

NOVARTIS AG
Form 6-K
July 29, 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 July 28, 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-

Exforge® helps nearly twice as many patients control their high blood pressure compared to amlodipine alone

- *New data show that patients on Exforge with baseline blood pressure ≥ 180 mmHg experienced significant reductions of up to 40 mmHg to help reach target levels(1)*
- *Significant blood pressure reductions seen with Exforge across difficult-to-treat groups such as the elderly, obese and people with diabetes(1)*
- *High blood pressure is a leading but treatable risk factor for cardiovascular disease – the world’s leading cause of death(2)*

Basel, July 28, 2008 New data show that Exforge, a single-pill combination of the world’s leading high blood pressure medicines Diovan® (valsartan) and amlodipine, gets nearly twice as many patients with high baseline blood pressure to a healthier blood pressure goal compared to amlodipine alone(1).

Results of a study in patients with systolic baseline blood pressure ≥ 160 mmHg, published in *The Journal of the American Society of Hypertension*, showed that 51.8% of patients on Exforge achieved systolic blood pressure control defined as < 140 mmHg at week four, compared to 27.7% of those on amlodipine alone(1). Systolic blood pressure, measured when the heart contracts and pumps, is an important indicator of a person’s risk of cardiovascular events(3).

The blood pressure drops achieved with Exforge are important since systolic blood pressure continues to increase with age. Therefore as population demographics shift towards older age, the cardiovascular disease burden could almost be entirely attributable to systolic blood pressure, said Dr. Maurizio Destro, lead investigator from the Azienda Ospedaliera di Pavia in Italy. Furthermore, 65% of people with high blood pressure do not achieve their blood pressure goal, and most require two or more medicines. Patients are more likely to keep taking a single pill a day rather than multiple medications, so Exforge is clearly an important and effective therapy option.

The primary endpoint of the study was the change from baseline Mean Sitting Systolic Blood Pressure (MSSBP) at week four. Results showed that on average, patients on Exforge experienced a significant 30.1 mmHg reduction in systolic blood pressure compared to a 23.5 mmHg reduction in patients on amlodipine alone(1).

In the same study, patients with systolic blood pressure ≥ 180 mmHg treated with Exforge experienced significant systolic blood pressure reduction of up to 40.1 mmHg, compared with 31.7 mmHg for those treated with amlodipine alone(1).

Exforge also demonstrated significantly better blood pressure-lowering efficacy than amlodipine alone across certain difficult-to-treat patient groups, including the elderly (over 65 years), obese people and those with diabetes(1).

Treatment guidelines recommend that patients with high blood pressure $\geq 160/100$ mmHg should be considered for a combination of two medicines from different drug classes(4).

To lower the risk of complications from uncontrolled high blood pressure, it is vital to treat patients early and effectively, said Trevor Mundel, MD, Head of Global Development Functions at Novartis Pharma AG. Exforge consistently demonstrates large blood pressure drops across all stages of high blood pressure and has been shown to get as many as nine out of 10 patients without diabetes to goal.

High blood pressure is a leading cause of cardiovascular disease, the world's number one cause of death(2). Controlling high blood pressure can reduce complications such as heart attack, heart failure, stroke, kidney failure and premature death(3).

The study was designed to investigate and compare the efficacy and safety of Exforge with amlodipine in patients with stage 2 high blood pressure (a more severe stage of the disease, with systolic blood pressure between 160 and 200 mmHg). It was a randomized, double-blind, multi-center parallel-group study carried out in 75 centers across Europe and the US. In total, 646 patients were randomized to receive treatment with Exforge 5-10/160 mg (n=322) or amlodipine 5-10 mg (n=324). Demographic and high blood pressure baseline characteristics were similar for both groups(1).

Overall blood pressure measurements consist of two values, both expressed in millimeters of mercury (mmHg). The first is the systolic blood pressure when the heart beats and the second is the diastolic pressure when the heart relaxes between beats. In this study, overall blood pressure control rates ($<140/90$ mmHg) were higher at all assessment points for patients treated with Exforge than for those receiving amlodipine alone. In this study both medications were well tolerated(1).

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 angiotensin receptor blocker, 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

Edgar Filing: NOVARTIS AG - Form 6-K

The foregoing release contains forward-looking statements that can be identified by terminology such as will, may, potential, could, or similar expressions, or by express or implied discussions regarding potential new indications or labelling for Exforge or regarding potential future revenues from 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 Exforge to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee

that Exforge will be approved for any additional indications or labelling in any market. Nor can there be any guarantee that Exforge will achieve any particular levels of revenue in the future. In particular, management's expectations regarding Exforge could be affected by, among other things, 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; 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, 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) Destro et al. Efficacy and Safety of Amlodipine/Valsartan Compared with Amlodipine Monotherapy in Patients with Stage 2 Hypertension: A Randomized, Double-blind, Multicenter Study: The EX-EFFeCTS Study. *The Journal of the American Society of Hypertension*. On-line publication doi:10.1016/j.jash.2008.01.004
- (2) Kearney et al. Global burden of hypertension: analysis of worldwide data. *The Lancet*. 2005;265:217-23
- (3) Chobanian et al. Seventh Report of the Joint National Committee on prevention, detection, evaluation, and treatment of high blood pressure. *Hypertension*. 2003;42:12006-1251.
- (4) Mancia G et al. The 2007 ESH/ESC Guidelines for the management of arterial hypertension. *J Hypertens* 2007;26(4):825-6.

###

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:

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

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

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: July 28, 2008

By: /s/ MALCOLM B. CHEETHAM

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