

NOVARTIS AG
Form 6-K
November 08, 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 November 7, 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: 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:

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

- Investor Relations Release -

Prexige® cleared for approval in the European Union as a new treatment option for patients suffering from osteoarthritic pain

- *Prexige offers patients effective osteoarthritic pain relief with significantly fewer serious gastrointestinal problems than NSAIDs(1)*
- *Prexige the best-studied NSAID pre-launch trial data from 34,000 patients offer largest-ever body of evidence to support the launch of an anti-inflammatory agent*
- *Novartis committed to supporting healthcare professionals with appropriate guidance for patient selection and product use*

Basel, November 7, 2006 Novartis announced today that Prexige® (lumiracoxib), an oral selective COX-2 inhibitor anti-inflammatory drug, has been cleared for approval in the European Union as a new treatment option for patients suffering from osteoarthritis. This is the most common form of arthritis and a leading cause of chronic pain(2).

Prexige has successfully completed the Mutual Recognition Procedure (MRP) in the European Union, and all 26 EU member states have agreed to issue national approval. Initial approval for Prexige was granted in the United Kingdom, where it has been available since December 2005.

In addition to the EU, Prexige is already approved in more than 25 countries. It is expected to become available in European countries during 2007 and 2008. Novartis plans to resubmit Prexige for US approval in 2007.

Prexige will be available in 100 mg tablets (once daily dosing) and indicated for the symptomatic relief in the treatment of knee and hip osteoarthritis. The decision was based on data from clinical trials involving 34,000 patients – the largest-ever body of evidence supporting the launch of an anti-inflammatory agent.

Prexige differs from other selective COX-2 inhibitors by targeting the site of pain, rapidly clearing from the blood and being quickly absorbed in the inflamed joint(4). Prexige offers similar pain relief to the commonly used osteoarthritis medication celecoxib(5),(6),(7),(8). However it has demonstrated a superior gastrointestinal safety profile to traditional non-steroidal anti-inflammatory drugs (NSAIDs)(1).

Many patients cannot tolerate the gastrointestinal side effects associated with NSAID pain treatments. In addition, not all osteoarthritis patients respond to currently available pain medications, said Dr. Gerd Burmester, Professor of Medicine at the Humboldt University in Berlin, Germany, and one of the leading investigators of the TARGET study. Lumiracoxib has

been extensively studied for both efficacy and safety and has the potential to provide a valuable new treatment option for physicians.

Gastrointestinal safety concerns for patients using NSAIDs are much more serious than an upset stomach or heartburn. Up to 16,500 people in the US⁽⁹⁾ and 2,500 in the UK⁽¹⁰⁾ die each year as a result of severe bleeding ulcers in the stomach and intestine, which usually occur without warning⁽¹¹⁾.

The TARGET study, the largest published one-year study of gastrointestinal safety outcomes in osteoarthritis patients to date (n=18,325), has demonstrated that Prexige significantly reduced the incidence of serious upper GI complications by 79% compared with the NSAIDs ibuprofen and naproxen in patients not taking aspirin⁽¹⁾. In further sub-analyses, Prexige reduced the risk of ulcer complications within the first month of use⁽¹²⁾ and offered significant benefit compared to naproxen in older patients at greater gastrointestinal risk⁽¹³⁾.

Furthermore, compared to NSAIDs, Prexige demonstrated a similar cardiovascular safety profile and a significantly smaller effect on blood pressure^{(14),(15)}.

Novartis has worked closely with the health authorities to ensure a full review of all Prexige efficacy and safety data, especially the cardiovascular data, to confirm the benefit for patients, said James Shannon, MD, Global Head of Development for Novartis Pharma AG. We are delighted that Prexige will soon be available to patients in Europe, and we are committed to providing physicians with the information they need to appropriately prescribe and select patients for Prexige.

Health authorities, including the European Medicines Agency and the US Food and Drug Administration (FDA), have concluded that the benefit/risk ratio for NSAIDs and selective COX-2 inhibitors remains positive when used in their target patient populations. Both Novartis and the health authorities agree that anti-inflammatory treatments should be used at the lowest possible dose for the shortest possible duration.

Disclaimer

The foregoing press release contains forward-looking statements that can be identified by the use of forward-looking terminology such as has the potential, will soon be, is expected to, plans to, or similar expressions, or by express or implied discussions regarding potential future regulatory filings, approvals or future sales of Prexige (lumiracoxib). 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 any current or future regulatory filings will satisfy the FDA's and other health authorities requirements regarding Prexige, that Prexige will be approved by the FDA or by any additional country's health authorities for any indication, or that Prexige will be brought to market in the US or any other country, or will reach any particular level of sales. In particular, management's expectations regarding Prexige could be affected by, among other things, regulatory actions or delays or government regulation generally; the public debate and regulatory activity regarding COX-2 inhibitors like Prexige; uncertainties relating to clinical trials and product development; and competition in general; as well as factors discussed in the Novartis AG's Form 20-F filed 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 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, 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>.

