

NOVARTIS AG
Form 6-K
September 10, 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 September 9, 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: 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 -

Data show Galvus® better tolerated by patients with type 2 diabetes, with no weight gain, a favorable cardiovascular profile and equal efficacy compared to widely-used TZDs

- *GALIANt* study in more than 2,400 patients shows Galvus as effective as commonly prescribed TZD drugs when added to metformin⁽¹⁾*
- *New pooled data show Galvus is associated with lower overall incidence of cardiovascular and cerebrovascular events, such as heart attacks and strokes, than placebo⁽²⁾ and confirm good tolerability in patients with mild-to-moderate renal impairment⁽³⁾*
- *Patients tolerated Galvus better than TZDs and did not gain weight – a common side effect of other type 2 diabetes medicines⁽¹⁾*
- *Galvus demonstrates strong efficacy in broad patient population with over 14,000 patients treated in clinical program to date*

Basel, September 9, 2008 New data show Galvus® (vildagliptin), an oral treatment for type 2 diabetes, is better tolerated and as effective as commonly prescribed anti-diabetic oral medicines, called thiazolidinediones (TZDs), when added to metformin⁽¹⁾. Patients treated with Galvus did not gain weight, a common side effect of other type 2 diabetes medicines, regardless of their race, body mass index or age⁽¹⁾.

The results come from GALIANt, a study involving more than 2,400 patients treated by primary care physicians⁽¹⁾. The GALIANt data were presented at the annual meeting of the European Association for the Study of Diabetes (EASD) in Rome, Italy.

Type 2 diabetes is estimated to affect more than 53 million people in Europe⁽⁴⁾. Controlling blood sugar is difficult and up to 65% of diabetes patients fail to meet their recommended blood sugar levels⁽⁵⁾. When left untreated or not kept under control, type 2 diabetes can lead to heart and kidney disease, blindness and vascular or neurological problems⁽⁶⁾.

Other data presented at EASD demonstrated the favorable cardiovascular safety profile of Galvus⁽²⁾ and confirmed its tolerability in patients with mild-to-moderate renal impairment⁽³⁾.

The GALIANT study reflects the true nature and diversity of the type 2 diabetes patient population, said Richard Pratley, MD, Director of the Diabetes & Metabolism Translational Medicine Unit at the University of Vermont College of Medicine, USA. The use of early combination therapy is becoming increasingly important to help patients achieve their recommended blood sugar levels. This study shows that Galvus is effective and well tolerated in this diverse group of patients in a primary care setting.

Galvus 100 mg once-daily was used in the GALIANT study. Galvus received European Commission approval for 50 mg twice-daily in combination with the most frequently prescribed oral anti-diabetes medicines, metformin or a TZD, and Galvus 50 mg once-daily in combination with sulphonylureas (SUs). The GALIANT study was amended to a smaller population from the initially planned patient study to ensure an earlier assessment of important comparative efficacy and safety of Galvus compared to TZDs.

The 12-week GALIANT study showed that the efficacy of Galvus 100 mg once-daily was non-inferior to that of TZDs (-0.68% vs. -0.57% HbA1c respectively, $p=0.001$) in patients with type 2 diabetes whose blood sugar levels were inadequately controlled (HbA1c $>7\%$) with metformin alone⁽¹⁾. HbA1c is the standard measure of blood sugar.

The study also showed that patients treated with Galvus lost weight, whereas those on TZDs put on weight (-0.58 kg \pm 0.09 kg vs. +0.33 kg \pm 0.11 kg respectively)⁽¹⁾. This is a key benefit as many patients with type 2 diabetes struggle to keep their weight under control.

The GALIANT study demonstrates that Galvus is an effective treatment option without the associated weight gain seen with commonly prescribed drugs for patients who are currently on metformin but not reaching their recommended blood sugar levels, said Trevor Mundel, MD, Head of Global Development Functions at Novartis Pharma AG.

Other data presented at EASD include a pooled analysis from approximately 6,000 patients demonstrating that Galvus has a favorable cardiovascular profile, with a lower overall incidence of cardiovascular and cerebrovascular events, such as heart attacks and strokes, than placebo⁽²⁾. Concerns have recently been raised over the cardiovascular safety profile of older oral anti-diabetic medicines, including TZDs and SUs⁽⁷⁾.

Separately, an analysis of pooled data from over 1,400 patients reinforced that Galvus is well tolerated in type 2 diabetes patients with mild-to-moderate renal impairment⁽³⁾. Decreased renal function is more common in patients with type 2 diabetes⁽⁸⁾, with the prevalence of kidney disease ranging from 20-40%⁽⁹⁾. The analysis also confirmed there were no adverse changes in renal function following long-term treatment with Galvus⁽³⁾. Similar efficacy was achieved in patients with mild renal impairment and those with normal renal function⁽³⁾. Galvus is currently not recommended for patients with moderate or severe renal impairment in Europe.

