NOVARTIS AG
Form 6-K
July 23, 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 July 20, 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

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**- Investor Relations Release -**

**New data show Tekturna® and Diovan® used together provide additive blood pressure reductions**

- *Study results show more patients receiving both Tekturna and Diovan reached target blood pressure goal compared to those taking either agent alone(1)*

- *Tekturna, first new type of high blood pressure medicine in more than a decade, works well alone or in combination with other high blood pressure medicines*

- *Tekturna provides significant blood pressure reductions for 24 hours and beyond with placebo-like tolerability*

- *Strong need for new therapies like Tekturna since nearly 70% of patients with high blood pressure still not achieving treatment goals(2)*

**Basel, July 20, 2007** Results from a new study involving high blood pressure patients taking Tekturna® (aliskiren) and Diovan® (valsartan) were published today in *The Lancet*. The study, presented earlier this year at the American College of Cardiology congress, shows this combination provides patients with greater blood pressure reductions than either medicine alone and demonstrated tolerability comparable to placebo.

Adding Tekturna to Diovan helped more patients reach their target blood pressure. Nearly half (49.3%) of the patients taking both Tekturna and Diovan reached the target blood pressure level of 140/90 mmHg, which is recommended by treatment guidelines. This proportion of patients was significantly more than with either drug alone (37.4% Tekturna, 33.8% Diovan).

We are encouraged by these results, because they demonstrate the value of complementary mechanisms of action when Tekturna and Diovan are used together, said James Shannon, MD, Global Head of Development at Novartis Pharma AG. Most people need at least two medicines to effectively control their high blood pressure.

Tekturna and Diovan work in different ways to target the Renin Angiotensin System, one of the body s key regulators of blood pressure. Tekturna targets renin, an enzyme responsible for triggering a process that can lead to high blood pressure. Diovan, an angiotensin receptor blocker (ARB) and one of the world s most-prescribed cardiovascular medicines, blocks a hormone later in this system that causes narrowing of blood vessels(3).

The study, involving almost 1800 patients, found that even at maximum doses of Tekturna and Diovan, the combination was safe and well-tolerated. A mild and transient increase in serum potassium levels above 5.5 mmol/L was seen in 4.2% of patients taking both Tekturna and Diovan

compared to placebo (2.7%). However, there were fewer reports of serum potassium levels above 6.0 mmol/L in patients taking both medicines (0.5%), compared to 1.5% taking placebo, 1.0% taking Tekturna alone and 1.1% taking Diovan alone. While mild increases in serum potassium may be clinically important in rare situations, potentially life-threatening events associated with increases in serum potassium rarely occur unless the serum potassium concentration exceeds 7.0-7.5 mmol/L(4), levels which were not seen in this study.

Commenting on an editorial in *The Lancet,* which questioned the safety of such a combination, the study s lead investigator Dr Suzanne Oparil, Professor of Medicine at the University of Alabama at Birmingham and President of the American Society of Hypertension said, In our study, this combination was clearly shown by the data to be no more likely to increase potassium to unhealthy levels than either drug alone or even placebo. Mild increases in potassium are expected with agents that block the Renin Angiotensin System, including ACE inhibitors and angiotensin receptor blockers, the most-commonly used medicines to treat high blood pressure. Physicians have managed these mild increases in potassium very successfully for over 20 years.

The need for new high blood pressure medicines, including using new combinations of medicines, is strong given that studies estimate that this condition may affect nearly one billion people globally and that more than 70% of patients with high blood pressure remain uncontrolled(5). In fact, many require two or more medications to reach their target blood pressure goal(2),(6). Uncontrolled high blood pressure can increase the risk of cardiovascular disease, the world s leading cause of death(6),(7).

Tekturna received approval in the US in March, 2007. Known as Rasilez outside the US, it received a positive CHMP opinion in June, 2007 recommending approval in the EU and was also recently approved in Switzerland.

Tekturna was developed in collaboration with Speedel.

**Disclaimer**

The foregoing release contains forward-looking statements which can be identified by the use of terminology such as can or similar expressions, or by express or implied discussions regarding potential future regulatory filings, approvals or future sales of Tekturna/Rasilez or potential future sales of Diovan. Such statements reflect the current views of Novartis regarding future events and 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 Tekturna/Rasilez will be approved for sale in any other market, or that Tekturna/Rasilez or Diovan will reach any particular sales levels. In particular, management s expectations regarding the approval and commercialization of Tekturna/Rasilez or Diovan could be affected by, among other things, unexpected clinical trial results, including additional analysis of existing clinical data and new clinical data; 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 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, 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 more than 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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**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: July 20, 2007

By: /s/ MALCOLM B. CHEETHAM

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

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