

NOVARTIS AG  
Form 6-K  
August 07, 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 August 6, 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:

Edgar Filing: NOVARTIS AG - Form 6-K

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  
CH-4002 Basel  
Switzerland  
<http://www.novartis.com>

- Investor Relations Release -

**Single-pill combinations Diovan HCT<sup>®</sup> and Exforge<sup>®</sup> approved in US as first-line treatments for high blood pressure**

- *Approvals consistent with current US treatment guidelines to start appropriate patients on combination therapies<sup>(1)</sup>*
- *Up to 80% of patients may need multiple medications to help them reach blood pressure goals<sup>(2)</sup>*
- *Single-pill combinations offer effective, convenient medications which could help patients reach treatment goals faster<sup>(3)</sup>*
- *High blood pressure is one of the most important but treatable risk factors for cardiovascular disease – the world's leading cause of death<sup>(4)</sup>*

**Basel, August 4, 2008** The US Food and Drug Administration (FDA) has approved two single-pill combination medications, Diovan HCT<sup>®(1)</sup> (valsartan and hydrochlorothiazide) and Exforge<sup>®</sup> (amlodipine and valsartan), as initial or first-line therapies in patients likely to need multiple drugs to achieve their blood pressure goals.

The FDA approval of Diovan HCT and Exforge for first-line use reinforces current US guideline recommendations to start appropriate patients on combination therapy<sup>(1)</sup>. Research suggests that up to 80% of patients may need multiple medications to help them reach blood pressure goals<sup>(2)</sup>.

These approvals provide flexibility and confidence to physicians to use well-proven and well-accepted therapies as first-line treatment, said Kenneth Jamerson, MD, Professor of Medicine, Department of Cardiovascular Medicine, University of Michigan Healthcare System. Patients will also benefit, as they may be able to get their blood pressure effectively and quickly under control with a single pill.

With the approvals, physicians will have simplified treatment strategies to help control high blood pressure with Diovan HCT and Exforge. In patients who are likely to need multiple drugs to achieve blood pressure goals, using single-pill combination medications first-line will help eliminate the added steps of starting on a single medication, increasing the dose and then adding on another medication(5).

The multiple steps often used in clinical practice may delay the time it takes to reach blood pressure goals and are likely to create patient frustration and a sense of failure(3). In addition, the first-line use of single-pill combination medications in patients who are likely to need multiple

---

(1) Primarily known as Co-Diovan® or Co-Tareg® in most other countries.

treatments to reach goal may reduce their pill burden<sup>(6),(7)</sup>. Research suggests that patients have higher satisfaction with their blood pressure medication if their blood pressure control is improved<sup>(8)</sup>.

High blood pressure affects approximately 73 million adult Americans<sup>(9)</sup>, and one in four adults worldwide<sup>(10)</sup>. It is one of the most important, but treatable, risk factors for cardiovascular disease – the world’s leading cause of death<sup>(4)</sup>.

While it is easy to measure and can be successfully managed, nearly 65% of patients with high blood pressure do not have the condition under control<sup>(9)</sup>, underscoring the critical need for more effective treatment regimens. If left untreated, patients with high blood pressure are at risk of cardiovascular events such as stroke, heart attack and heart failure, as well as organ damage including kidney failure and eye problems.

We are very pleased that the FDA recognizes the therapeutic value and the need of some patients to start therapy with a single-pill combination, said Trevor Mundel, MD, Head of Global Development Functions at Novartis Pharma AG. These approvals demonstrate our confidence in combination medications for this therapeutic category, while reinforcing the Novartis commitment to provide physicians with well-researched and effective treatments for high blood pressure.

Diovan HCT combines in one tablet Diovan® (valsartan), the world’s number one selling branded high blood pressure medication, and hydrochlorothiazide (HCT), a high blood pressure treatment from the diuretics drug class. Exforge is the first treatment to combine two of the most commonly prescribed high blood pressure medications in their classes – Diovan (an angiotensin receptor blocker, or ARB) and the calcium channel blocker (CCB) amlodipine besylate – into a convenient, once-daily single tablet.

The Diovan HCT and Exforge first-line approvals were based on several clinical trials in approximately 2,000 and 3,500 patients respectively, in which both products demonstrated efficacy and tolerability in patients with mild-to-severe high blood pressure<sup>(11),(12),(13)</sup>.

Diovan HCT was approved in the US in 1998 for second-line treatment of high blood pressure and over five million patients have been prescribed the medicine. Exforge was approved in 2007 and since its introduction last year, it has been prescribed to over a quarter of a million patients.

Novartis is focused on improving the lives of the hundreds of millions of people with cardiovascular and metabolic diseases. As a global leader in cardiovascular and metabolic health for nearly 50 years, Novartis provides innovative therapies and support programs to treat high blood pressure and diabetes – both major public health issues.

