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 September 8, 2011

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

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Switzerland

(Address of Principal Executive Offices)

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Novartis International AG

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- Investor Relations Release -

Novartis receives EU approval for Votubia®, the first medication to treat children and adults with SEGA associated with TSC

- *Approval follows recent CHMP positive opinion based on Phase II study showing SEGA tumor reduction in patients with TSC*

- *Subependymal giant cell astrocytoma (SEGA) is a non-cancerous brain tumor that can cause life-threatening brain swelling in children and adults with TSC(2),(3),(4)*

Basel, September 8, 2011 Novartis announced today that the European Commission (EC) has approved Votubia® (everolimus) tablets* for the treatment of patients aged 3 years and older, with subependymal giant cell astrocytoma (SEGA) associated with tuberous sclerosis complex (TSC), who require therapeutic intervention but are not amenable to surgery(1). Prior to the approval of Votubia, an oral medication, brain surgery was the only treatment option for children and adults in the European Union with SEGA associated with TSC(2).

Tuberous sclerosis complex, also known as tuberous sclerosis (TS), affects approximately one to two million people worldwide and is associated with a variety of resulting disorders including seizures, swelling in the brain (hydrocephalus), developmental delays and skin lesions(2),(5). In Europe, the prevalence in the general population is estimated to be nearly nine cases per 100,000(6). TSC is a genetic disorder that may cause non-cancerous tumors to form in vital organs and can affect many different parts of the body, most commonly the brain and kidney(5),(7). Signs and symptoms of TSC vary depending on which system and which organs are involved(5). SEGAs, or non-cancerous brain tumors, occur in up to 20% of patients with TSC(2).

The approval from the EC follows a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) in June and is based on a prospective, open-label, single-arm, Phase II study of 28 patients(1),(2),(8). Results from this trial showed that 78% of patients (21 of 27) experienced a reduction of 30% or greater in the size of their largest SEGA and 33% (9 of 27) experienced a reduction of 50% or greater at six months relative to baseline(1),(2). An additional placebo-controlled phase III study examining this patient population was recently presented at the International TSC Research Conference in July. This trial met its primary endpoint of SEGA response rate(9).

The approval of Votubia in the European Union means that for the first time, patients living with SEGA associated with tuberous sclerosis complex will have an effective therapeutic option, said Hervé Hoppenot, President, Novartis Oncology. This milestone serves as another example of the potential of mTOR inhibition with everolimus and we remain steadfast in our commitment to studying other manifestations of TSC.

Everolimus targets mTOR, a protein that acts as an important regulator of tumor cell division, blood vessel growth and cell metabolism(10). Tuberous sclerosis complex is caused by defects in the *TSC1* and/or *TSC2* genes(5). 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. By inhibiting mTOR activity in this signaling pathway, everolimus may reduce cell proliferation, blood vessel growth and glucose uptake related to SEGA associated with TSC(2).

This approval is an important step forward in managing SEGAs associated with tuberous sclerosis complex, as surgery was previously the only available treatment option in the EU for these patients, said Dr. Sergiusz Jozwiak, Professor, Department of Child Neurology, The Children s Memorial Health Institute, Warsaw, Poland. As the first approved medication for this patient community, Votubia will help fill a critical unmet treatment need.

About everolimus

Everolimus is approved in the European Union (EU) as Votubia® (everolimus) tablets for the treatment of patients aged 3 years and older, with SEGA associated with TSC, who require therapeutic intervention but are not amenable to surgery. The evidence is based on analysis of change in SEGA volume. Further clinical benefit, such as improvement in disease-related symptoms, has not been demonstrated.

In the EU, Afinitor® (everolimus) tablets is approved 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 whose disease has progressed on or after treatment with vascular endothelial growth factor (VEGF)-targeted therapy.

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.

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 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 could be fatal. Mouth ulcers and mouth sores are common side effects. Votubia can affect blood cell counts, kidney and liver function, and 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, 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 have been reported.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as can, may, will, potential, commitmen 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, 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 8, 2011

By: /s/ MALCOLM B. CHEETHAM

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