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 April 27, 2012

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

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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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Novartis drug Afinitor® approved by FDA as first medication to treat patients with non-cancerous kidney tumors associated with TSC

- *Kidney tumors affect up to 80% of patients with tuberous sclerosis complex (TSC) and growing tumors may lead to unpredictable life-threatening complications(1)*

- *Prior to the approval of Afinitor, surgical intervention was the only treatment option for patients with these kidney tumors associated with TSC,(2),(3)*

- *Approval marks the second TSC-related indication for Afinitor in the US, where it is also approved to treat subependymal giant cell astrocytoma (SEGA) in TSC(2)*

Basel, April 26, 2012 Novartis announced today that the US Food and Drug Administration (FDA) approved Afinitor® (everolimus) tablets* for the treatment of adult patients with kidney tumors known as renal angiomyolipomas and tuberous sclerosis complex (TSC), who do not require immediate surgery (2). This marks the first approval of a medical treatment in this patient population(2),(3).

The accelerated approval was based on the Phase III EXIST-2 (EXamining everolimus In a Study of TSC) trial, which found that 42% of patients on everolimus experienced an angiomyolipoma response versus 0% of patients in the placebo arm ($p<0.0001$)(2),(4). The time to angiomyolipoma progression was also statistically significantly longer in patients on everolimus ($p<0.0001$). Among the 97% of trial patients with skin lesions, one of the key concerns for the majority of patients with TSC, a 26% response rate was seen with everolimus versus 0% with placebo ($p=0.0011$)(2),(5).

Renal angiomyolipomas are one of the greatest causes of morbidity and mortality in adult TSC patients and can be one of the most challenging aspects of the disease to treat, said John Bissler, MD, Clark D. West Endowed Chair of Nephrology at Cincinnati Children s Hospital Medical Center. Today marks an important step for the TSC community, as Afinitor is now the only approved medicine to reduce the kidney tumor burden in these patients.

Up to 80% of patients with TSC, a genetic disorder that may cause non-cancerous tumors to form in vital organs, will develop renal angiomyolipomas. Typical onset occurs between the ages of 15 and 30 and prevalence increases with age. Over time, these tumors may grow large enough to cause severe internal bleeding, require emergency surgical interventions, such as embolization and nephrectomy, or lead to

kidney failure(1). The tumors can be difficult to manage as they often form in both kidneys(5),(6). In addition, skin lesions occur in more than 90% of patients with TSC(7). They may develop in infancy, can become more prevalent with age and cause disfigurement(1),(5).

With this FDA approval, Afinitor becomes the first medical option to treat two of the most debilitating manifestations of this challenging, lifelong disease kidney tumors called renal angiomyolipomas and brain tumors known as SEGAs, said Hervé Hoppenot, President, Novartis Oncology. This approval further strengthens our commitment to

*Known as Votubia® (everolimus) tablets for certain patients with SEGA associated with TSC in the EU and Switzerland.

address unmet needs in TSC as we continue to research everolimus and mTOR inhibition across other manifestations of the disease.

Based on an effect on a clinical endpoint other than survival or irreversible morbidity, this indication was approved under the FDA s accelerated approval program, which provides patients access to a treatment for a serious or life-threatening illness and provides meaningful therapeutic benefit to patients over existing treatments(2). Novartis previously received approval for everolimus for the treatment of adult and pediatric patients, aged three or older, with subependymal giant cell astrocytoma (SEGA) associated with TSC who require therapeutic intervention but are not candidates for curative surgical resection, in the US and in more than 40 additional countries. Filings for renal angiomyolipoma are under way in multiple countries outside of the US.

Afinitor works by inhibiting mTOR, a protein implicated in many tumor-causing pathways(1),(8). TSC is caused by defects in the *TSC1* and/or *TSC2* genes(1). When these genes are defective, mTOR activity is increased, which can cause uncontrolled tumor cell growth and proliferation, blood vessel growth and altered cellular metabolism(8),(9). According to preclinical studies, by inhibiting mTOR activity in this signaling pathway, everolimus reduces cell proliferation and blood vessel growth(1),(2).

Affecting approximately one to two million people worldwide, TSC can affect many different parts of the body, including the kidneys and brain, as well as the heart, lungs and skin. Tuberous sclerosis complex is associated with a variety of resulting disorders, including skin lesions, seizures, swelling in the brain (hydrocephalus), kidney failure, developmental delays and behavioral issues(1).

