

NOVARTIS AG  
Form 6-K  
March 16, 2010

# 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 March 14, 2010**

(Commission File No. 1-15024)

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**Novartis AG**

(Name of Registrant)

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**Switzerland**

(Address of Principal Executive Offices)

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Yes:  No:

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**- Investor Relations Release -**

**NAVIGATOR shows valsartan delayed progression to type 2 diabetes in at-risk cardiovascular patients with impaired glucose tolerance**

- *NAVIGATOR study involved more than 9,000 patients, making it one of the largest and longest global trials to date in pre-diabetic patients*
- *Valsartan-based regimen reduced risk of developing new-onset diabetes by 14%, but did not reduce risk of cardiovascular events*
- *Nateglinide-based regimen did not reduce incidence of new-onset diabetes or of cardiovascular events*

**Basel, March 14, 2010** Results from a landmark study involving more than 9,000 people showed that the high blood pressure medicine valsartan delayed progression to type 2 diabetes in patients with cardiovascular disease or risk factors and impaired glucose tolerance (IGT), a common pre-diabetic condition.

Primary data from the NAVIGATOR (Nateglinide And Valsartan in Impaired Glucose Tolerance Outcomes Research) trial, initiated in 2001, were presented today at the American College of Cardiology Annual Meeting in Atlanta, USA(i) and simultaneously published online in the *New England Journal of Medicine*(ii),(iii). The study assessed whether valsartan or the oral anti-diabetic agent nateglinide could delay progression to diabetes or reduce the incidence of cardiovascular events in people with IGT and cardiovascular disease or risk factors.

Obesity and hypertension are global health epidemics, and many of these patients have problems with impaired glucose tolerance. From numerous studies, we know that patients with IGT have an increased risk for type 2 diabetes and cardiovascular disease, said Dr. Robert Califf, Vice Chancellor for Clinical Research at Duke University School of Medicine and Director of the Duke Translational Medicine Institute, Durham, NC, USA. It is critical that we continue to search for pharmacologic interventions that may reduce the incidence of diabetes and cardiovascular disease while emphasizing to our patients that weight loss, as little as 5%, may improve outcomes.

Patients in the study with IGT and cardiovascular disease or other risk factors, who received valsartan for at least five years in addition to background therapy and a study-specific lifestyle-modification program, achieved a statistically significant 14% reduction in their risk of developing new-onset diabetes compared to those in the non-valsartan group(i),(ii).

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Valsartan therapy did not show a reduction in the risk of cardiovascular events in this well-managed group of patients(i),(ii), while nateglinide-based therapy did not show a reduction in the incidence of new-onset diabetes or of cardiovascular events in this study population(i),(iii).

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Trevor Mundel, M.D., Global Head of Development at Novartis Pharma AG said: As a global leader in cardiovascular and metabolic health, Novartis is committed to advancing public health and policy pertaining to diabetes. We are very pleased with the findings of the NAVIGATOR study as they add to the large body of scientific information on valsartan.

The worldwide prevalence of diabetes is expected to increase by 50% (i.e. from 285 to 439 million patients) by 2030(iv). IGT is a defined stage in the development of diabetes(v), and it has been suggested that up to 70% of people with impaired fasting glucose (IFG) and IGT are likely to develop type 2 diabetes over their lifetime(vi). Current guidance from the American Diabetes Association, American College of Endocrinology/American Association of Clinical Endocrinologists and the World Health Organization recommends a variety of interventions for the management of pre-diabetes, based on lifestyle modification(vii),(viii),(ix).

Lifestyle modification remains the primary intervention for the prevention of diabetes. The NAVIGATOR study shows that valsartan, when added to a lifestyle-modification program, can delay progression to diabetes in people who are at high cardiovascular risk and have impaired glucose tolerance, said Dr Rury Holman, Professor of Diabetic Medicine at the Oxford Centre for Diabetes, Endocrinology & Metabolism, University of Oxford, United Kingdom.

Novartis plans to discuss the results of this study with the U.S. Food and Drug Administration with a view to applying for a label change for valsartan. Valsartan is currently indicated for the treatment of high blood pressure for the treatment of heart failure, and reducing the risk of cardiovascular mortality in patients who have suffered a heart attack (myocardial infarction). Nateglinide is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes. Neither valsartan nor nateglinide is currently indicated for the treatment of patients with IGT.

#### **About the study**

NAVIGATOR was a prospective, multinational, randomized, double-blind, placebo-controlled, two-by-two factorial design trial being conducted in 39 countries at nearly 800 sites. The 9,306 patients enrolled in the trial had IGT and were either older than age 50 with diagnosed cardiovascular disease or older than age 55 with at least one risk factor for cardiovascular disease, such as high blood pressure, family history of heart disease, high cholesterol or smoking. In addition to background therapy and a study-specific lifestyle modification program, patients were randomized to receive either valsartan, nateglinide, valsartan and nateglinide together, or placebo(ii),(iii).

NAVIGATOR had three co-primary endpoints. The first endpoint was confirmed progression to overt diabetes, defined according to standard WHO/ADA criteria. The second ( core cardiovascular) endpoint was a composite of time to first occurrence of cardiovascular death, non-fatal myocardial infarction, non-fatal stroke or hospitalization for heart failure. The third ( extended cardiovascular) endpoint consisted of the core cardiovascular endpoint plus revascularization and hospitalization for unstable angina. The median follow-up time (for vital status) was 6.5 years(ii).

The primary NAVIGATOR results for valsartan were as follows:(i),(ii)

- Statistically significant reduction in the risk of progression to diabetes of 14% (HR 0.86, 95% CI 0.80 0.92; p<0.001) compared to non-valsartan treatment

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- No statistically significant reduction of the core (HR 0.99, 95% CI 0.86 1.14; p=0.42) and extended (HR 0.96, 95% CI 0.86 1.07; p=0.22) CV endpoints

The primary results for nateglinide were as follows:(i),(iii)

- No reduction compared to non-nateglinide treatment in terms of progression to diabetes (HR 1.07, 95% CI 1.00 1.15, p=0.98)
  - No statistically significant reductions of the core (HR 0.94, 95% CI 0.82 1.09, p=0.22) and extended (HR 0.93, 95% CI 0.83 1.03, p=0.08) CV endpoints
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Valsartan was dosed up to 160 mg once daily. During the course of the study, 556 participants (12%) in the valsartan group and 531 (11%) in the non-valsartan group discontinued the study drug due to an adverse event. The most common adverse event seen in the valsartan group was hypotension. Nateglinide was dosed up to 60 mg three times daily. During the course of the study, 520 participants (11%) in the nateglinide group and 485 (10%) in the non-nateglinide group discontinued study drug due to an adverse event. The most common adverse events seen in the nateglinide group were hypotension-related events and hypoglycemia(ii),(iii).

## **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as risk, continue to search, may, committed, expected, likely, can, plans, or similar expressions, or by express or implied discussions regarding potential new indications or labeling for valsartan or regarding potential future revenues from valsartan as a result. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of management regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results with valsartan to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that valsartan will be submitted or approved for any additional indications or labeling in any market. Nor can there be any guarantee that any such additional indications or labeling will result in valsartan achieving any particular levels of revenue in the future. In particular, management's expectations regarding valsartan could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; 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 clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; the impact that the foregoing factors could have on the values attributed to the Novartis Group's assets and liabilities as recorded in the Group's consolidated balance sheet, 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 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 2009, the Group's continuing operations achieved net sales of USD 44.3 billion, while approximately USD 7.5 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 100,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit <http://www.novartis.com>.

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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: March 14, 2010

By: /s/ MALCOLM B. CHEETHAM

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

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