

NOVARTIS AG  
Form 6-K  
March 31, 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 March 30, 2009

(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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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: ☐

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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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- Investor Relations Release -

**Afinitor® approved in US as first treatment for patients with advanced kidney cancer after failure of either sunitinib or sorafenib**

- *Afinitor more than doubled time without tumor growth and reduced the risk of disease progression or death by 67% compared with placebo*
- *Only once-daily oral cancer treatment to directly target mTOR, a protein inside the cell that controls tumor cell division and blood vessel growth*
- *Phase III trials underway to explore potential of Afinitor in multiple additional cancers*

**Basel, March 30, 2009** Novartis announced today that Afinitor® (everolimus) tablets has been approved by the US Food and Drug Administration (FDA) for patients with advanced renal cell carcinoma (RCC) after failure of treatment with Sutent® (sunitinib)\* or Nexavar® (sorafenib)\*\*.

Prior to Afinitor, no other therapy has been studied in a Phase III trial in this patient population where there is an important unmet medical need(1). Sutent and Nexavar are commonly used as initial treatments for advanced RCC(2).

The approval is based on data that showed Afinitor, when compared with placebo, more than doubled the time without tumor growth or death in patients with advanced kidney cancer (4.9 vs. 1.9 months) and 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)(3). Furthermore, additional data show that after 10 months of treatment with Afinitor, approximately 25% of patients still had no tumor growth(1), \*\*\*.

This approval provides a new and useful tool for treating advanced renal cell cancer, representing an important step forward in managing this disease, said Robert J. Motzer, MD, attending physician, Memorial Sloan-Kettering Cancer Center, New York and principal investigator of the RECORD-1 trial, the basis for FDA approval of Afinitor. New treatment options are vital to help us continue to offer patients with advanced

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kidney cancer new ways to battle their difficult-to-treat disease. Based on clinical trial data, this option should be considered when sunitinib or sorafenib fail.

In 2008, the FDA granted priority review status to Afinitor, previously known as RAD001, based on its potential to fill an unmet medical need for patients with advanced kidney cancer. Novartis has filed regulatory submissions in the European Union, Switzerland and Japan, as well as with other regulatory agencies globally(1).

Afinitor inhibits 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(1).

With this approval, we can now offer patients a targeted therapy proven to fulfill an important unmet need in the treatment of advanced kidney cancer, said David Epstein, President and CEO, Novartis Oncology, Novartis Molecular Diagnostics. We continue to study Afinitor in kidney cancer, and through a broad clinical program to explore its potential in many other tumor types.

#### **About renal cell carcinoma**

Renal cell carcinoma is often referred to as kidney cancer. Kidney cancer accounts for approximately 2% of all new cancers(4). RCC is the most common type of kidney cancer, with occurrence rates rising steadily around the world due in part to smoking and obesity(5),(6). It is estimated that about 54,000 new cases of RCC developed in the US in 2008 and more than 13,000 people died from the disease(7).

In RCC, cancer cells develop in the lining of the kidney's tubes and grow into a tumor(8). If left untreated, the tumor can spread to neighboring lymph nodes and eventually other organs(9).

#### **RECORD-1 trial**

The FDA 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 with sunitinib, sorafenib or both sequentially. 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).

This international, multi-center, randomized, double-blind trial involved 416 patients with advanced RCC whose cancer progressed despite prior treatment with sunitinib, sorafenib or both sequentially. 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(10).

#### **About Afinitor**

Afinitor is the first oral, daily therapy (5 mg and 10 mg tablets) to treat advanced kidney cancer after failure of treatment with sunitinib or sorafenib. In cancer cells, Afinitor continuously targets mTOR, a protein that acts as a central regulator of tumor cell division, blood vessel growth and cell metabolism. 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(11).

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. Certican is not approved for use in the US<sup>(1)</sup>.

For more information on Afinitor, visit [www.afinitor.com](http://www.afinitor.com). US patients who may be eligible for financial assistance can learn about the AfiniTRAC reimbursement support program by contacting +1-888-5AfiniTRAC or visiting the website for Afinitor.

#### **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. Afinitor should not be used in patients with severe hepatic impairment. Afinitor may cause fetal harm in pregnant women.

The most common adverse reactions (incidence  $\geq 30\%$ ) were stomatitis, infections, asthenia, fatigue, cough and diarrhea. The most common grade 3/4 adverse reactions (incidence  $\geq 3\%$ ) were infections, dyspnea, fatigue, stomatitis, dehydration, pneumonitis, abdominal pain and asthenia. The most common laboratory abnormalities (incidence  $\geq 50\%$ ) were anemia, hypercholesterolemia, hypertriglyceridemia, hyperglycemia, lymphopenia and increased creatinine. The most common grade 3/4 laboratory abnormalities (incidence  $\geq 3\%$ ) 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 for patients receiving Afinitor.

#### **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as risk, options, potential, continue to study, explore, estimated, 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 the Company 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 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, preventive vaccines, diagnostic tools, cost-saving generic pharmaceuticals 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 96,700 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit <http://www.novartis.com>.

## References

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\* Sutent® is a registered trademark of Pfizer Inc.

\*\* Nexavar® is a registered trademark of Bayer HealthCare Pharmaceuticals, Inc. and Onyx Pharmaceuticals.

\*\*\* Data from RECORD-1 study findings presented at the 33rd European Society for Medical Oncology Congress.

**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 30, 2009

By: /s/ MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham  
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Reporting and Accounting