NOVARTIS AG
Form 6-K
May 22, 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 May 21, 2007

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

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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**

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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 -

Single-tablet combination of Tekturna® and diuretic, an important new option for people with high blood pressure, submitted for US approval

- *Tekturna, approved in the US in March 2007, represents the first new type of medicine for treating high blood pressure in more than a decade*

- *New data show Tekturna, when used alone or in combination with the diuretic hydrochlorothiazide, delivers significant blood pressure lowering over one-year period*(1)

- *Single-tablet combination therapies could help people with high blood pressure better comply with treatment by reducing pill burden* (2)

- *About 70% of high blood pressure patients still not reaching their treatment goals and many require two or more medicines*(3),(4)

Basel, May 21, 2007 A single-tablet combination of two high blood pressure medicines the recently approved direct renin inhibitor Tekturna® (aliskiren) and the widely-used diuretic hydrochlorothiazide has been submitted for US regulatory approval.

Tekturna HCT®(1) represents the first regulatory submission for a single-tablet combination therapy involving Tekturna, which is the first new type of high blood pressure medicine in more than a decade. Tekturna was approved by the US Food and Drug Administration in March 2007, while a decision on European Union approval is expected by the end of 2007.

Single-tablet combination therapies like Tekturna HCT may make blood pressure management easier for people by reducing the number of pills they take daily. High blood pressure affects one in four adults around the world, and an estimated 70% of these patients do not currently reach their target blood pressure level(3). In fact, most patients require two or more medicines to reach their goal(4).

Several studies show that many adults with high blood pressure remain uncontrolled despite treatment. This is because too often physicians fail to treat aggressively enough, said Dr. Alan Gradman, Chief of the Division of Cardiovascular Diseases at the Western Pennsylvania Hospital in Pittsburgh. A tablet combining the first direct renin inhibitor and a diuretic would give doctors an important new treatment option to help patients reach their treatment goals.

(1) Brand name awaiting regulatory approval in certain markets, including the US

New clinical data involving 1,625 patients, presented today at the American Society of Hypertension meeting in Chicago, showed that Tekturna produced significant blood pressure lowering effects over a one-year period. These results were seen both alone and in combination with hydroclorothiazide(1). Tekturna was generally well tolerated, with the most common side effects being bronchitis (6.1%), nasopharyngitis (5.1%) and headache (3.5%)(1).

Hydrochlorothiazide is a diuretic, commonly known as a water pill , that helps the body get rid of unneeded water and salt through urine. It was among the first high blood pressure treatments, since removing excess fluid makes it easier for the heart to pump and control blood pressure.

The submission of Tekturna HCT was based on data from seven clinical trials involving more than 6,200 patients(5), including the data presented at the ASH meeting. Submissions were made for four different dosage combinations of Tekturna and hydrochlorothiazide: 150/12.5 mg tablets, 150/25 mg tablets, 300/12.5 mg tablets and 300/25 mg tablets.

Tekturna, developed in collaboration with Speedel, is the first approved direct renin inhibitor and received US approval based on results of an extensive clinical trial program showing significant blood pressure reductions for a full 24 hours. It is known as Rasilez® outside the US. Tekturna should not be used by women who are pregnant or plan to become pregnant.

Tekturna HCT represents an initial success in our efforts to explore the benefits of combining this innovative medicine with other complementary high blood pressure agents. We will continue to assess other combinations that would be of use for patients and physicians, said Dr. James Shannon, Global Head of Development at Novartis Pharma AG.

Disclaimer

The foregoing release contains forward-looking statements which can be identified by the use of terminology such as submitted for approval , could , expected , may , estimated , would , will , or similar expressions, or by express or implied discussions regarding potential future regul approvals, potential additional Tekturna combination products or potential future sales of Tekturna HCT or Tekturna / Rasilez. Such statements reflect the current views of the Novartis group of companies with respect to future events and are subject to certain risks, uncertainties and assumptions. There can be no guarantee that Tekturna HCT will be approved for sale in the United States or any other market or that Tekturna / Rasilez will be approved for sale in any market where it has not already been approved. Neither can there be any guarantee that Novartis will submit any additional Tekturna combination products to health authorities for approval. Nor can there be any guarantees that Tekturna HCT or Tekturna / Rasilez will reach any particular sales levels. In particular, management s expectations regarding the approval and commercialization of Tekturna HCT or Tekturna / Rasilez could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including additional analysis of existing clinical data and new clinical data; competition in general; increased government, industry, and general public pricing pressures; the company s 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, 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

1. Gradman A, Kolloch RE, Myers M, et al. Aliskiren in combination with hydrochlorothiazide is effective and well tolerated during long-term treatment of hypertension. Poster presented at the American Society of Hypertension 2nd Scientific Meeting & Exposition (Presentation # P-384). May 21, 2007.

2. Zhang J, Ghadanfar M. 2.5 Clinical Overview in hypertension. Clinical Development. Tekturna HCT Aliskiren/hydrochlorothiazide combination. February 22, 2007

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4. 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.

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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: May 21, 2007

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