

NOVARTIS AG
Form 6-K
September 04, 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 September 3, 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**

Novartis International AG

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

- Investor Relations Release -

Study shows Rasilez®, the first and only approved direct renin inhibitor, reduces a marker of heart failure severity and is well-tolerated

- *Rasilez significantly reduces brain natriuretic peptide (BNP), a widely accepted indicator of heart failure severity⁽¹⁾*
- *Rasilez generally well-tolerated when added to standard heart failure treatment⁽¹⁾, unlike some other blood pressure medicines that can worsen heart failure^{(2),(3)}*
- *ALOFT study is the first to highlight potential benefits of Rasilez beyond blood pressure lowering*
- *Heart failure a growing cause of hospitalization and death^{(4),(5)}*

Basel, September 2, 2007 Rasilez® (aliskiren), the first new type of high blood pressure medicine in more than a decade, is generally well-tolerated and can potentially reduce the severity of heart failure⁽¹⁾ based on new data showing significant reductions in BNP, a substance secreted by the heart and whose levels are viewed as an indicator of disease severity.

The ALOFT (Aliskiren Observation of Heart Failure Treatment) study results, presented today at the European Society of Cardiology Congress in Vienna, were the first to highlight the potential benefits of Rasilez beyond blood pressure lowering. Rasilez, which is the first in a new class of high blood pressure medicines called direct renin inhibitors, was launched in the US in March 2007 and received European Union approval in August.

Heart failure, also often referred to as congestive heart failure, may develop slowly over years and occurs when the heart's ability to pump blood is weaker than normal. This condition is particularly seen in patients with high blood pressure⁽⁴⁾ and is a growing cause of hospitalization and death. Most cases of heart failure lead to death within five years⁽⁷⁾.

Unlike some other blood pressure medicines, such as calcium channel blockers and some beta blockers that can worsen heart failure^{(2),(3)}, Rasilez demonstrated good safety and a tolerability profile similar to placebo (or sugar pill)⁽¹⁾ when used in this hard-to-treat patient population.

In the 12-week trial, Rasilez was added to existing standard-of-care therapies including ACE inhibitors and angiotensin receptor blockers (ARBs), which are other types of high blood pressure medicines. As expected, a slightly higher but non-significant number of patients receiving Rasilez experienced hyperkalemia (elevated potassium levels) compared to those receiving a placebo. This was usually mild and did not lead to an adverse outcome⁽¹⁾.

The results showed that the addition of Rasilez to standard heart failure treatments resulted in reductions in BNP (brain natriuretic peptide) nearly five times greater than the standard therapy alone (-61 pg/ml versus -12 pg/ml). This difference in BNP reductions was highly significant ($p=0.016$)(1).

The results showed that the addition of Rasilez to standard heart failure treatments resulted in reductions in BNP (brain natriuretic peptide) nearly five times greater than the standard therapy alone (-61 pg/ml versus -12 pg/ml). This difference in BNP reductions was highly significant ($p=0.016$)(1).

BNP is a substance released from the heart's lower ventricles in response to increased wall tension. The level of BNP in the bloodstream increases when heart failure symptoms worsen, and decreases when the heart failure condition is stable.

Blocking the renin angiotensin aldosterone system (RAAS) with an angiotensin converting enzyme (ACE) inhibitor is of unequivocal benefit in heart failure, said Professor John McMurray, British Heart Foundation Cardiovascular Research Centre, University of Glasgow, Scotland.

The question we asked is whether adding aliskiren to an ACE inhibitor, to further block the RAAS, would be safe and have potentially greater benefit in heart failure. In our study, aliskiren, when added to standard therapy, was well-tolerated and reduced the plasma concentration of BNP, a blood test used as a marker of cardiac strain. Further research is needed to tell us whether this reduction in BNP might be associated with improvements in clinical outcomes, Dr. McMurray said.

The ALOFT study is the first of a series of trials in ASPIRE HIGHER, an extensive ongoing clinical program studying the benefits of Rasilez beyond reducing blood pressure due to its direct inhibition of renin, an enzyme that triggers a process that can lead to high blood pressure. Additional data involving the use of Rasilez in patients with heart failure and new data in patients with kidney failure are expected to be presented later this year.

Rasilez is the first in a new class of high blood pressure medicines called direct renin inhibitors and has demonstrated significant blood pressure lowering when used alone(8),(9) or in combination with other blood pressure medicines(8),(10),(11),(12). It is not currently indicated for use in treating patients with heart failure, and additional long-term studies are needed to assess its potential effects on heart failure.

