

NOVARTIS AG
Form 6-K
August 31, 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 August 30, 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
<http://www.novartis.com>

- Investor Relations Release -

Exjade®, a breakthrough for patients with transfusional iron overload, gains European Union approval

- *Exjade the only oral iron chelator to provide continuous chelation coverage to remove excess total body iron with a single daily dose(1)*
- *Adults and children receiving regular blood transfusions now have a convenient alternative to burdensome standard therapy through a once-daily drink*
- *Iron chelation needed to help patients with thalassemia, sickle cell disease, myelodysplastic syndromes and other anemias who regularly receive transfusions*

Basel, August 30, 2006 - The European Commission (EC) has granted approval for Exjade® (deferasirox) as a new treatment to help patients with transfusional iron overload in all 25 member states of the European Union (EU).

The approval brings to children and adults with a broad range of transfusion-dependent anemias the only oral iron chelator to provide continuous chelation coverage with a single daily dose(1). The current standard of care is a cumbersome infusion via pump that often lasts eight to 12 hours and must often be done daily.

Exjade is the first oral iron chelator approved in the EU for use in patients with transfusional iron overload who have a wide range of underlying diseases. Exjade is approved in the EU for the treatment of chronic iron overload due to frequent blood transfusions in patients age six and older with beta thalassemia major.

It is also indicated in the EU for the treatment of chronic iron overload when the medicine deferoxamine is contraindicated or considered inadequate in patients with other anemias, children age two to five years and patients with beta thalassemia major with iron overload due to infrequent blood transfusions(1).

Iron chelation is often necessary to prevent potentially life-threatening complications of excess iron(3) in patients who receive regular blood transfusions for diseases such as thalassemia, myelodysplastic syndromes, sickle cell disease and other anemias.

Tens of thousands of children and adults around the world have these diseases(5),(6),(8). For many, the need for transfusions and chelation are life-long. A single dose of Exjade works throughout the entire day, removing excess iron - including highly toxic labile plasma (unbound) iron - from key organs such as the liver and heart.

A breakthrough in iron chelation therapy, Exjade is administered once-daily as a drink. Exjade was developed specifically to meet the high unmet medical need for iron chelation despite the availability of deferoxamine, the standard iron chelator used around the world.

While effective, deferoxamine requires nightly infusions by needle and pump, often lasting eight to 12 hours per night for five to seven nights a week as long as the patient continues to receive blood transfusions or has excess iron within the body. As a result, many patients may have stopped or avoided iron chelation therapy, thus risking the toxic effects of iron overload.

The approval of Exjade is fantastic news for people like me who need regular blood transfusions, said Anand Ghattaura, who lives in London, England. I've always found chelation with a pump and needle difficult to keep up with. I often used to worry all day about my infusion in the evening. Now I can take Exjade in the morning with a glass of juice and can forget about it until the next day.

Due to the burdensome administration of deferoxamine, compliance with standard chelation therapy is poor(2). Previous studies of patients with thalassemia have shown that good compliance with deferoxamine improves survival and quality of life(3).

The approval of Exjade in the Europe Union as a new therapy for transfusional iron overload is most welcome. This allows for the first time an effective, once daily oral monotherapy for transfusional iron overload, said Prof. John B. Porter, MA, MD, FRCP, FRCPATH at Department of Haematology at the University College London. This is also the first oral treatment available for transfusional iron overload where the dose response effect on iron balance has been systematically studied on a scale not previously undertaken with iron chelation therapy.

About iron overload and iron chelation

Iron overload is a cumulative, potentially life-threatening, consequence of frequent blood transfusions. Iron starts to build up in the body after as few as 10 transfusions(3) because the body cannot remove it on its own(4). Iron chelation is the only effective drug treatment for transfusion-related iron overload. In iron chelation, an agent binds to iron in the body and tissues and helps remove it through the urine and/or feces.

Filing data(1)

The clinical trials for Exjade were part of the largest prospective global clinical trials program ever implemented for an investigational iron chelator. Data involving more than 1,000 patients with a broad range of underlying diseases demonstrated that Exjade is effective at managing and reducing body iron burden, particularly in patients with moderate to severe iron overload, as measured by liver iron content (LIC). LIC, a measure of iron accumulation in the liver, is an indicator for body iron content in patients receiving blood transfusions. The main Phase III study showed that when dosed appropriately, Exjade was as effective as deferoxamine (Desferal®) in reducing iron burden. A sub-study also indicated that Exjade is effective at managing and reducing the content of iron in the heart, as measured by magnetic resonance imaging (MRI T2*).

