

NOVARTIS AG  
Form 6-K  
June 03, 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 June 3, 2010**

**(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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**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):

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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:

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

**- Investor Relations Release -**

**Pivotal Phase III trial of Novartis drug Afinitor® met primary endpoint in study of patients with advanced pancreatic neuroendocrine tumors**

- *RADIANT-3 study results show everolimus significantly extends progression-free survival in patients with advanced pancreatic neuroendocrine tumors (NET)*
- *Patients with advanced pancreatic NET have a rare and aggressive form of cancer with limited treatment options(1),(2)*
- *Full results to be submitted for presentation at the European Society for Medical Oncology annual meeting and worldwide regulatory filings planned for 2010*

**Basel, June 3, 2010** Novartis announced today that a Phase III study of Afinitor® (everolimus) tablets plus best supportive care met its primary endpoint, showing the drug significantly extended progression-free survival, or time without tumor growth, in patients with advanced pancreatic neuroendocrine tumors (NET). The study, RADIANT-3 (RAD001 In Advanced Neuroendocrine Tumors), is part of the largest clinical trial program of its kind.

Everolimus is approved under the trade name Afinitor® (everolimus) tablets for the treatment of patients with advanced renal cell carcinoma (RCC) whose disease has progressed on or after treatment with vascular endothelial growth factor (VEGF)-targeted therapy.

Pancreatic NET can grow aggressively and at time of diagnosis nearly 60% of all patients have advanced disease, meaning the cancer has spread to other parts of the body and has become more difficult to treat(1),(2). The median survival rate for patients with advanced pancreatic NET is 17 months(2). Currently, surgery and chemotherapy are the only approved treatment options for patients with advanced pancreatic NET(1).

Everolimus was developed to inhibit the mTOR protein, which is a critical target in treating various cancers, including NET. Results from RADIANT-3 demonstrate that everolimus has the potential to become an important treatment option for patients with advanced pancreatic NET, where there is a major unmet need, said Herve Hoppenot, President, Novartis Oncology. These study results will serve as the basis of worldwide regulatory filings for everolimus and bring us one step closer to our goal of offering these patients a new therapy.

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Full results from the RADIANT-3 study will be submitted for presentation at the European Society for Medical Oncology annual meeting taking place in Milan, Italy in October. Additionally, worldwide regulatory filings are planned for 2010.

### **Study details**

RADIANT-3 is a Phase III prospective, double-blind, randomized, parallel group, placebo-controlled, multicenter study. The trial examined the efficacy and safety of everolimus plus best supportive care versus placebo plus best supportive care in 410 patients with advanced

pancreatic NET, also known as islet cell tumors. Patients who met the study's entry criteria were randomized 1:1 to receive either daily everolimus (10 mg) or daily placebo orally.

The primary endpoint of RADIANT-3 is progression-free survival. Secondary endpoints include safety, objective response rate and overall survival.

#### **About neuroendocrine tumors**

Neuroendocrine tumors arise from cells that can produce and secrete a variety of hormones that regulate bodily functions. There are many types of NET that can occur throughout the body; however, most are found in the gastrointestinal tract, pancreas and lungs(3). Because NET are relatively rare, there is no routine screening and patients often experience delays of five to seven years before receiving an accurate diagnosis(3),(4). As a result of this, patients with NET often have advanced disease when diagnosed(3). Although considered a rare cancer, the incidence of NET is increasing dramatically, having quadrupled in the past 30 years(3).

#### **About everolimus**

In the European Union (EU), everolimus is approved under the trade name Afinitor® (everolimus) tablets for the treatment of patients with advanced renal cell carcinoma (RCC) whose disease has progressed on or after treatment with vascular endothelial growth factor (VEGF)-targeted therapy. In the US, Afinitor is approved for the treatment of patients with advanced RCC after failure of treatment with sunitinib or sorafenib.

In the EU, everolimus is available in different dosage strengths under the trade name Certican® for the prevention of organ rejection in heart and kidney transplant recipients. In the US, everolimus is available in different dosage strengths under the trade name Zortress® for the prevention of rejection of kidney transplants in adult patients at low-to-moderate immunologic risk.

With once-daily dosing, Afinitor works by targeting mTOR in cancer cells, a protein that acts as a central regulator of tumor cell division, blood vessel growth and cell metabolism.

