NOVARTIS AG
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SECURITIES AND EXCHANGE COMMISSION

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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 August 6, 2009

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

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(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:

Form 20-F: x Form 40-F: o

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- Investor Relations Release -

Afinitor® approved in EU as first treatment proven to benefit patients with advanced kidney cancer after failure of targeted therapy

- *Afinitor more than doubled median time without tumor growth and reduced the risk of disease progression or death by 67% compared with placebo*

- *Patients with advanced kidney cancer have limited options once they experience tumor progression after VEGF-targeted therapy*

- *Several European treatment guidelines recently updated to recommend Afinitor as second-line therapy for advanced kidney cancer*

- *Phase III trials underway to explore potential in multiple additional cancers*

Basel, August 6, 2009 The European Commission (EC) has approved Afinitor® (everolimus) tablets for the treatment of patients with advanced renal cell carcinoma (RCC) whose disease progressed on or after treatment with vascular endothelial growth factor (VEGF)-targeted therapy.

Nearly 40% of all RCC patients have advanced cancer at time of diagnosis, meaning that their tumors have spread outside of the kidneys(1). Standard initial treatment for these patients may include VEGF-targeted therapies(2). Prior to Afinitor, there were no proven treatment options for advanced RCC patients whose cancer progressed while on or after treatment with VEGF-targeted therapy.

This approval means that across Europe thousands of patients with advanced kidney cancer now have the opportunity for a clear treatment path with Afinitor if their disease progresses after treatment with a targeted therapy, said David Epstein, President and CEO, Novartis Oncology, Novartis Molecular Diagnostics.

The EC based its approval of Afinitor on data from a pivotal Phase III trial demonstrating that Afinitor, when compared with placebo, more than doubled the median time without tumor growth or death in patients with advanced kidney cancer whose disease progressed following prior VEGF-targeted therapy (4.9 vs. 1.9 months). Additionally, the data showed Afinitor reduced the risk of disease progression or death by 67% based on the primary endpoint of progression-free survival (PFS) (hazard ratio=0.33 with 95% confidence interval 0.25 to 0.43; P<0.0001)(3).

Several European treatment guidelines have been updated to recommend Afinitor as a second-line advanced kidney cancer therapy after progression on targeted therapies, including those from the European Association of Urology (EAU), the Spanish Oncology Genitourinary Group (SOGUG), the European Organisation for Research and Treatment of Cancer (EORTC), the European Society for Medical Oncology (ESMO) and the UK Consensus Guidelines(4),(5),(6),(7),(8).

The EC decision applies in all 27 European Union (EU) member states. Afinitor is currently under regulatory review in Switzerland, Japan and other countries.

Study details

The approval is 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 VEGF-targeted treatment(9). 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 progression or death compared with patients receiving placebo.

This international, multicenter, randomized, double-blind clinical trial involved 416 patients with advanced RCC whose cancer progressed despite prior treatment with sunitinib or sorafenib. 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 PFS, which was assessed via a blinded, independent, central radiological review(9).

About RCC

Renal cell carcinoma, which accounts for approximately 2% of all new cancers, is often referred to as kidney cancer(10). The occurrence rates of RCC are rising steadily around the world due, in part, to smoking and obesity(11). In the EU, there were more than 63,000 new cases of RCC diagnosed and more than 26,000 people died from the disease in 2006(12).

In RCC, cancer cells develop in the lining of the kidney s tubes and grow into a tumor. If left untreated, the tumor can spread to neighboring lymph nodes and eventually to other organs(13),(14).

About Afinitor

In the EU, Afinitor is indicated for patients with advanced RCC whose disease progressed on or after treatment with VEGF-targeted therapy. Afinitor is also approved in the US to treat advanced RCC 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 being studied in multiple cancer types, including RCC, neuroendocrine, breast, gastric and hepatocellular carcinoma (HCC), as well as tuberous sclerosis complex (TSC) and non-Hodgkin s lymphoma.

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.

For more information on Afinitor, visit www.afinitor.com.

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 to Afinitor 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 of Afinitor. Renal function, blood glucose and hematological parameters should be evaluated prior to the start of therapy with Afinitor and periodically thereafter.
Co-administration with CYP3A4 or P-glycoprotein inhibitors and inducers should be avoided. If co-administration of a moderate CYP3A4 and/or PgP inhibitor or inducer cannot be avoided, dose adjustments of Afinitor can be taken into consideration. The use of live vaccines should be avoided by patients taking Afinitor. Afinitor should not be used in patients with

severe hepatic impairment. Patients with galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption should not take Afinitor. Caution should be used during the peri-surgical period as Afinitor may impair wound healing. Afinitor is not recommended during pregnancy or for women of childbearing potential not using contraception. Afinitor may cause fetal harm in pregnant women.

The most common adverse drug reactions (incidence ≥1/10) include stomatitis, rash, fatigue, asthenia, diarrhea, anorexia, nausea, mucosal inflammation, vomiting, cough, infections, peripheral edema, pneumonitis, epistaxis, dry skin, pruritus, dyspnea and abnormal taste, as well as decreased hemoglobin, lymphocytes, phosphate, platelets, neutrophils, and increased cholesterol, triglycerides, glucose, creatinine, aspartate aminotransferase and alanine aminotransferase.

The most frequent grade 3-4 adverse reactions (incidence ≥2%) were lymphocytes decreased, glucose increased, hemoglobin decreased, phosphate decreased, cholesterol increased, infections, stomatitis, fatigue and pneumonitis.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as risk, potential, may, can, potentially, should, or similar expressions, or by express or implied discussions regarding future regulatory filings, marketing approvals or 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 sale in any additional markets, or 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 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 99,000 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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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: August 6, 2009	By:	/s/ MALCOLM B. CHEETHAM
	Name:	Malcolm B. Cheetham
	Title:	Head Group Financial Reporting and Accounting