

NOVARTIS AG  
Form 6-K  
June 15, 2007

## 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 June 14, 2007

(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:  Form 40-F:

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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:

Novartis International AG  
Novartis Global Communications  
CH-4002 Basel  
Switzerland  
<http://www.novartis.com>

- Investor Relations Release -

**Prexige® study shows significantly less impact on blood pressure than ibuprofen in osteoarthritis patients with controlled hypertension**

- *New data from 741-patient trial show those treated with Prexige experienced significantly smaller impact on blood pressure compared to ibuprofen(1)*
- *Many patients with osteoarthritis also have high blood pressure; even small changes in blood pressure can impact cardiovascular risk(2),(3)*
- *Prexige approved in more than 50 countries and currently under review in US for use in osteoarthritis patients*

**Basel, June 15, 2007** Patients with osteoarthritis who also have controlled hypertension experienced a slight decrease in average daily blood pressure when treated with the selective COX-2 inhibitor Prexige® (lumiracoxib) compared to a slight increase in those taking ibuprofen, a commonly-used non-steroidal anti-inflammatory drug (NSAID)(1).

These new results, presented today at the Annual European Congress of Rheumatology (EULAR) in Barcelona, are important because around 40% of patients with osteoarthritis also have high blood pressure (or hypertension)(4),(5).

Independent research shows that even small elevations in blood pressure can contribute to an increased risk of cardiovascular events(2),(3),(6),(7),(8). Osteoarthritis is the most common form of arthritis affecting 139 million people worldwide(9).

NSAIDs, including some COX-2s, have been associated with raised blood pressure, and this effect may be in part responsible for the increased risk of cardiovascular disease associated with this class of medications, said Tom MacDonald, Ph.D., Professor of Clinical Pharmacology at the Hypertension Research Centre at Ninewells Hospital & Medical School in Dundee, Scotland. These data indicate that lumiracoxib may have less impact on blood pressure than the most commonly used NSAID ibuprofen.

Prexige, which is given to patients as a 100 mg once-daily tablet, is approved for use in certain types of patients with osteoarthritic pain of the knee and hip in more than 50 countries, including the European Union, Canada and Latin America.

In the US, this medicine is under review by the Food and Drug Administration (FDA) for relief of the signs and symptoms of osteoarthritis.

Evidence from the large-scale TARGET study has shown that Prexige is associated with significantly smaller increases in blood pressure than commonly used NSAIDs, said James Shannon, MD, Global Head of Development at Novartis Pharma AG. The new research underlines how important it is for osteoarthritis patients to have a treatment option such as Prexige.

The study presented at EULAR was a four-week, multicenter, randomized, double-blind, double-dummy, parallel group trial of 787 hypertensive osteoarthritis patients age 50 or older with ambulatory blood pressure of 140/90 mmHg or below, who were being treated with a antihypertensive medicine. A total of 741 patients completed the study, which compared Prexige 100 mg once-daily with ibuprofen 600 mg taken three times daily.

At the end of the study, patients on Prexige showed a decrease in mean ambulatory systolic blood pressure of 2.7 mmHg compared to a 2.2 mmHg increase in patients taking ibuprofen, giving an estimated difference of 5.0 mmHg between the groups ( $p < 0.001$ ). Mean ambulatory diastolic blood pressure decreased by 1.5 mmHg in Prexige patients compared to a 0.5 mmHg increase in those on ibuprofen, an estimated difference of 2.0 mmHg ( $p < 0.001$ ).

Systolic pressure represents the pressure within blood vessels when the heart contracts, while diastolic pressure is measured when the heart is at rest between beats. Both are monitored while the patient is active (or ambulatory), considered to be the most rigorous way of studying blood pressure. They are measured in millimeters of mercury or mmHg.

Results further showed Prexige and ibuprofen had similar efficacy as well as a comparable incidence of adverse events. These were mostly mild and did not indicate treatment-limiting toxicity. The most common adverse event in both treatment groups was upper abdominal pain, which occurred in less than 2% of patients.

