NOVARTIS AG
Form 6-K
May 06, 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 May 5, 2011

(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 -

Novartis gains FDA approval for Afinitor® as first new treatment in nearly three decades for patients with advanced pancreatic NET

- *Data show Afinitor delays tumor growth and reduces risk of disease progression in patients with advanced neuroendocrine tumors (NET) of pancreatic origin(1)*

- *Afinitor represents a new approach to treat advanced pancreatic NET, an aggressive cancer for which there has been limited treatment options(1),(2),(3)*

- *Regulatory filings outside the US have been submitted for everolimus in advanced NET and are being reviewed by health authorities worldwide*

Basel, May 5, 2011 Novartis announced today that the US Food and Drug Administration (FDA) approved Afinitor® (everolimus) tablets for the treatment of progressive neuroendocrine tumors of pancreatic origin (PNET) in patients with unresectable, locally advanced or metastatic disease(4). This marks the first approval of a treatment for this patient population in the US in nearly 30 years(5).

The approval was based on Phase III data from the RADIANT-3 (RAD001 In Advanced Neuroendocrine Tumors) trial showing treatment with Afinitor more than doubled the time without tumor growth (median 4.6 to 11.0 months) and reduced the risk of cancer progression by 65% when compared with placebo in patients with advanced pancreatic NET (hazard ratio=0.35 [95% confidence interval (CI), 0.27 to 0.45]; p<0.001). A consistent improvement in progression-free survival was seen with Afinitor in all patient subgroups(1). The FDA determined that the safety and effectiveness of Afinitor in the treatment of patients with carcinoid tumors have not been established(4).

The FDA approval of Afinitor represents an important step forward for patients with advanced pancreatic NET, said James Yao, MD, Associate Professor of Medicine, The University of Texas MD Anderson Cancer Center, Houston, Texas. Patients will now have access to a treatment that has been shown to significantly delay tumor growth and reduce the risk of disease progression.

Approximately 60% of pancreatic NET patients are diagnosed with advanced disease(2). This means that the cancer has already spread to other parts of the body, and is considered aggressive and difficult to treat(3). The five-year survival rate for these patients is 27%(6).

With this approval, US physicians can now offer their patients with progressive pancreatic NET a new treatment helping to fulfill a critical unmet need, said Hervé Hoppenot, President, Novartis Oncology. This is the third indication for Afinitor in the US in just over two years, providing further evidence that inhibiting mTOR plays an important role in treating multiple tumor types.

Afinitor targets mTOR, a protein that acts as an important regulator of tumor cell division, blood vessel growth and cell metabolism(7). Preclinical and clinical data have established the role of

mTOR in the development and progression of several types of tumors, including advanced pancreatic NET(1),(7).

Novartis has submitted marketing applications for everolimus for the treatment of patients with advanced NET of gastrointestinal, lung or pancreatic origin to the European Medicines Agency (EMA) and the Swiss Agency for Therapeutic Products (Swissmedic), and additional regulatory submissions are being reviewed by health authorities worldwide.

About neuroendocrine tumors of pancreatic origin (pancreatic NET)

Neuroendocrine tumors arise from cells that can produce and secrete a variety of hormones that regulate bodily functions(8). These tumors can occur anywhere in the body; however, most are found in the pancreas (pancreatic NET), gastrointestinal tract or lungs (carcinoid tumors)(6),(9). Pancreatic NET, also known as islet cell tumors, is a rare type of cancer different from pancreatic exocrine cancer, which is generally referred to as pancreatic cancer(3),(10). There have been limited treatment options for patients with pancreatic NET(2).

About RADIANT-3

RADIANT-3 is a Phase III prospective, double-blind, randomized, parallel group, placebo-controlled, multicenter study. The trial examined the efficacy and safety of Afinitor plus best supportive care (BSC) versus placebo plus BSC in 410 patients with advanced, low- or intermediate-grade pancreatic NET. Patients who met the study entry criteria were randomized 1:1 to receive either Afinitor 10 mg once-daily (n=207) or daily placebo (n=203) orally, both in conjunction with BSC(1).

The primary endpoint of RADIANT-3 is progression-free survival. Secondary endpoints include safety, objective response rate (confirmed according to RECIST), duration of response and overall survival(1).

About Afinitor (everolimus)

Afinitor® (everolimus) tablets is approved in the US for the treatment of progressive neuroendocrine tumors of pancreatic origin in patients with unresectable, locally advanced or metastatic disease. The FDA determined that the safety and effectiveness of Afinitor in the treatment of patients with carcinoid tumors have not been established.

Afinitor is approved in the European Union (EU) 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 and also in the US for the treatment of patients with advanced RCC after failure of treatment with sunitinib or sorafenib.

Afinitor is also approved in the US to treat patients with subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis who require therapeutic intervention but are not candidates for curative surgical resection. The effectiveness of Afinitor is based on an analysis of change in SEGA volume. Clinical benefit such as improvement in disease-related symptoms or increase in overall survival has not been shown. Novartis has submitted marketing applications for everolimus for this use to the European Medicines Agency (EMA) and the Swiss Agency for Therapeutic Products (Swissmedic), and additional regulatory submissions are under way worldwide.

In the EU, everolimus is available in different dosage strengths for the non-oncology patient population 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 prophylaxis of organ rejection in adult patients at low-moderate immunologic risk receiving a kidney transplant.

Everolimus is exclusively licensed to Abbott and sublicensed to Boston Scientific for use in drug-eluting stents.

Not all indications are available in every country. As an investigational compound the safety and efficacy profile of everolimus has not yet been established in all countries in pancreatic or any other type of NET. Access to everolimus outside of the approved indications has been carefully controlled and monitored in clinical trials designed to better understand the potential benefits and risks of the compound. Because of the uncertainty of clinical trials, there is no guarantee that everolimus will become commercially available for pancreatic or any other type of NET, or additional indications anywhere else in the world.

Important Safety Information about Afinitor (everolimus) tablets

Afinitor can cause serious side effects including lung or breathing problems, infections, and renal failure which can lead to death. Mouth ulcers and mouth sores are common side effects. Afinitor can affect blood cell counts, kidney and liver function, blood sugar and cholesterol levels. Afinitor may cause fetal harm in pregnant women. Women taking Afinitor should not breast feed.

The most common adverse drug reactions (incidence ≥15%) are mouth ulcers, rash, diarrhea, fatigue, acneiform dermatitis, infections, weakness, nausea, peripheral swelling, decreased appetite, headache, pneumonitis, abnormal taste, nose bleeds, mucosal inflammation, weight decreased and vomiting. The most common grade 3-4 adverse drug reactions (incidence ≥2%) are mouth ulcers, fatigue, decreased white blood cell count, diarrhea, infections, pneumonitis and diabetes mellitus. Cases of hepatitis B reactivation and pulmonary embolism have been reported.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as will, risk, under way, potential, or similar expressions, or by express or implied discussions regarding potential submissions or approvals for new indications or labeling for Afinitor, or regarding the potential timing of any such submissions or approvals, 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 submitted or 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; government, industry and general public pricing pressures; competition in general; 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, eye care, cost-saving generic pharmaceuticals, consumer health products,

preventive vaccines and diagnostic tools. 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 and operate in more than 140 countries around the world. For more information, please visit http://www.novartis.com.

Novartis is on Twitter. Sign up to follow @Novartis at http://twitter.com/novartis.

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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: May 5, 2011	By:	/s/ MALCOLM B. CHEETHAM
	Name:	Malcolm B. Cheetham
	Title:	Head Group Financial Reporting and Accounting