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 May 11, 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 drug Votubia® approved as first medication in Switzerland for SEGA, a benign brain tumor associated with tuberous sclerosis

- *Subependymal giant cell astrocytomas (SEGAs) associated with tuberous sclerosis (TS) primarily affect children and adolescents(1),(2)*

- *Approval based on Phase II US study of 28 patients showing 75% of patients had 30% or greater reduction in the size of their largest SEGA at six months(3)*

- *Prior to the approval of Votubia, brain surgery was the only treatment option in Switzerland for patients with growing SEGAs(4)*

- *Worldwide regulatory submissions for everolimus to treat this patient population are under way; first approval received in the US in 2010 as Afinitor®*

Basel, May 11, 2011 Swissmedic, the Swiss Agency for Therapeutic Products, has approved Votubia® (everolimus) tablets* for the treatment of patients 3 years of age and older, with subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis (TS), for whom surgery is not a suitable option(3). Votubia is the first medication approved in Switzerland to treat these patients, who are primarily children and adolescents(1),(2). In the US, everolimus is approved for patients with SEGA under the trade name Afinitor® tablets(5).

Tuberous sclerosis is a genetic disorder that may cause benign tumors to form in vital organs and can affect many different parts of the body, most commonly the brain(6),(7). Signs of TS vary depending on which system and which organs are involved(6). SEGAs, or benign brain tumors, occur in up to 20% of patients with TS and may lead to a variety of resulting disorders including seizures, swelling in the brain, developmental delays and skin lesions(4),(8). Prior to this approval, surgery was the only treatment option for Swiss patients with growing SEGAs associated with TS(4).

The approval is based on a prospective, open-label, single-arm Phase II study of 28 patients. Results showed 75% of patients (21 of 28) experienced a reduction of 30% or greater in the size of their largest SEGA and 32% (9 of 28) experienced a reduction of 50% or greater at six months relative to baseline. Of 16 patients with seizures at the start of the study, nine experienced decreases in seizure frequency, six reported no change and one experienced an increase at 6 months relative to baseline. Facial angiofibromas (red elevated skin lesions) improved in 87% of patients (13 of 15 evaluated patients) from baseline to six months(3).

This approval of Votubia is significant for children and adults who have SEGA associated with tuberous sclerosis and, until now, have had limited treatment options, said Hervé Hoppenot, President, Novartis Oncology. This milestone represents our first approval in Europe for Votubia and underscores our commitment to help patients worldwide improve their management of this difficult-to-treat disease.

Everolimus targets mTOR, a protein that acts as an important regulator of tumor cell division, blood vessel growth and cell metabolism(9). Tuberous sclerosis is caused by defects in the *TSC1* and *TSC2* genes(6). 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, leading to the formation of benign tumors throughout the body, including the brain(4). By inhibiting mTOR activity in this protein pathway, everolimus may reduce cell proliferation, blood vessel growth and glucose uptake related to SEGA associated with TS(4).

Regulatory approvals have also been granted in this disease setting in the United States, Brazil, Guatemala and the Philippines. Submissions to the European Medicines Agency (EMA) and other global regulatory agencies are under review.

Tuberous sclerosis affects approximately one to two million people worldwide(6). In Europe, the prevalence in the general population is estimated to be nearly nine cases per 100,000(10). SEGAs occur in up to 20% of patients with TS(8).

About the Phase II study

In a prospective, open-label, single-arm study, 28 patients aged three years and above (median age=11, range 3-34) with evidence of SEGA growth initially received everolimus orally at a dose of 3 mg/m(2) daily or every other day. In total, 16 of the 28 patients were treated with Votubia for at least 21 months(3).

In the study, 75% of patients (21 of 28) experienced a reduction of 30% or greater in the size of their largest SEGA and 32% (9 of 28) experienced a reduction of 50% or greater at six months relative to baseline(3).

Of 16 patients with seizures at the start of the study for whom 24-hour video electroencephalograms (EEG) were available, nine experienced decreases in seizure frequency, six reported no change and one experienced an increase at six months relative to baseline. Facial angiofibromas improved in 87% of patients (13 of 15 evaluated patients) from baseline to six months. None of the patients developed new symptoms of intracranial pressure or an increase in hydrocephalus (swelling in the brain). No patient underwent surgery(3).

The most common adverse events reported (incidence $\geq$30%) in the prospective, open-label, single-arm trial were mouth sores, upper respiratory tract infections, sinusitis, middle ear infections and fever(3). However, the reliability of the frequency of adverse reactions and laboratory abnormalities reported in this trial is limited because of the small number of patients.

All data from the study submitted to Swissmedic are based on the cut-off date of December 9, 2009.

About everolimus

Votubia® (everolimus) tablets is approved in Switzerland for the treatment of patients 3 years of age and older, with SEGA associated with tuberous sclerosis (TS), for whom surgery is not a suitable option. Should everolimus be approved in the EU, the trade name will be Votubia. In the US, Afinitor® (everolimus) tablets is approved to treat patients with SEGA associated with tuberous sclerosis who require therapeutic intervention but are not candidates for curative surgical resection. The effectiveness of everolimus 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.

Afinitor 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.

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. Because of the uncertainty of clinical trials, there is no guarantee that everolimus will become commercially available for SEGAs anywhere else in the world.

Important Safety Information about 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. Votubia can affect blood cell counts, kidney and liver function, blood sugar and cholesterol levels. Votubia may cause fetal harm in pregnant women. Women taking Votubia 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 commitment, will, 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 submitted or approved for any additional indications or labeling in any market. 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; government, industry and general public pricing pressures; competition in general; 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 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 11, 2011

By: /s/ MALCOLM B. CHEETHAM

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