NOVARTIS AG
Form 6-K
April 02, 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 March 30, 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: 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

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: 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

Novartis International AG
Novartis Global Communications

CH-4002 Basel
Switzerland
http://www.novartis.com

- Investor Relations Release -

Novartis suspends US marketing and sales of Zelnorm® in response to request from FDA

- *Retrospective analysis of pooled clinical trial data shows numerical imbalance in cardiovascular events in patients taking Zelnorm compared to those on placebo*

- *FDA asks Novartis to suspend marketing and sales to permit further discussion of benefits and risks of Zelnorm*

- *Novartis believes Zelnorm provides important benefits for appropriate patients suffering from irritable bowel syndrome with constipation*

- *Discussions ongoing with FDA to evaluate best way to continue to make Zelnorm available to appropriate US patients*

Basel, March 30, 2007 Novartis is complying with a request from the Food and Drug Administration (FDA) to suspend US marketing and sales of Zelnorm®(1) (tegaserod maleate), a treatment for irritable bowel syndrome (IBS) with constipation and chronic constipation.

This action has been taken after Novartis notified the FDA about a retrospective analysis of data from more than 18,000 patients in the clinical trial database. This was the result of an ongoing review involving a number of health authorities including the FDA.

A small (but not statistically significant) imbalance in cases of angina pectoris was recorded and included in the US label when Zelnorm was approved in 2002. A recent analysis of the entire clinical database revealed a statistically significant imbalance in the incidence of cardiovascular ischemic events in patients taking Zelnorm/Zelmac compared to those taking placebo. These events included myocardial infarction, stroke, and unstable angina pectoris.

The data, which were reviewed by independent experts, showed that events occurred in 13 out of 11,614 patients treated with Zelnorm/Zelmac (0.11%), compared to one case in 7,031 placebo-treated patients (0.01%). All patients affected had pre-existing cardiovascular disease and/or CV risk factors.

The rate of cardiovascular ischemic events seen in Zelnorm/Zelmac-treated patients in controlled trials corresponds approximately with the expected rates for such events in the general population.

(1) Also marketed as Zelmac in some countries

My review of the data suggested that a causal relationship is unlikely between tegaserod and the rare cardiovascular ischemic events observed in clinical trials, said Jeffrey L. Anderson, MD, Professor of Internal Medicine at the University of Utah and Associate Chief, Cardiology Division, LDS Hospital in Salt Lake City and an independent cardiologist who reviewed the data. Furthermore, the data did not show any consistent pattern of event type, time to event or dose relationship in tegaserod-treated patients.

Multiple studies do not suggest any constrictive effects of Zelnorm on coronary arteries.

An estimated 12 million Americans suffer from the painful and disruptive symptoms of IBS with constipation. Many have symptoms for five to 10 years, which trigger missed work-days and often prevent them from participating in everyday activities with their family and friends.

Zelnorm/Zelmac provides unique benefits to patients by treating the multiple symptoms of abdominal pain, bloating and constipation that are associated with IBS with constipation, said James Shannon, MD, Global Head of Development at Novartis Pharma AG. Although we have complied with the FDA s request and are collaborating with the agency, we continue to believe that Zelnorm/Zelmac provides important benefits for appropriate patients.

Nevertheless, Novartis has suspended the marketing, sales and distribution of Zelnorm in response to the FDA s request, so that public discussion and an Advisory Committee meeting can take place to determine the risks and benefits of this medicine.

Novartis and the FDA will communicate this information to physicians and patients, and will discuss the best way to continue to make Zelnorm available to appropriate patients, including through a Treatment IND. US patients taking Zelnorm are being advised to consult their physicians.

Novartis is in discussion with health authorities in other countries where Zelnorm/Zelmac is available to determine next steps. Patients outside the US who have any concerns about Zelnorm/Zelmac should discuss the situation with their healthcare professional.

About Zelnorm

Zelnorm received FDA approval for the short-term treatment of women with IBS in the US on July 24, 2002. Zelnorm also received FDA approval for the treatment of men and women less than 65 years of age with chronic idiopathic constipation in the US on August 20, 2004.

Zelnorm/Zelmac is approved for the treatment of IBS with constipation in 50 countries including Australia, Switzerland, Canada, the US, Mexico, China and Brazil. Zelnorm/Zelmac is also approved for the treatment of chronic constipation in more than 20 countries including the US, Canada and Mexico. Novartis markets the therapy under the trademark Zelnorm (tegaserod maleate) in the US, Canada, Philippines and South Africa; and as Zelmac (tegaserod) in Switzerland, Latin America and the Asia-Pacific region.

Financial update

For its 2007 financial guidance, Novartis has revised its outlook for net sales growth, barring unforeseen events, for the Group to above five percent, and for the Pharmaceuticals division to a low- to mid-single-digit rate, both in local currencies.

Novartis is still evaluating the impact on the full-year 2007 operating and net income results from continuing operations (excluding the announced divestiture of Medical Nutrition expected to be completed in 2007).

An invitation will be issued to financial analysts to join an update telephone conference call at 19:00 Central European Summer Time (CEST) on Friday, March 30. A listen-only version of this event will be available on the Internet at www.novartis.com, where a recorded version of this conference call will be made available after the event.

Disclaimer

The foregoing release contains certain forward-looking statements that can be identified by terminology such as will, outlook, or similar expressions, or by express or implied discussions regarding potential future approvals to return Zelnorm/Zelmac to the market, or potential future sales of Zelnorm/Zelmac, or the potential impact of Zelnorm/Zelmac on the potential future sales or earnings of the Novartis Group or its Pharmaceuticals Division. Such forward-looking statements involve known and unknown risks, uncertainties or other factors that may cause the 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 Zelnorm/Zelmac will be approved by the FDA or other health authorities for return to the market for any indication, or that Zelnorm/Zelmac will achieve any particular level of sales. Nor can there be any guarantees that the Novartis Group, or the Pharmaceuticals Division, will achieve any particular financial results. In particular, management s expectations regarding these matters could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results or results of data analysis, including additional analysis of existing clinical data and other data regarding patients experience with Zelnorm/Zelmac, or unexpected new clinical or other such data; competition in general; government, industry and general public pricing pressures; the ability to obtain or maintain patent or other proprietary intellectual property protection; as well as factors discussed in the Company s Form 20-F filed with the US Securities and Exchange Commission. 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 (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 101,000 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

John Gilardi

Novartis Global Media Relations

+41 61 324 3018 (direct)

+41 79 596 1408 (mobile)

john.gilardi@novartis.com

Novartis Investor Relations

International:

Ruth Metzler-Arnold	+41 61 324 7944
Katharina Ambühl	+41 61 324 5316
Nafida Bendali	+41 61 324 3514
Jason Hannon	+41 61 324 2152
Thomas Hungerbuehler	+41 61 324 8425
Richard Jarvis	+41 61 324 4353

North America:

Ronen Tamir	+1 212 830 2433
Arun Nadiga	+1 212 830 2444
Jill Pozarek	+1 212 830 2445
Edwin Valeriano	+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: March 30, 2007

By: /s/ MALCOLM B. CHEETHAM

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