

NOVARTIS AG  
Form 6-K  
April 01, 2011

# 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 31, 2011**

**(Commission File No. 1-15024)**

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**Novartis AG**

(Name of Registrant)

**Lichtstrasse 35**

**4056 Basel**

**Switzerland**

(Address of Principal Executive Offices)

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Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

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Yes:  No:

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**Novartis International AG**

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**- Investor Relations Release -**

**Novartis first-in-class antiviral DEB025 achieved sustained viral response in 76% of patients with chronic hepatitis C, new phase II study shows**

- *DEB025 plus standard of care (pegylated-interferon alfa 2a/ribavirin) showed superior viral cure vs standard of care alone (p=0.008)(1)*
- *A cyclophilin inhibitor, DEB025 belongs to a new class of medicines that limit hepatitis C virus replication and have the potential to reshape hepatitis C therapy*
- *Phase III study with DEB025 commenced recently with previously untreated patients infected by the most common form of hepatitis C virus*

**Basel, March 31, 2011** Novartis announced today that a Phase II study with the first-in-class antiviral DEB025 (alisporivir) met its primary endpoint for achieving viral cure (24 weeks after stopping treatment) in 76% of patients with chronic hepatitis C (1). The study involved nearly 300 previously untreated patients infected with the most common form of hepatitis C virus (HCV), the genotype 1 (G1)(1).

The data were presented today at the European Association for the Study of the Liver (EASL) congress in Berlin, Germany. The findings show that 76% of G1 chronic hepatitis C patients treated with DEB025 plus standard of care (pegylated-interferon alfa 2a/ribavirin) achieved superior viral cure (known as sustained viral response, or SVR) compared to 55% of patients on standard of care alone (p=0.008)(1). Treatment with DEB025 demonstrated a low incidence of adverse events, with discontinuation rates comparable between treatment groups(1).

Hepatitis C is difficult to treat and current therapies are only effective in about half of patients infected with the most prevalent genotype of HCV(2), said Stefan Zeuzem, Professor of Medicine at the Goethe University Hospital in Frankfurt, Germany, and the study's principal investigator. These results are exciting because a large majority of patients achieved sustained viral response with DEB025, with some who also benefited from a shorter duration of treatment compared to standard therapy(1).

DEB025 is the first in a new class of drugs called cyclophilin inhibitors. Unlike other compounds in development that target the virus directly, DEB025 is a host targeting antiviral (HTA) that targets so-called host proteins which are essential for the replication of HCV. As these proteins

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play a key role in the replication of all types of HCV, DEB025 may offer an effective treatment option for a broad range of HCV forms. In other clinical trials, DEB025 has also shown effective antiviral activity against other common HCV genotypes (G2, G3 and G4) (3).

There is a critical need for more effective drugs to treat chronic hepatitis C, and Novartis is dedicated to developing medicines that will reduce the burden of this disease for patients and physicians, said Trevor Mundel, MD, Global Head of Development at Novartis Pharma AG.

DEB025 has a new mode of action that may stop the virus from replicating and could reshape the future approach to treatment of hepatitis C.

More than 170 million people worldwide are infected with HCV, which can cause serious liver disease leading to cirrhosis, liver cancer, and in some cases death. HCV is a blood borne virus that predominantly affects the liver(4),(5). As an RNA (ribonucleic acid) virus, it mutates much more than DNA (deoxyribonucleic acid) viruses. This ability to change makes it harder for the immune system to clear (or eliminate) the virus. There are six major variations of HCV, known as genotypes and labelled from G1 to G6(5).

The study presented at EASL was a 48-week, global, double-blind, randomized, placebo-controlled trial in G1 treatment-naïve chronic hepatitis C patients. It evaluated the efficacy and safety of DEB025 combined with pegylated-interferon alfa 2a/ribavirin (PegIFN/RBV) vs. PegIFN/RBV alone. The primary endpoint was sustained viral response after 24 weeks (SVR24)(1).

Transient and reversible increase in bilirubin was observed in association with the initial DEB025 loading dose(1). A small proportion of patients (4.2%) had a transient increase in bilirubin more than five times the upper limit of normal (ULN), but this was not associated with liver damage(1).

A pivotal Phase III study with DEB025 commenced recently to evaluate the efficacy and safety of DEB025 combined with standard of care and enrolling previously untreated HCV G1 patients. Other Phase II studies are ongoing in other patient populations i.e., G1 treatment-experienced patients and G2 and G3 treatment-naïve patients.

Novartis in-licensed DEB025 from Debiopharm Group, an independent biopharmaceuticals company based in Switzerland, under an agreement which gives Novartis exclusive worldwide development, manufacturing and marketing rights (excluding Japan).

## **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as potential, exciting, may, dedicated, will, could, launched, or similar expressions, or by express or implied discussions regarding potential marketing submissions or approvals for DEB025, or the potential timing of any such submissions or approvals, or regarding potential future revenues from DEB025. 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 DEB025 to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that DEB025 will be submitted or approved for sale in any market. Nor can there be any guarantee that DEB025 will achieve any particular levels of revenue in the future. In particular, management's expectations regarding DEB025 could be affected by, among other things, unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; competition in general; government, industry and general public pricing pressures; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; 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 2010, the Group's continuing operations achieved net sales of USD 50.6 billion, while approximately USD 9.1 billion (USD 8.1 billion excluding impairment and amortization charges) was invested in R&D throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 119,000 full-time-equivalent associates (including 16,700 Alcon associates) and operate in more than 140 countries around the world. For more information, please visit <http://www.novartis.com>.

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## References

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- (2) Hoofnagle JH. A step forward in therapy for hepatitis C. *N Engl J Med.* 2009; 360 (18):1899-901.
- (3) Flisiak R, et al. The cyclophilin inhibitor Debio 025 combined with peg IFN $\alpha$ 2a significantly reduces viral load in treatment-naïve hepatitis C patients. *Hepatology.* 2009; 49:1460-68.
- (4) Lauer GM, Walker BD. Hepatitis C virus infection. *N Engl J Med.* 2001; 345 (1):41-52.
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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 31, 2011

By: /s/ MALCOLM B. CHEETHAM

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