

NOVARTIS AG  
Form 6-K  
June 25, 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 22, 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:

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

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**- Investor Relations Release -**

**Rasilez®, an important new treatment for high blood pressure, receives positive opinion recommending European Union approval**

- *Strong need for new therapies like Rasilez as studies estimate that nearly 70% of patients with high blood pressure do not achieve treatment goals(1),(2)*
- *Rasilez the first new type of high blood pressure medicine in more than a decade, launched in US in March 2007*
- *Used alone or in combination with other medicines, Rasilez provides significant blood pressure reductions for 24 hours and beyond(3)*

**Basel, June 22, 2007** Novartis has received a positive opinion recommending European Union approval of Rasilez® (aliskiren) as the first new type of high blood pressure treatment in more than a decade.

The Committee for Medicinal Products for Human Use (CHMP), which reviews medicines for the European Commission, issued the positive opinion for Rasilez based on data from more than 7,800 patients in 44 clinical studies. The Commission generally follows the CHMP's recommendations and is expected to issue a decision within three months.

The clinical trial program showed that Rasilez provided significant blood pressure reductions for 24 hours and beyond<sup>3</sup>. Furthermore, Rasilez provided added efficacy when used in combination with other commonly used blood pressure medications<sup>(4),(5)</sup>.

Studies estimate that nearly one billion people may have high blood pressure and that nearly 70% of patients with high blood pressure never reach healthy blood pressure levels. As a result, they live at risk of complications like heart attack, stroke, blindness and premature death, creating a strong need for new therapies like Rasilez<sup>(1),(2),(3)</sup>.

This important milestone for Rasilez comes just days after the US approval of Exforge as our new fixed combination therapy. Following the anticipated EU approval of Rasilez, our new antihypertensive medicines will be made available to patients in the US, Europe and elsewhere as quickly as possible. We have made significant progress in developing a broad and complementary portfolio of medicines to help physicians worldwide treat patients with high blood pressure, said Thomas Ebeling, CEO of Novartis Pharma.

Rasilez is the first in a new class of drugs called direct renin inhibitors. It acts by directly inhibiting renin, an enzyme that triggers a process leading to high blood pressure. The medication received its

first approval in March 2007 from the US Food and Drug Administration under the trade name Tekturna®.

If approved, Rasilez will offer millions of Europeans an important new treatment option for high blood pressure, said James Shannon, MD, Global Head of Development at Novartis Pharma AG. This positive opinion is highly encouraging since Rasilez has been shown to help a wide variety of people by providing long-lasting blood pressure control.

In clinical trials, the approved doses of Rasilez demonstrated a placebo-like tolerability profile(4). Rasilez was developed in collaboration with Speedel.

Blood pressure measurements consist of two values: the first represents the pressure within blood vessels when the heart contracts, while the second represents the pressure when the heart is at rest between beats. Blood pressure is measured in millimeters of mercury (mmHg), with normal blood pressure levels between 120/80 mmHg and 140/90 mmHg.

#### **Disclaimer**

The foregoing release contains forward-looking statements which can be identified by the use of terminology such as generally follows, anticipated, will, expected, may, estimate or similar expressions, or by express or implied discussions regarding the potential regulatory approval of Rasilez or future sales of Rasilez. 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 to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Rasilez will be approved for any indications or brought to market in the European Union or in any other market or that Rasilez will reach any particular sales levels. In particular, management's expectations regarding the approval and commercialization of Rasilez could be affected by, among other things, additional analysis of clinical data; new clinical data; unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; our ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; increased government, industry, and general public pricing pressures; as well as other risks and factors referred to in Novartis AG's 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.

#### **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>.

**References**

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- (2). Chobanian AV, Bakris GL, Black HR, et al. and the National High Blood Pressure Education Program Coordinating Committee. The seventh report of the Joint National Committee on prevention, detection, evaluation, and treatment of high blood pressure. *Hypertension*. 2003;42:1206-1252.
- (3). American Heart Association. International Cardiovascular Disease Statistics fact sheet. [www.americanheart.org](http://www.americanheart.org).
- (4). Mitchell B, Oh J, Chung J, et al. Once-Daily Aliskiren Provides Effective, Smooth 24-Hour Blood Pressure Control in Patients with Hypertension. Presented at the American Society of Hypertension 21st Scientific Meeting & Exposition, May 17, 2006
- (5). Oparil S, Yarows S, Patel S, et al. The Direct Renin Inhibitor Aliskiren in Combination With the Angiotensin Receptor Blocker Valsartan Provides Additional Blood Pressure-Lowering Effects Compared With Either Agent Alone in Patients With Hypertension. Poster presented at American College of Cardiology 56th Annual Scientific Session, March 2007.
- (6). Uresin Y, Taylor A, Kilo C, Tschöpe D, Santonastaso M, Ibram G, Fang H, Satlin A. Aliskiren, a novel renin inhibitor, has greater BP lowering than ramipril and additional BP lowering when combined with ramipril in patients with diabetes and hypertension. Poster to be presented at the 16th Scientific Meeting of the European Society of Hypertension. 2006.

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**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 22, 2007

By: /s/ Malcolm B. Cheetham

Name: Malcolm B. Cheetham

Title: Head Group Financial  
Reporting and Accounting