Prexige has a different chemical structure from other COX-2 inhibitors. It is the only one that does not contain a sulphur molecule, which has been associated with sulphur-related skin reactions in some patients. Prexige also has a short plasma half-life of approximately four hours, yet provides 24-hour pain relief with a once-daily dose.

The clinical trial database for Prexige comprises approximately 40,000 patients, making it one of the largest bodies of evidence for any drug in its class. This includes the results of TARGET (Therapeutic Arthritis Research and Gastrointestinal Trial) involving more than 18,000 patients<sup>(10)</sup>. Results of this trial showed Prexige also significantly reduced the incidence of upper gastrointestinal complications by 79% in patients not taking aspirin compared to ibuprofen and naproxen<sup>(11)</sup>.

Novartis supports the recommendation of health authorities that anti-inflammatory treatments should be used in appropriate patients at the lowest possible dose for the shortest possible duration.

#### **Disclaimer**

The foregoing press release contains forward-looking statements such as can, may, or similar expressions, or by express or implied discussions regarding potential future regulatory filings or approvals or potential future sales of Prexige® (lumiracoxib). Such forward-looking statements reflect the current views of Novartis regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results with Prexige® (lumiracoxib) to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Prexige® (lumiracoxib) will be approved for sale in the U.S. or any other additional markets, or for any additional indications. Neither can there be any

guarantee that Prexige® (lumiracoxib) will reach any particular level of sales. In particular, management's expectations regarding Prexige® (lumiracoxib) could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; the public debate and regulatory activity regarding COX-2 inhibitors like Prexige® (lumiracoxib); unexpected clinical trial results, including additional analysis of existing clinical data and new clinical data; government, industry, and general public pricing pressures; competition in general; Novartis' ability to obtain or maintain patent or other proprietary intellectual property protection; as well as other risk factors discussed in Novartis AG's Form 20-F filed with the U.S. 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 described herein as anticipated, believed, estimated or expected. Novartis is providing this information as of this date and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

#### About Novartis

Novartis AG (NYSE: NVS) is a world leader in offering medicines to protect health, cure disease and improve well-being. Our goal is to discover, develop and successfully market innovative products to treat patients, ease suffering and enhance the quality of life. We are strengthening our medicine-based portfolio, which is focused on strategic growth platforms in innovation-driven pharmaceuticals, high-quality and low-cost generics, human vaccines and leading self-medication OTC brands. Novartis is the only company with leadership positions in these areas. In 2006, the Group's businesses achieved net sales of USD 37.0 billion and net income of USD 7.2 billion. Approximately USD 5.4 billion was invested in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 100,000 associates and operate in over 140 countries around the world. For more information, please visit <http://www.novartis.com>.

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**Novartis Media Relations**

**Corinne Hoff**

Novartis Global Media Relations  
+41 61 324 9577 (direct)  
+41 79 248 5717 (mobile)  
corinne.hoff@novartis.com

e-mail: media.relations@novartis.com

**Irina Ferluga**

Novartis Pharma Communications  
+ 41 61 324 2422 (direct)  
+ 41 79 824 1121 (mobile)  
irina.ferluga@novartis.com

**Novartis Investor Relations**

**International**

**Ruth Metzler-Arnold**

Katharina Ambühl  
Nafida Bendali  
Jason Hannon  
Thomas Hungerbuehler  
Richard Jarvis

+41 61 324 7944  
+41 61 324 5316  
+41 61 324 3514  
+41 61 324 2152  
+41 61 324 8425  
+41 61 324 4353

**North America**

**Ronen Tamir**

Jill Pozarek  
Edwin Valeriano

+1 212 830 2433  
+1 212 830 2445  
+1 212 830 2456

e-mail: investor.relations@novartis.com

**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: June 14, 2007

By: /s/ MALCOLM B. CHEETHAM

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