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 April 12, 2011

(Commission File No. 1-15024)

Novartis AG

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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

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- Investor Relations Release -

Novartis drug Afinitor® recommended by FDA oncology advisory committee for approval to treat advanced NET of pancreatic origin

- *Committee votes unanimously in favor of everolimus to treat patients with advanced neuroendocrine tumors (NET) of pancreatic origin*

- *Phase III results showed everolimus more than doubled median progression-free survival from 4.6 to 11.0 months when compared with placebo in patients with advanced pancreatic NET(1)*

- *Everolimus represents a targeted approach for the treatment of patients with advanced pancreatic NET, for which there are limited options(1),(2),(3)*

Basel, April 12, 2011 Novartis announced today that the US Food and Drug Administration (FDA) Oncologic Drugs Advisory Committee (ODAC) recommended approval of Afinitor® (everolimus) tablets for the treatment of patients with advanced neuroendocrine tumors (NET) of pancreatic origin.

The recommendation was provided after presentation of data from the everolimus RADIANT (RAD001 In Advanced Neuroendocrine Tumors) trial program, the largest conducted in patients with advanced NET. The Phase III RADIANT-3 trial studied patients with advanced NET of pancreatic origin and showed a statistically significant improvement in progression-free survival with everolimus versus placebo(1).

The FDA can seek the advice of its advisory committees as it reviews and decides whether to approve treatments, although it is not obliged to follow the recommendation(4),(5).

We look forward to working with the FDA as it completes its review and we are encouraged by the advisory committee s recommendation to approve everolimus for patients with advanced pancreatic NET, said Hervé Hoppenot, President, Novartis Oncology. The study of everolimus in this patient population is an example of our commitment to identify targeted options for patients with critical unmet medical needs.

When pancreatic NET becomes advanced, meaning the cancer has spread to other parts of the body, it is considered aggressive and difficult to treat(6). Approximately 60% of pancreatic NET patients are diagnosed with advanced disease, and the five-year survival rate for these patients is 27%(3),(7).

Everolimus 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, for which there are limited treatment options(1),(2),(3).

Earlier this year, the FDA granted everolimus priority review designation for the application and proposed indication for the treatment of advanced NET of gastrointestinal (GI), lung or pancreatic origin. Based on feedback from the FDA, Novartis amended the proposed indication to focus on patients with one specific type of NET, advanced NET of pancreatic origin.

Priority review status is granted to therapies that offer major advances in treatment or provide a treatment where no adequate therapy exists. This status accelerates the standard review time from 10 to six months(8). There is the potential that the outcome of an ODAC meeting could result in the FDA extending the review period.

Worldwide regulatory filings for everolimus as a treatment for advanced NET of GI, lung or pancreatic origin are being reviewed by health authorities.

About pancreatic neuroendocrine tumors (NET)

Neuroendocrine tumors arise from cells that can produce and secrete a variety of hormones that regulate bodily functions(9). These tumors can occur anywhere in the body; however, most are found in the pancreas, gastrointestinal tract or lungs(7),(10). Pancreatic NET, also known as islet cell tumors, is a rare type of cancer that is different from pancreatic exocrine cancer, generally referred to as pancreatic cancer(6),(11). There are currently limited treatment options for pancreatic NET patients(3).

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 everolimus 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(1).

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

Results from the trial showed that everolimus more than doubled median PFS from 4.6 to 11.0 months when compared with placebo and reduced the risk of cancer progression by 65% (hazard ratio=0.35 [95% CI, 0.27 to 0.45]; p<0.001) in patients with advanced pancreatic NET(1).

In the study, everolimus maintained a safety profile consistent with the prescribing information and previous studies of the drug. The most frequent all grade, drug-related adverse events (≥20%) were stomatitis/oral mucositis/ulcers (64% everolimus vs. 17% placebo; includes stomatitis, aphthous stomatitis, mouth ulceration and tongue ulceration), rash (49% vs. 10%), diarrhea (34% vs. 10%), fatigue (31% vs. 14%), infections (23% vs. 6%), nausea (20% vs. 18%), peripheral edema (20% vs. 3%) and decreased appetite (20% vs. 7%); most were grade one or two. Grade three and four adverse events (≥5%) include stomatitis/oral mucositis/ulcers (7% vs. 0%; includes stomatitis, aphthous stomatitis, mouth ulceration and tongue ulceration), anemia (6% vs. 0%) and hyperglycemia (5% vs. 2%). Median exposure to everolimus was 2.3-fold longer than exposure to placebo (38 vs. 16 weeks)(1).

About Afinitor (everolimus)

Afinitor® (everolimus) tablets 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 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 any additional indications anywhere 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 recommended, recommendation, look forward to, encouraged, commitment, priority review, potential, under way, will, or similar expressions, or by express or implied discus regarding potential submissions or approvals for new indications or labeling for everolimus, or regarding the potential timing of any such approvals, 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 submitted or 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 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; uncertainties involved in the development of new pharmaceutical products; 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, 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:	April 12, 2011	By:	/s/ MALCOLM B. CHEETHAM
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