References

-
- (1) Schnitzer T, et al. Comparison of lumiracoxib with naproxen and ibuprofen in the Therapeutic Arthritis Research and Gastrointestinal Event Trial (TARGET), reduction in ulcer complications: a randomized controlled trial. *Lancet*. 2004; 364(9435): 665-674.
 - (2) Wolf AD, Pflieger B. Burden of Major Musculoskeletal Conditions. Policy and Practice. Special Theme-Bone and Joint Decade 2000-2010. *Bulletin of the World Health Organization* 2003, 81 (9): 646-656.
 - (3) Pain in Europe Survey 2003.
 - (4) Rordorf C, et al. Clinical pharmacology of lumiracoxib: a selective cyclo-oxygenase-2 inhibitor. *Clin Pharmacokinet* 2005; 44(12):1247-1266
 - (5) Pavelka K, et al. Lumiracoxib is effective and well tolerated in the long-term treatment of knee osteoarthritis. *Ann Rheum Dis* 2005;64(Suppl. 3):353 (Abstract FRI0319).
 - (6) Sheldon E, Beaulieu A, Paster Z, Dutta D, Yu S, Sloan VS. Efficacy and tolerability of lumiracoxib in the treatment of osteoarthritis of the knee: a 13-week, randomized, double-blind comparison with celecoxib and placebo. *Clin Ther* 2005;27(1):64-77.
 - (7) Lehmann R, Brzosko M, Kopsa P, Nischik R, Kreiss A, Thurston H, Litschig S, Sloan VS. Efficacy and tolerability of lumiracoxib 100 mg once daily in knee osteoarthritis: a 13-week, randomized, double-blind study vs. placebo and celecoxib. *Curr Med Res Opin* 2005;21(4):517-526.
 - (8) Berenbaum F, Grifka J, Brown JP, Zacher J, Moore A, Krammer G, Dutta D, Sloan VS. Efficacy of lumiracoxib in osteoarthritis: a review of nine studies. *J Int Med Res* 2005;33(1):21-42
 - (9) Singh G, Triadafilopoulos G. Epidemiology of NSAID induced gastrointestinal complications. *J Rheumatol* 1999; Suppl.56: 18-24.
 - (10) Tramer M, et al. Quantitative estimation of rare adverse events, which follow a biological progression: a new model applied to chronic NSAID use. *Pain* 2000; 85:169-182.
 - (11) Wolfe M, Lichenstein D, et al. Gastrointestinal toxicity of nonsteroidal inflammatory drugs. *N. Engl. J. Med.* 1999; 340:1888-1899.
 - (12) Hawkey CJ, et al. Early reduction of ulcer complications with lumiracoxib compared with nonselective

NSAIDs in the Therapeutic Arthritis Research and Gastrointestinal Event Trial (TARGET). *Ann Rheum Dis* 2006;65(Suppl. II):231 (Abstract THU0378).

(13) Hawkey CJ, *et al.* Improved gastrointestinal safety profile with lumiracoxib compared with naproxen and ibuprofen in patients at least 65 years old at increased risk of gastrointestinal events. *Gastroenterology* 2006;130(4)(Suppl. 2) (Abstract 218493).

(14) Farkouh M, *et al.* Comparison of lumiracoxib with naproxen and ibuprofen in the Therapeutic Arthritis Research and Gastrointestinal Event Trial (TARGET), cardiovascular outcomes: a randomized controlled trial. *Lancet*. 2004; 364(9435): 675 684.

(15) Matchaba P, *et al.* Cardiovascular Safety of Lumiracoxib: A Meta-analysis of All Randomized Controlled Trials \geq 1 Week and up to 1 Year in Duration of Patients with Osteoarthritis and Rheumatoid Arthritis. *Clin Ther* 2005; 27(8):1196 1214.

###

Media contacts

Vivienne Schneider

Novartis Pharma Communications
+41 61 324 6162 (direct)
+41 79 619 1335 (mobile)
vivienne.schneider@novartis.com

Corinne Hoff

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

Novartis Global Investor Relations

International:

Ruth Metzler-Arnold	+41 61 324 99 80
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: November 7, 2006

By: /s/ MALCOLM B. CHEETHAM

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