The core of the Novartis portfolio is its cardiovascular medications for the treatment of high blood pressure and diabetes. These include the world’s most-prescribed ARB, the first and only approved direct renin inhibitor, a single pill combining two leading high blood pressure medicines, and a novel DPP-4 inhibitor. Novartis is dedicated to helping physicians and patients improve cardiovascular and metabolic health through effective medicines, programs and an ongoing commitment to research.

**Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as may, could, likely, suggests, will, confidence, or similar expressions, or by express or implied discussions regarding potential future revenues from Diovan HCT and Exforge. Such forward-looking statements reflect the current views of the Company regarding future events,

and involve known and unknown risks, uncertainties and other factors that may cause actual results with Diovan HCT and Exforge to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Diovan HCT and Exforge will achieve any particular levels of revenue in the future. In particular, management's expectations regarding Diovan HCT and Exforge could be affected by, among other things, the company's ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; government, industry and general public pricing pressures; unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; 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 healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic pharmaceuticals, preventive vaccines, 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 98,000 full-time associates and operate in over 140 countries around the world. For more information, please visit <http://www.novartis.com>.

---

### References

- (1) JNC-VII, The Seventh Report on the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure, JAMA 2003; 289(19):2560-72
- (2) Dahlöf B, Poulter NR, Wedel H, et al. Prevention of cardiovascular events with an antihypertensive regimen of amlodipine adding perindopril as required versus atenolol adding bendroflumethiazide as required, in the Anglo-Scandinavian Cardiac Outcomes Trial-Blood Pressure Lowering Arm (ASCOT-BPLA): a multicenter randomised controlled trial. Lancet 2005;366:895-906
- (3) Ofili EO. Dispelling the Myth of Aggressive Antihypertensive Therapy. J Clin Hypertens. 2006 Jan;8(1 Suppl 1):4-11
- (4) World Health Organization. Main causes of death and global burden of disease (DALYs), world, all ages, projections for 2005. Available at: <http://www.who.int/whosis/highlight05.png> (accessed 26 June 2008)

- (5) Saleh SS, Szebenyi S, Carter JA, et al. Patterns and Associated Health Services Costs of Antihypertensive Drug Modifications. *J Clin Hypertens*. 2008 January; 10(1):43-50
- (6) Weber MA, Ruilope L, Giles T, et al. First-Step Use of Fixed-Dose Combination Treatment in Stage 2 Hypertensive Patients: Has the Time Come? *J Clin Hypertens*. 2007 April;9(4):276-284
- (7) Sica D. Fixed-Dose Combination Antihypertensive Drugs. Do They Have a Role in Rational Therapy? *Drugs*. 1994 Jul;48(1):16-24
- (8) Chen K. Patient satisfaction with antihypertensive therapy. *Journal of Human Hypertension* (2005) 19, 793-799
- (9) Rosamond W, Flegal K, Friday G, et al. Heart Disease and Stroke Statistics 2008 Update. A report from the American Heart Association Statistics Committee and Stroke Statistics Subcommittee. *Circulation* 2008; 117:e25-e146
- (10) Kearney PM, Whelton M, Reynolds K, et al.. Global burden of hypertension: analysis of worldwide data. *The Lancet*; 365: 217-223



(11) Diovan HCT [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; 2008

(12) Pool JL, Glazer R, Weinberger M, et al. Comparison of Valsartan/ Hydrochlorothiazide Combination Therapy at Doses Up to 320/25 mg Versus Monotherapy: A Double-Blind, Placebo-Controlled Study Followed by Long-Term Combination Therapy in Hypertensive Adults. *Clinical Therapeutics* 2007; 29 (1):61-73

(13) Exforge [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; 2008

###

**Novartis Media Relations**

**Eric Althoff**

Novartis Global Media Relations  
+41 61 324 7999 (direct)  
+41 79 593 4202 (mobile)  
eric.althoff@novartis.com

**Vivienne Schneider**

Novartis Pharma Communications  
+41 61 324 6162 (direct)  
+41 79 619 1335 (mobile)  
vivienne.schneider@novartis.com

e-mail: media.relations@novartis.com

**Novartis Investor Relations**

**Central phone:**

Ruth Metzler-Arnold	+41 61 324 7944
Pierre-Michel Bringer	+41 61 324 9980
John Gilardi	+41 61 324 1065
Thomas Hungerbuehler	+41 61 324 3018
Isabella Zinck	+41 61 324 8425
	+41 61 324 7188

e-mail: investor.relations@novartis.com

**North America:**

Richard Jarvis	+1 212 830 2433
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: August 6, 2008

By: /s/ MALCOLM B. CHEETHAM

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