As an investigational compound, the safety and efficacy profile of everolimus has not yet been established in NET. Access to everolimus for NET has been carefully controlled and monitored in clinical trials designed to better understand the potential benefits and risks of the compound. For more information about ongoing everolimus clinical trials, healthcare professionals can visit [www.theWIDEprogram.com](http://www.theWIDEprogram.com). Because of the uncertainty of clinical trials, there is no guarantee that everolimus will become commercially available for NET anywhere in the world.

#### **Afinitor (everolimus) tablets important safety information**

Afinitor is contraindicated in patients with hypersensitivity to everolimus, to other rapamycin derivatives or to any of the excipients.

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Cases of non-infectious pneumonitis have been described; some of these have been severe and occasionally fatal. Management of pneumonitis may require dose adjustment and/or interruption, or discontinuation of treatment and/or addition of corticosteroid therapy.

Afinitor is immunosuppressive. Localized and systemic bacterial, fungal, viral or protozoal infections (e.g. pneumonia, aspergillosis, candidiasis, hepatitis B reactivation) have been described; some of these have been severe and occasionally fatal. Pre-existing infections should be treated prior to starting treatment. Patients and physicians should be vigilant for symptoms and signs of infection; in case of emergent infections, appropriate treatment should be promptly instituted and interruption or discontinuation of Afinitor should be considered. Patients with systemic invasive fungal infections should not receive Afinitor.

Mouth ulcers, stomatitis and oral mucositis have been seen in patients treated with Afinitor. Monitoring of renal function, blood glucose and complete blood counts is recommended prior to initiation and periodically during treatment.

Afinitor is not recommended in patients with severe hepatic impairment. Use of live vaccines should be avoided. Afinitor is not recommended during pregnancy or for women of childbearing potential not using contraception. Afinitor may cause fetal harm in pregnant women. Women taking Afinitor should not breast feed.

Avoid concurrent treatment with strong CYP3A4 and PgP inhibitors and use caution with moderate inhibitors. Avoid concurrent treatment with strong CYP3A4 or PgP inducers.

The most common adverse reactions ( $\geq 10\%$ ) include stomatitis, rash, fatigue, asthenia, diarrhea, anorexia, nausea, mucosal inflammation, vomiting, cough, infections, peripheral edema, dry skin, epistaxis, pneumonitis, pruritus, dyspnea and dysgeusia. Common adverse reactions ( $\geq 1$  to  $<10\%$ ) include headache, dry mouth, pyrexia, weight loss, hand-foot syndrome, abdominal pain, erythema, insomnia, dyspepsia, dysphagia, hypertension, increased daytime urination, dehydration, chest pain, hemoptysis and exacerbation of diabetes mellitus. Uncommon adverse reactions ( $<1\%$ ) include ageusia, congestive cardiac failure, new-onset diabetes mellitus, impaired wound healing, grade 1 hemorrhage and hepatitis B reactivation.

#### **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as to be submitted, planned, can, potential, will, goal, or similar expressions, or by express or implied discussions regarding potential new indications or labeling for Afinitor or regarding potential future revenues from Afinitor. 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 Afinitor to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Afinitor will be approved for any additional indications or labeling in any market. Nor can there be any guarantee that Afinitor will achieve any particular levels of revenue in the future. In particular, management's expectations regarding Afinitor 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; 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 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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**References**

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- (4) Modlin, et al. Priorities for Improving the Management of Gastroenteropancreatic Neuroendocrine Tumors. *J Natl Cancer Inst* 2008;100:1282-1289.

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**Novartis Media Relations**

**Central media line :** +41 61 324 2200  
**Eric Althoff**

Novartis Global Media Relations

+41 61 324 7999 (direct)

+41 79 593 4202 (mobile)

[eric.althoff@novartis.com](mailto:eric.althoff@novartis.com)

e-mail: [media.relations@novartis.com](mailto:media.relations@novartis.com)

**Denise Brashear**

Novartis Oncology

+1 862 778 7336 (direct)

[denise.brashear@novartis.com](mailto:denise.brashear@novartis.com)

**Novartis Investor Relations**

**Central phone:** +41 61 324 7944  
Susanne Schaffert +41 61 324 3769  
Pierre-Michel Bringer +41 61 324 1065  
Isabella Zinck +41 61 324 7188  
Thomas Hungerbuehler +41 61 324 8425

e-mail: [investor.relations@novartis.com](mailto:investor.relations@novartis.com)

**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](mailto: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: June 3, 2010

By: /s/ MALCOLM B. CHEETHAM

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