Additionally, at EASD Novartis celebrated the 10th annual Novartis Prize in Diabetes, an award created to stimulate innovation in diabetes clinical research and to recognize outstanding individuals who have dedicated themselves to improving the lives of people with diabetes. For more information about the Novartis Prize in Diabetes, please visit www.diabetesaward.novartis.com.

Galvus and Eucreas, a single-pill combination of Galvus and metformin, are approved as oral treatments for type 2 diabetes patients in all 27 countries of the European Union as well as in Norway and Iceland. Galvus is currently available in 18 countries, namely Italy, the UK, Germany, Netherlands, Denmark, Norway, Greece, Malta, Poland, Ireland, Spain, Switzerland, Mexico, Brazil, Argentina, the Philippines, Singapore and India, and is approved in 51 countries. Eucreas is available in 10 countries.

Edgar Filing: NOVARTIS AG - Form 6-K

In the US, some small clinical studies have started amid discussions with the FDA on overall steps needed for approval after an approvable letter in February 2007. However, resubmission for US approval is not planned at this time.

Galvus works through a novel mechanism of action by targeting the dysfunction in the pancreatic islets that causes high blood sugar levels in people with type 2 diabetes. Islet dysfunction, along with insulin resistance, is a contributory factor in type 2 diabetes. In combination with the most widely prescribed type 2 diabetes medicines, Galvus delivers significant blood sugar reductions with a good tolerability profile in a broad range of patients^{(10),(11)}. Galvus demonstrates strong efficacy in a broad patient population with over 14,000 patients treated in the clinical program to date.

The overall incidence of side effects has been shown to be similar to placebo with the most frequent being stuffy nose, headaches, dizziness and upper respiratory tract infection(10). Galvus is not recommended for patients with liver impairment, and liver monitoring should be conducted at the start of treatment, every three months for the first year, and periodically thereafter. Galvus should not be used in patients with type 1 diabetes.

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 portfolio includes 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 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 becoming, approvable, planned, commitment, or similar expressions, or by express or implied discussions regarding potential future approvals to sell Galvus in additional markets, including in the US, or regarding potential future revenues from Galvus. 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 Galvus to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Galvus will be approved for sale in any additional market. Nor can there be any guarantee that Galvus will achieve any particular levels of revenue in the future. In particular, management’s expectations regarding Galvus 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; the affect that the foregoing factors could have on the values attributed to the Group’s assets and liabilities as recorded in the Group’s 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 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

Edgar Filing: NOVARTIS AG - Form 6-K

- (1) Braceras R, et al. Vildagliptin is as Effective as TZDs in Metformin Failures: Results of GALIANT - A Primary Care Diabetes Study. Presented at EASD 6-11 September 2008 (Abstract P-914).
- (2) Kothny W, et al. Cardiovascular Safety Profile of Vildagliptin, a New DPP-4 Inhibitor for the Treatment of Type 2 Diabetes. Presented at EASD 6-11 September 2008 (Poster P-915).
- (3) Thuren T, et al. Vildagliptin is Safe and Well Tolerated in Patients with Mild or Moderate Renal Impairment. Presented at EASD 6-11 September 2008 (Oral Presentation OP-74).
- (4) International Diabetes Federation. Diabetes Atlas. 2006: Third edition.

- (5) Saydah S, et al. Race and ethnic differences in glycemic control among adults with diagnosed diabetes in the United States. *Ethn Dis* 2007; 17:529-535.
- (6) International Diabetes Federation. *Complications of Diabetes* 2008: <http://www.idf.org/home/index.cfm?node=13>.
- (7) Dluhy RG, et al. Intensive Glycemic Control in the ACCORD and ADVANCE Trials. *The New England Journal of Medicine* 2008; 358 (24): 2630-2633.
- (8) Coresh J. Prevalence of Chronic Kidney Disease and Decreased Kidney Function in the Adult US Population: Third National Health and Nutrition Examination Survey. *American Journal of Kidney Diseases* 2003;41;1:1-12.
- (9) Young BA, et al. Diabetes and Renal Disease in Veterans. *Diabetes Care* 27 (suppl 2): B45-49.
- (10) Novartis: Data on File.
- (11) Garber A, et al. Effects of Vildagliptin on Glucose Control in Patients with Type 2 Diabetes Inadequately Controlled with a Sulphonylurea. *Diabetes, Obesity and Metabolism* 2008; 10:1326-1463.

###

Novartis Media Relations

Eric Althoff

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

Navjot Rai

Novartis Pharma Communications
+41 61 324 6498 (direct)
+41 79 777 6400 (mobile)
navjot.raai@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: September 9, 2008

By: /s/ MALCOLM B. CHEETHAM

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