About EXIST-2

EXIST-2 is the first double-blind, randomized, placebo-controlled, international, multicenter Phase III study for the treatment of patients with renal angiomyolipoma associated with TSC(2),(4). Trial patients (median age=31, range 18-61) were randomized 2:1 to receive either everolimus (n=79) or placebo (n=39) at a daily starting dose of 10 mg. By the cut-off of October 14, 2011, the median treatment duration in the double-blind period was 48 weeks in the everolimus arm and 45 weeks in the placebo arm(2).

In the study, 42% of patients on everolimus (33 of 79; 95% CI 30.8-53.4) experienced an angiomyolipoma response versus 0% on placebo (0 of 39; 95% CI 0.0-9.0)($p<0.0001$), defined as a 50% or greater reduction in the sum of angiomyolipoma volume relative to baseline, the absence of new tumor growth at least 1 cm in longest diameter, absence of kidney volume increase of 20% or greater and no renal angiomyolipoma-related bleeding of Grade 2 or higher(2).

Everolimus demonstrated superiority to placebo for both supportive efficacy outcomes measured: time to angiomyolipoma progression and skin lesion response rate. There were three patients in the Afinitor arm and eight patients in the placebo arm with documented angiomyolipoma progression by central radiologic review. The time to angiomyolipoma progression was statistically significantly longer in patients on everolimus ($p<0.0001$; HR 0.08, 95% CI 0.02-0.37). Skin lesion response rate was significantly higher in the everolimus arm. A partial clinical response in skin lesions (corresponding to a 50% or greater improvement) was observed by Physician Global Assessment in 26% of patients on everolimus, compared with 0% of patients on placebo ($p=0.0011$). No complete responses were observed(2).

The most common adverse event (AE) in the everolimus arm (with an incidence of at least 30%) was stomatitis. The most common Grade 3-4 adverse reactions (incidence ≥ 2%) were stomatitis, amenorrhea and convulsion. The most common laboratory abnormalities (incidence≥ 50%) were hypercholesterolemia, hypertriglyceridemia and anemia. The most common Grade 3-4 laboratory abnormality (incidence ≥ 3%) was

hypophosphatemia. Adverse events observed in this study were for the most part consistent with the known safety profile of everolimus in the TSC setting(2).

About everolimus

Everolimus is now approved as Afinitor® (everolimus) tablets in the United States (US) for the treatment of adult patients with renal angiomyolipomas and tuberous sclerosis complex (TSC), who do not require immediate surgery. The effectiveness of Afinitor in treatment of renal angiomyolipoma is based on an analysis of durable objective responses in patients treated for a median of 8.3 months. Further follow-up of patients is required to determine long-term outcomes. Everolimus is also approved in the European Union (EU) as Votubia® (everolimus) tablets and in the US as Afinitor to treat adult and pediatric patients, aged three years or older, with SEGA associated with TSC who require therapeutic intervention but are not candidates or amenable for surgery. The effectiveness of everolimus is based on an analysis of change in SEGA volume in patients three years of age and older. Further clinical benefit has not been demonstrated.

Everolimus is approved as Afinitor in more than 80 countries including the US and throughout the EU in the adult oncology settings of advanced renal cell carcinoma following progression on or after vascular endothelial growth factor (VEGF)-targeted therapy in the EU and after failure of treatment with sunitinib or sorafenib in the US. Afinitor is approved for the treatment of locally advanced, metastatic or unresectable progressive neuroendocrine tumors of pancreatic origin in adults in the US and EU.

Everolimus is also available from Novartis for use in other non-oncology patient populations under the brand names Certican® and Zortress® and is exclusively licensed to Abbott and sublicensed to Boston Scientific for use in drug-eluting stents.

Indications vary by country and not all indications are available in every country.

Important safety information about Afinitor/Votubia

Afinitor/Votubia 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/Votubia can affect blood cell counts, kidney and liver function, and blood sugar and cholesterol levels. Afinitor/Votubia may cause fetal harm in pregnant women. Women taking Afinitor/Votubia 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, diabetes and amenorrhea. 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 commitment, continue to, under way, or similar expressions, or by express or implied discussions regarding 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 any new indications or labeling in any market, or at any particular time. 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; competition in general; government, industry and general public pricing pressures; unexpected manufacturing issues; the company s ability to obtain or maintain patent or other proprietary intellectual property protection; 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 innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care, cost-saving generic pharmaceuticals, preventive vaccines and diagnostic tools, over-the-counter and animal health products. Novartis is the only global company with leading positions in these areas. In 2011, the Group s continuing operations achieved net sales of USD 58.6 billion, while approximately USD 9.6 billion (USD 9.2 billion excluding impairment and amortization charges) was invested in R&D throughout the Group. Novartis Group companies employ approximately 124,000 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 27, 2012

By: /s/ MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham
Title: Head Group Financial Reporting and Accounting