NOVARTIS AG
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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 September 5, 2011

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

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4056 Basel

Switzerland

(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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Yes: o **No**: x

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- Investor Relations Release -

Novartis drug Afinitor® gains EU approval to treat patients with advanced pancreatic neuroendocrine tumors

- *Phase III trial showed Afinitor reduced risk of cancer progression by 65% vs. placebo in patients with advanced pancreatic neuroendocrine tumors (NET)(1)*

- *Afinitor gives patients with limited treatment options a new targeted approach by inhibiting mTOR, a key regulator of tumor cell function(2)*

Basel, September 5, 2011 Novartis announced today that the European Commission has approved Afinitor® (everolimus) tablets for the treatment of unresectable or metastatic, well- or moderately-differentiated neuroendocrine tumors (NET) of pancreatic origin in adults with progressive disease(3).

The approval was based on Phase III data from the largest clinical trial to date in advanced pancreatic NET. The RADIANT-3 (RAD001 In Advanced Neuroendocrine Tumors) trial showed 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, including patients who had not received prior chemotherapy(1).

Approximately 60% of pancreatic NET patients are diagnosed with advanced disease(4). This means that the cancer has already spread to other parts of the body, and is considered aggressive and difficult to treat(5). The five-year survival rate for these patients is 27%(6).

Today s approval of Afinitor means that thousands of advanced pancreatic NET patients across Europe will have a new targeted approach for the treatment of this aggressive cancer type for which few therapeutic options are available, said Hervé Hoppenot, President, Novartis Oncology. We remain committed to the development of everolimus and to further researching the role of mTOR inhibition in multiple tumor types to address significant unmet medical needs for patients.

Afinitor targets mTOR, a protein that acts as an important regulator of tumor cell division, blood vessel growth and cell metabolism(2). 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),(2). Afinitor is the first mTOR inhibitor approved in the EU for the treatment of NET of pancreatic origin.

The decision applies in all 27 European Union member states, plus Iceland and Norway. Additional regulatory submissions for everolimus in advanced NET are under way 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(7). These tumors can occur anywhere in the body; however, most are found in the pancreas (pancreatic NET), gastrointestinal tract or lungs (carcinoid tumors)(6),(8). 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(5),(9).

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 everolimus 10 mg once-daily (n=207) or daily placebo (n=203) orally, both in conjunction with BSC. The primary endpoint is progression-free survival(1).

About Afinitor (everolimus)

Afinitor® (everolimus) tablets is approved in the European Union (EU) for the treatment of unresectable or metastatic, well- or moderately-differentiated neuroendocrine tumors (NET) of pancreatic origin in adults with progressive disease. Afinitor is also approved in the 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.

Everolimus is also available in the EU 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.

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. 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. As an investigational compound the safety and efficacy profile of everolimus has not yet been established outside the approved indications. Because of the uncertainty of clinical trials, there is no guarantee that everolimus will become commercially available for additional indications.

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, and 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, diarrhea, feeling weak or tired, skin problems (such as rash or acne), infections, nausea, swelling of extremities or other parts of the body, loss of appetite, headache, inflammation of lung tissue, abnormal taste, nose bleeds, inflammation of the lining of the digestive system, weight decreased and vomiting. The most common Grade 3-4 adverse drug reactions (incidence ≥2%) are mouth ulcers, feeling tired, low white blood cells (a type of blood cell that fights infection), diarrhea, infections, inflammation of lung tissue, and diabetes. Cases of hepatitis B reactivation and blood clot in the lung and leg have been reported.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as will, committed, potential, or similar expressions, or by express or implied discussions regarding potential new indications or labeling for everolimus or regarding potential future revenues from everolimus. 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 everolimus to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that everolimus will be approved for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that everolimus will achieve any particular levels of revenue in the future. In particular, management s expectations regarding everolimus 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; 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 121,000 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: **September 5, 2011**	By:	/s/ MALCOLM B. CHEETHAM
	Name:	Malcolm B. Cheetham
	Title:	Head Group Financial Reporting and Accounting