Rasilez has consistently shown good tolerability and strong blood pressure lowering across trials, said James Shannon, MD, Global Head of Development at Novartis Pharma AG. The ALOFT study highlights the potential benefits of Rasilez beyond blood pressure lowering in a vulnerable, hard-to-treat patient population.

Rasilez was approved in the European Union in August 2007 and in the US in March 2007 under the trade name Tekturna®. In July 2007, Novartis announced Swiss approval of Rasilez. It 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 potential, , may, can and expected or similar expressions, or by express or implied discussions regarding the potential regulatory approval of Rasilez/Tekturna, or potential future revenue from 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 Rasilez/Tekturna reach any particular sales levels. In particular, management's expectations regarding Rasilez/Tekturna could be affected by, among other things, unexpected clinical trial results, including 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; 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 (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

- (1) McMurray J et al. ALOFT – a 12 week safety evaluation of aliskiren 150 mg vs. placebo when added to standard therapy for stable heart failure. Oral presentation in Hotline I session at European Society of Cardiology Congress 2007.
- (2) Packer M. Calcium Channel Blockers in Chronic Heart Failure. The Risks of Physiologically Rational Therapy. *Circulation* 1990; 82:2254-2257.
- (3) Swedberg K, Cleland J, Gargie H, Drexler H, Follath F, et al. Guidelines for the diagnosis and treatment of chronic heart failure: executive summary (update 2005). *European Society of Cardiology* (Accessed 2007 August 14, cited 2005.) Available at: http://www.escardio.org/NR/rdonlyres/A13E135D-5C0C-4A51-B632-03F36AF92010/0/guidelines_CHF_ES_2005.pdf
- (4) Mosterd A, Hoes A. Clinical epidemiology of heart failure. *Heart Online* 2007;93:1137-46.
- (5) Mancia G, De Backer D, Dominiczak A, et al. 2007 Guidelines for the Management of Arterial Hypertension SC guidelines. *European Heart Journal* 2008;28:1462-1536.
- (6) Remme WJ, McMurray JJV, Rauch B, et al. Public awareness of heart failure in Europe: first results from SHAPE. *European Heart Journal* 2005;26:2413-2421.
- (7) National Heart, Lung and Blood Institute. Congestive Heart Failure Data Fact Sheet (Accessed 2007 Feb 19, cited 1996.) Available from <http://library.thinkquest.org/27533/facts.html>
- (8) Uresin Y, Taylor A, Kilo C, Tschope D, Santonastaso M, Ibram G, Fang H, Satlin A. Aliskiren, a novel renin inhibitor, has greater BP lowering than ramipril and additional BP lowering when combined with ramipril in patients with diabetes and hypertension. Poster presented at 16th Scientific Meeting of European Society of Hypertension 2006.
- (9) Philipp T, Schmieder RE et al. Aliskiren-based therapy provides long term renin suppression in patients with hypertension in a 52 week comparator trial with hydrochlorothiazide-based therapy. Poster presented at American Society of Hypertension 22nd Scientific Meeting & Exposition 2007.
- (10) Munger MA, Drummond W, Essop ER, et al. Aliskiren as add-on to amlodipine provides significant additional blood pressure lowering without increased oedema associated with doubling the amlodipine dose. Poster presented at World Congress of Cardiology 2006.
- (11) 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 American Society of Hypertension 22nd Scientific Meeting & Exposition 2007.
- (12) Oparil S, Yarows SA, Patel S, Fang H, Zhang J, Satlin A. Efficacy and safety of combined use of aliskiren and valsartan in patients with hypertension: a randomised, double-blind trial. *Lancet* 2007; 370: 221 – 29.

###

Novartis Media Relations

John Gilardi

Novartis Global Media Relations

+41 61 324 3018 (direct)

+41 79 596 1408 (mobile)

john.gilardi@novartis.com

e-mail: media.relations@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

Nafida Bendali

Pierre-Michel Bringer

Jason Hannon

Thomas Hungerbuehler

Richard Jarvis

Central phone no: +41 61 324 7944

e-mail: investor.relations@novartis.com

North America

Ronen Tamir

Jill Pozarek

Edwin Valeriano

+1 212 830 2433

+1 212 830 2445

+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: September 3, 2007

By: /s/ MALCOLM B. CHEETHAM

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