NOVARTIS AG
Form 6-K
December 22, 2006

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 December 22, 2006

(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

hppt://www.novartis.com

- Investor Relations Release -

Exforge® receives US regulatory approval as a new and highly effective treatment option for patients with high blood pressure

- ***Exforge offers in one tablet the complementary actions of valsartan and amlodipine besylate, two of the most prescribed branded antihypertensive medicines*(1), (2), (3)**
- ***Approval based on clinical data showing improved efficacy and side effect profile compared to amlodipine alone(4),(5)***
- ***Clinical trials show Exforge helped up to 9 out of 10 patients get to goal*(4)***
- ***US Food and Drug Administration grants tentative approval pending expiration of market exclusivity and patent protection for amlodipine besylate in September 2007***

* Diastolic blood pressure under 90 mmHg or more than a 10 mmHg reduction in diastolic blood pressure from baseline.

Basel, December 22, 2006 Novartis announced today the US regulatory approval of Exforge as a new treatment option for patients with high blood pressure. Exforge combines in one tablet the two most commonly prescribed hypertension medicines in their categories Diovan® (valsartan) and Norvasc®# (amlodipine besylate).

The US Food and Drug Administration (FDA) issued this tentative approval because Exforge has met all the required standards for safety, efficacy and manufacturing quality.(6) Exforge is expected to be available to patients in the US in late September 2007, pending the expiration of market exclusivity and patent protection for amlodipine besylate.

In an extensive clinical program involving over 5,000 patients, Exforge helped up to nine out of 10 patients reach their treatment goal (diastolic blood pressure under 90 mmHg or more than a 10 mmHg reduction in diastolic blood pressure from baseline).(4)

The combination of these two well-known and powerful antihypertensive medications in one tablet will now give patients additional blood pressure control with favorable tolerability, said Bertram Pitt, MD, FACC, Professor of Medicine Emeritus at the University of Michigan School of Medicine Division of Cardiology in Ann Arbor, Michigan, USA.

The need for new antihypertensive medicines is urgent, as seven out of 10 patients are not at their target blood pressure goal.(7),(8) High blood pressure is a leading risk factor for cardiovascular disease, which is the world s leading cause of death.(9)

Exforge is appropriate for patients whose blood pressure is not adequately controlled on any dihydropyridine calcium channel blocker (CCB) or angiotensin receptor blocker (ARB). Also, it is appropriate for patients who experience dose-limiting side effects on either component, such as amlodipine-induced edema, dizziness and flushing.(6)

Diovan blocks angiotensin II, a hormone that causes blood vessels to tighten and narrow(5), while amlodipine blocks the entrance of calcium into the blood vessel walls. Both allow blood vessels to relax so blood can flow more easily.(2),(3) Exforge also provides the convenience of a single once-daily tablet, which could reduce the overall number of pills a patient may need to take.(10)

Most patients need two or more medicines to control their blood pressure and achieve guideline targets, (6) said James Shannon, MD, Global Head of Development at Novartis Pharma AG. Exforge promises to be an attractive therapy option because it brings together two of the most powerful mechanisms of action in a single pill.

In November, Exforge was granted a positive opinion by the Committee for Medicinal Products for Human Use (CHMP), the regulatory agency that reviews European Union submissions for new medicines. Novartis expects to receive approval from the European Commission and to make Exforge available in the EU during the first half of 2007.

Disclaimer

The foregoing release contains forward-looking statements which can be identified by the use of terminology such as, tentative approval, pending expiration, expected, will, could, promises to be , or similar expressions, or by express or implied discussions regarding the potentia final marketing approvals of Exforge, or potential future revenue from Exforge. Such forward-looking statements 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 Exforge will be approved for any indications in the European Union, the United States or any other market, that Exforge will be brought to market in the EU, the US or in any other country, nor that Exforge will reach any particular sales levels. In particular, management s expectations regarding the approval and commercialization of Exforge could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected intellectual property issues involving the expiration of market exclusivity of amlodipine besylate; competition in general; increased government, industry, and general public pricing pressures; unexpected clinical trial results, including additional analysis of clinical data, or new clinical data; our ability to obtain or maintain patent or other proprietary intellectual property protection; 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 (NYSE: NVS) is a world leader in offering medicines to protect health, treat 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. Novartis is the only company with leadership positions in both patented and generic pharmaceuticals. 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. In 2005, the Group s businesses achieved net sales of USD 32.2 billion and net income of USD 6.1 billion. Approximately USD 4.8 billion was invested in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 99,000 people and operate in over 140 countries around the world. For more information, please visit http://www.novartis.com.

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(4) Data on File (Study VAA489A2201 and Study VAA489A2307). Novartis Pharmaceuticals Corporation. East Hanover, New Jersey. 07936.

(5) Data on File (Exforge Summary Clinical Efficacy). Novartis Pharmaceuticals Corporation. East Hanover, New Jersey. 07936.

(6) U.S. Food and Drug Administration. Manual of Policies and Procedures. Communicating Drug Approval Information. Available at: http://www.fda.gov/cder/mapp/4520-1.pdf. Accessed October 16, 2006.

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(10) Bloom BS. Daily regimen and compliance with treatment. BMJ 2001 September 22;323(7314):647. Available at: http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1121223. Accessed 10.17.06

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Media contacts

Richard Booton

Novartis Pharma Communications

+41 61 324 4356 (direct)

+41 79 753 2593 (mobile)

richard.booton@novartis.com

Corinne Hoff

Novartis Global Media Relations

+41 61 32 49577 (direct)

+41 79 248 5717 (mobile)

corinne.hoff@novartis.com

e-mail: media.relations@novartis.com

Novartis Global Investor Relations

International:

Ruth Metzler-Arnold	+41 61 324 79 44
Katharina Ambühl	+41 61 324 53 16
Nafida Bendali	+41 61 324 35 14
Jason Hannon	+41 61 324 21 52
Richard Jarvis	+41 61 324 43 53
Silke Zentner	+41 61 324 86 12

North America:

Ronen Tamir	+1 212 830 24 33
Arun Nadiga	+1 212 830 24 44
Jill Pozarek	+1 212 830 24 45
Edwin Valeriano	+1 212 830 24 56

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: December 22, 2006

By: /s/ Malcolm B. Cheetham

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