NOVARTIS AG
Form 6-K
January 22, 2008

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 January 22, 2008

(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 -

Tekturna HCT®, a single-tablet combination of Tekturna®* and a diuretic, receives US approval for treatment of high blood pressure

- *Tekturna HCT combines first approved direct renin inhibitor with the diuretic hydrochlorothiazide (HCT) in a single tablet[(1)]*

- *Approved in more than 40 countries, Tekturna used alone lowers blood pressure for 24 hours and beyond[(2),(3)]*

- *Data show combination of Tekturna and HCT resulted in significant additional blood pressure reductions compared to either drug alone[(4)]*

- *Many patients not at goal and most require two or more medicines[(5)] single-tablet combinations simplify treatment by reducing number of pills patients take[(6)]*

Basel, January 21, 2008 Tekturna HCT® (aliskiren and hydrochlorothiazide) has been approved by the US Food and Drug Administration as a single-tablet combination of two high blood pressure medicines Tekturna® (aliskiren), the first new type of high blood pressure medicine in more than a decade, and the diuretic hydrochlorothiazide (HCT)[(1)].

The two medicines in this single-tablet combination work together to lower blood pressure, with clinical data showing that the combination of Tekturna and HCT offers greater blood pressure reductions than either component alone[(4)].

This is the first regulatory approval of a single-tablet combination therapy involving Tekturna, known as Rasilez® outside the US, which has been shown to consistently lower blood pressure for 24 hours and beyond[2],[3]. HCT, sometimes called a water pill, is one of the most commonly used high blood pressure medicines[7]. Tekturna HCT is approved for patients not controlled by either medicine alone[1].

The efficacy of Tekturna for 24 hours and beyond is important because many high blood pressure medicines fail to work around the clock, especially during the early morning hours when blood pressure often surges. Tekturna has also been shown to maintain blood pressure reductions for up to four days after the last dose[8].

Current guidelines call for aggressive treatment of high blood pressure and many patients are still not controlled, said Alan Gradman, MD, Division of Cardiovascular Diseases at the Western Pennsylvania Hospital in Pittsburgh, USA. Tekturna HCT offers patients an effective new

* Tekturna® is the US trade name for aliskiren. Aliskiren is known as Rasilez® outside the US

treatment option with significant blood pressure reductions and improved convenience, by combining the complementary mechanisms of action of the first direct renin inhibitor and a diuretic in one tablet.

High blood pressure is estimated to affect nearly one in four adults worldwide and remains uncontrolled in nearly 70% of people who have this condition[5]. Most patients require two or more medicines to reach their target blood pressure[5]. Single-tablet combinations such as Tekturna HCT simplify high blood pressure management by reducing the number of pills people take daily[6].

The US approval of Tekturna HCT was based on clinical trials involving more than 2,700 patients treated with Tekturna and HCT[1].

Tekturna works by targeting renin and decreasing the activity of the renin system as measured by plasma renin activity (PRA). By reducing the effects of renin, Tekturna helps blood vessels to widen so blood pressure is lowered. Diuretics work to lower blood pressure by ridding the body of unneeded water and salt, but are also known to increase PRA.

Most patients need at least two medicines to control their high blood pressure, said James Shannon, MD, Chief Medical Officer at Novartis Pharma AG. The rationale for combining a diuretic, which raises plasma renin activity, with Tekturna, which counters this increase, is compelling and unique, and Novartis is very proud to introduce this innovative combination.

The most common side effects experienced by more patients taking Tekturna HCT than those taking a placebo (or sugar pill) were dizziness, flu-like symptoms, diarrhea, cough and tiredness.

The long-term potential of Tekturna and direct renin inhibition is being studied in an extensive clinical program known as ASPIRE HIGHER, which focuses on the effects of using Tekturna in patients with cardiovascular or kidney disease.

Tekturna was discovered by Novartis and developed in collaboration with Speedel.

Disclaimer

The foregoing release contains forward-looking statements which can be identified by the use of terminology such as will, may or similar expressions, or by express or implied discussions regarding the effectiveness of Tekturna HCT or Rasilez/Tekturna, potential future regulatory filings or approvals of Tekturna HCT or Rasilez/Tekturna or potential future sales of Tekturna HCT or Rasilez/Tekturna. 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 Tekturna HCT or Rasilez/Tekturna will be approved in any additional markets or for any additional indication in any market or that Tekturna HCT or Rasilez/Tekturna will reach any particular sales levels. In particular, management s

expectations regarding Tekturna HCT or Rasilez/Tekturna could be affected by, among other things, unexpected clinical trial results, including unexpected additional analysis of clinical data, or unexpected new clinical data; unexpected regulatory actions or delays or government regulation generally; competition in general; increased government, industry, and general public pricing pressures; production delays or business interruption generally; our 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 provides healthcare solutions that address the evolving needs of patients and societies. Focused solely on growth areas in healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic pharmaceuticals, preventive vaccines and diagnostic tools, and consumer health products. Novartis is the only company with leading positions in these areas. In 2007, the Group s continuing operations (excluding divestments in 2007) achieved net sales of USD 38.1 billion and net income of USD 6.5 billion. Approximately USD 6.4 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 98,200 full-time associates and operate in over 140 countries around the world. For more information, please visit http://www.novartis.com.

References

(1) Tekturna HCT US Prescribing Information.

(2) Oh BH, Mitchell J, Herron JR, et al. Aliskiren, an oral renin inhibitor, provides dose-dependent efficacy and sustained 24-hour blood pressure control in patients with hypertension. J Am Coll Cardiol 2007;49:1157 1163.

(3) Sica D, Gradman AH, Lederballe O, et al. Aliskiren, a novel renin inhibitor, is well tolerated and has sustained BP-lowering effects alone or in combination with HCTZ during long-term (52 weeks) treatment of hypertension. Eur Heart J 2006;27(Suppl):121 P-797.

(4) Villamil A, et al. Renin inhibition with aliskiren provides additive antihypertensive efficacy when used in combination with hydrochlorothiazide. Journal of Hypertension 2007, 25: 217-226

(5) Ong KL, Cheung BMY, Man YB, et al. Prevalence, awareness, treatment, and control of hypertension among United States adults 1999-2004. Hypertension 2007; 49:69-75.

(6) Boolell M, Glasspool J. Cardiovascular Disease Health Burden, Treatment Benefits and Challenges: Need for Partnership. Health & Productivity Management Vol 5, No 4 December 2006, p 11-14.

(7) 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.

(8) Herron J, et al. The Novel Renin Inhibitor Aliskiren Is Not Associated With Rebound Effects On Blood Pressure Or Plasma Renin Activity Following Treatment Withdrawal. Poster presented at American Society of Hypertension Annual Session May 2006.

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Media Contacts

John Gilardi
Novartis Global Media Relations
+41 61 324 3018 (direct)
+41 79 596 1408 (mobile)
john.gilardi@novartis.com

Peter Shelby
Novartis Pharma Communications
+41 61 324 4470 (direct)
+41 79 597 6353 (mobile)
peter.shelby@novartis.com

Novartis Investor Relations

International
Ruth Metzler-Arnold
Katharina Ambuehl
Pierre-Michel Bringer
Jason Hannon
Thomas Hungerbuehler
Richard Jarvis
Isabella Zinck

Central phone no: +41 61 324 7944
e-mail: investor.relations@novartis.com

North America
Jill Pozarek +1 212 830 2445
Edwin Valeriano +1 212 830 2456

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: January 22, 2008

By: /s/ MALCOLM B. CHEETHAM

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