The approval of Exjade starts a new era in treating iron overload by providing effective continuous chelation coverage that is easy for patients to use, said David Epstein, CEO and President, Novartis Oncology. The introduction of this innovative product continues the decades-long support and leadership Novartis has brought to the iron chelation community.

Safety data followed patients for up to 2.5 years. In the clinical studies, Exjade was generally well tolerated, with the most frequently reported adverse events being nausea, vomiting, diarrhea, abdominal pain, skin rash and increases in serum creatinine. In patients who develop diarrhea, care should be given to maintain adequate hydration, especially in patients who have experienced an increase in serum creatinine. As with deferoxamine, cases of ocular and auditory disturbances have uncommonly been reported.

Mild, non-progressive increases in serum creatinine, mostly within the normal range, occur in about one-third of Exjade-treated patients. These are dose-dependent, often resolve spontaneously and can sometimes be alleviated by reducing the dose. Serum creatinine, creatinine clearance and/or plasma cystatin C levels should be assessed in duplicate before initiating therapy and should be monitored weekly during the first month of treatment and monthly thereafter to determine if dose modification, interruption, or discontinuation is necessary. Proteinuria should be monitored monthly. Exjade is contraindicated in patients with creatinine clearance less than 60 ml/min. Liver function should be assessed prior to initiating therapy and then monitored monthly. If there is an unexplained, persistent, or progressive increase in serum transaminase levels, Exjade should be interrupted or discontinued. Hearing and eye exams should be performed yearly(1).

Already approved in 29 countries, Exjade was granted approval after the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) issued a positive opinion recommending marketing authorization. Designated an orphan drug in the EU, US, Switzerland and Australia, additional regulatory submissions for Exjade have been made around the world.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as breakthrough, only, first, significant advance, should help, showed, new era, or similar expressions, or by express or implied discussions regarding potential additional marketing approvals or future sales of Exjade. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Exjade to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Exjade will receive any additional marketing approvals in any other countries, or that it will reach any particular sales levels. In particular, management's expectations regarding commercialization of Exjade could be affected by, among other things, additional analysis of Exjade clinical data; new clinical data; unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; increased government, industry, and general public pricing pressures; and other risks and factors referred to in the Company's current Form 20-F on file 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 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.

For prescribing information on deferoxamine (Desferal®) please contact your local Novartis affiliate.

More information for health care providers:

Some clinical trials with Exjade are ongoing. To learn more about Exjade clinical trials, health care providers can call +44 (0) 1506 814899.

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 97,000 people and operate in over 140 countries around the world. For more information, please visit <http://www.novartis.com>.

References

- (1). Exjade Summary of Product Characteristics (DATE)
- (2). Nisbet-Brown E. Effectiveness and safety of ICL670 in iron loaded patients with thalassemia: a randomised, double-blind, placebo controlled, dose-escalation trial. *The Lancet*. 2003. 361.
- (3). Gabutti V, Piga A. Results of Long-Term Iron-Chelating Therapy. *Acta Haematologica*. 1996. 95:26-36.
- (4). Centers for Disease Control and Prevention. Hemochromatosis for Health Care Professionals: Pathophysiology: Iron Overload. Available at: http://www.cdc.gov/hemochromatosis/training/pathophysiology/iron_overload.htm.
- (5). Siddiqui AK, et al. Pulmonary manifestations of sickle cell disease. *Postgraduate Medical Journal*. 2003. 79:384-390.
- (6). National Human Genome Research Institute at the National Institutes of Health. Learning about thalassemia. Available at: www.genome.gov/10001221.
- (7). Porter JP. A risk-benefit assessment of iron-chelation therapy. *Drug Saf*. 1997 Dec; 17(6):407-21
- (8). Novartis data on file. E-mail correspondence from Alice Berringer, dated May 1, 2006

###

Contacts

Kim Fox

Novartis Oncology

+1 862 778 7692 (direct)

kim.fox@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:

Jean-Jacques Charhon, Global Head IR ad interim

Katharina Ambühl

Nafida Bendali

+41 61 324 79 44

+41 61 324 53 16

+41 61 324 35 14

Edgar Filing: NOVARTIS AG - Form 6-K

Richard Jarvis
Silke Zentner

+41 61 324 43 53
+41 61 324 86 12

North America:

Ronen Tamir

Arun Nadiga
Jill Pozarek
Edwin Valeriano

+1 212 830 24 33
+1 212 830 24 44
+1 212 830 24 45
+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: August 30, 2006

By: /s/ MALCOLM B. CHEETHAM

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