NOVARTIS AG
Form 6-K
June 02, 2009

# 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 May 29, 2009**

**(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:

**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**

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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**

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**- Investor Relations Release -**

**Afinitor® recommended for use in the European Union for patients with advanced kidney cancer**

- *Afinitor more than doubled time without tumor growth and reduced the risk of disease progression or death by 67% compared with placebo*
- *Only treatment shown to benefit patients with advanced kidney cancer whose disease progressed following targeted therapy*
- *CHMP opinion follows recent US approval of Afinitor in advanced kidney cancer*
- *Phase III trials underway to explore potential in multiple additional cancers*

**Basel, May 29, 2009** Novartis has received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) supporting European Union (EU) approval of Afinitor® (everolimus) Tablets for the treatment of patients with advanced renal cell carcinoma (RCC)(1).

The CHMP has recommended approval of Afinitor based on data demonstrating that when compared with placebo, Afinitor more than doubled the time without tumor growth or death in patients with advanced kidney cancer (4.9 vs. 1.9 months) whose disease progressed following prior therapy(1),(2). Additionally, the data showed Afinitor reduced the risk of disease progression or death by 67% (hazard ratio=0.33 with 95% confidence interval 0.25 to 0.43; P<0.0001)(2).

The European Commission generally follows the recommendations of the CHMP and delivers its final decision within two to three months. The decision will apply in all 27 EU member states. Regulatory reviews of Afinitor are underway in Switzerland, Japan and other countries(1).

This positive opinion is good news for those living with advanced kidney cancer and puts us one step closer to offering these patients a new treatment choice that will fulfill an important unmet medical need, said David Epstein, President and CEO, Novartis Oncology, Novartis Molecular Diagnostics. We also are studying the role of Afinitor for early kidney cancer, as well as its potential as a treatment for other tumor types.

In March 2009, the US Food and Drug Administration (FDA) approved Afinitor for use in patients with advanced RCC after failure of treatment with sunitinib or sorafenib, following a priority review of Afinitor based on its potential to fill an unmet medical need for these patients(1),(2). Sunitinib and sorafenib are VEGF-targeted therapies, commonly used as initial treatments for advanced RCC(1).

**Filing data**

The EU regulatory filing for Afinitor was based on data from RECORD-1 (REnal Cell cancer treatment with Oral RAD001 given Daily), the largest Phase III clinical trial to study the effects of an oral mTOR inhibitor in advanced RCC patients whose cancer progressed despite prior treatment. In February 2008, based on a recommendation from an independent data monitoring

committee, Novartis stopped the trial after interim results showed that patients receiving Afinitor experienced a significant delay in cancer progressing or death compared with patients receiving placebo(1),(2).

This international, multicenter, randomized, double-blind trial involved 416 patients with advanced RCC whose cancer progressed despite prior treatment with sunitinib or sorafenib. In addition, prior therapy with bevacizumab, interferon alfa and interleukin-2 was allowed. Patients were randomized to receive Afinitor (10 mg) daily or placebo, in conjunction with best supportive care. The primary endpoint of the study was progression-free survival, which was assessed via a blinded independent, central radiological review(2).

**About RCC**

RCC, which accounts for approximately 2% of all new cancers, is often referred to as kidney cancer. The occurrence rates of RCC are rising steadily around the world due in part to smoking and obesity(3).

In RCC, cancer cells develop in the lining of the kidney s tubes and grow into a tumor(4). If left untreated, the tumor can spread to neighboring lymph nodes and eventually to other organs(5).

**About Afinitor**

Afinitor is approved in the US as the first oral, daily therapy (5 mg and 10 mg tablets) to treat patients with advanced RCC after failure of treatment with sunitinib or sorafenib(1),(2). Afinitor works by directly targeting mTOR, a protein in the cancer cell that controls tumor cell division and blood vessel growth. Preclinical and clinical data have established the important role of mTOR in the development and progression of several types of tumors. Afinitor is also being studied in multiple cancer types, including neuroendocrine, breast, gastric and hepatocellular carcinoma (HCC), as well as tuberous sclerosis complex (TSC) and non-Hodgkin s lymphoma(1).

The active ingredient in Afinitor is everolimus, which is available in different dosage strengths under the trade name Certican® for the prevention of organ rejection in heart and kidney transplant recipients. Certican was first approved in the EU in 2003(1).

**Important safety information**

Afinitor is contraindicated in patients with hypersensitivity to everolimus, to other rapamycin derivatives or to any of the excipients. Potentially serious adverse reactions include non-infectious pneumonitis and infections for which patients should be monitored carefully and treated as needed. In addition, non-infectious pneumonitis may require temporary dose reduction and/or interruption or discontinuation. Patients with systemic invasive fungal infections should not receive Afinitor. Oral ulceration is a common side effect with Afinitor. Renal function, blood glucose, lipids and hematological parameters should be evaluated prior to the start of therapy with Afinitor and periodically thereafter. Strong or moderate CYP3A4 or P-glycoprotein inhibitors should be avoided. An increase in the dose of Afinitor is recommended when co-administered with a strong CYP3A4 inducer. Live vaccinations and close contact with those who have received live vaccines should be avoided by patients taking Afinitor. Afinitor should not be used in patients with severe hepatic impairment. Afinitor may cause fetal harm in pregnant women.

The most common adverse reactions irrespective of causality (incidence ≥30%) were stomatitis, infections, asthenia, fatigue, cough and diarrhea. The most common grade 3/4 adverse reactions irrespective of causality (incidence ≥3%) were infections, dyspnea, fatigue, stomatitis, dehydration, pneumonitis, abdominal pain and asthenia. The most common laboratory abnormalities (incidence ≥50%) were anemia,

hypercholesterolemia, hypertriglyceridemia, hyperglycemia, lymphopenia and increased creatinine. The most common grade 3/4 laboratory abnormalities (incidence ≥3%) were lymphopenia, hyperglycemia, anemia, hypophosphatemia and hypercholesterolemia. Deaths due to acute respiratory failure (0.7%), infection (0.7%) and acute renal failure (0.4%) were observed in patients receiving Afinitor.

**Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as recommended, risk, potential, generally follows the recommendations of the CHMP and delivers , will, can, or similar expressions, or by express or implied discussions regarding potential new indications or labeling for Afinitor, potential approvals of Afinitor in additional markets, 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 sale in any additional markets. Neither can there be any 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 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 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 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 2008, the Group s continuing operations achieved net sales of USD 41.5 billion and net income of USD 8.2 billion. Approximately USD 7.2 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 98,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit http://www.novartis.com.

**References**

(1) Novartis data on file.
(2) Afinitor Prescribing Information.
(3) Eisen, et al. Sorafenib for Older Patients With Renal Cell Carcinoma: Subset Analysis From a Randomized Trial. *Journal of the National Cancer Institute.* 2008; 100(20):1454-1463.
(4) National Cancer Institute. General Information About Renal Cell Cancer. Available at: http://www.cancer.gov/cancertopics/pdq/treatment/renalcell/patient. Accessed April 2009.
(5) National Cancer Institute. Stages of Renal Cell Cancer. Available at: http://www.cancer.gov/cancertopics/pdq/treatment/renalcell/Patient/page2. Accessed April 2009.

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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**

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| Date: May 29, 2009 | By: | /s/ MALCOLM B. CHEETHAM |
| | Name: | Malcolm B. Cheetham |
| | Title: | Head Group Financial Reporting and Accounting |