

- (1) Grosso, A., Jin J., Chen J. An 8-week, multi-centre, randomized, double-blind, parallel-group study to evaluate the efficacy and safety of the combination of valsartan/HCTZ/amlodipine compared to valsartan/HCTZ, valsartan/amlodipine, and HCTZ/amlodipine in patients with moderate to severe hypertension. Novartis Full Clinical Study Report. 2008.
- (2) Pepine CJ, Handberg EM, Cooper-DeHoff RM, et al, for the INVEST Investigators. A calcium antagonist vs. a non-calcium antagonist hypertension treatment strategy for patients with coronary artery disease. The International Verapamil-Trandolapril Study (INVEST): a randomized controlled trial. *JAMA* 2003; 290:2805-2816.
- (3) IMS MIDAS sales data. February 2008 -January 2009
- (4) Exforge HCT US Product Information. April 2009
- (5) Lloyd-Jones, D., Adams, R, Carnethon, M. et al. Heart Disease and Stroke Statistics 2009 Update. A Report from the American Heart Association Statistics Committee and Stroke Statistics Committee. *Circulation*. 2009; ICD-9 401-404, ICD-10 I10-I15.
- (6) CDC High Blood Pressure Fact Sheet. June 2005.

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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