NOVARTIS AG
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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 November 3, 2010

(Commission File No. 1-15024)

Novartis AG

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Form 20-F: x Form 40-F: o

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Yes: o **No**: x

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- Investor Relations Release -

Study in NEJM shows Novartis drug Afinitor® reduces size of SEGAs, benign brain tumors associated with tuberous sclerosis

- *Subependymal giant cell astrocytoma (SEGA) is a benign brain tumor found in children and adults with tuberous sclerosis (TS) that can cause severe brain swelling(1)*

- *These data previously reported at ASCO show nearly one-third of the 28 patients studied had a reduction of 50% or greater in the size of their largest SEGA(2)*

- *Additional study findings showed treatment with everolimus resulted in a clinically relevant reduction in overall frequency of seizures, which are associated with TS(2)*

- *Afinitor approved in US for patients with SEGA associated with TS who require therapeutic intervention but are not candidates for curative surgical resection(3)*

Basel, November 3, 2010 *The New England Journal of Medicine* (NEJM) today published a study that found patients taking Afinitor® (everolimus) tablets experienced a decrease in the size of their subependymal giant cell astrocytoma (SEGA), a benign brain tumor associated with tuberous sclerosis (TS)(1),(2). This study, which was previously presented at the 46th American Society of Clinical Oncology annual meeting, is the first prospective clinical trial of a drug to show treatment benefit in these patients.

Tuberous sclerosis is a genetic disorder affecting approximately 25,000 to 40,000 people in the US. Tuberous sclerosis may cause benign tumors to form in vital organs, including the brain, where they can cause seizure and developmental delay, as well as the kidney, heart, eyes, lungs and skin(4). SEGAs, benign brain tumors, occur in up to 20% of patients with TS and primarily affect children and adolescents(1),(5),(6). SEGAs may pose a significant medical risk, including the potential for swelling in the brain, or hydrocephalus(1).

According to data published in NEJM from this Phase I/II study of 28 patients conducted by Cincinnati Children s Hospital Medical Center, treatment with everolimus was associated with a significant reduction in primary SEGA volume at six months relative to baseline on independent central review ($p<0.001$). Seventy-five percent 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(2).

The published study findings also showed that everolimus therapy was associated with a clinically relevant reduction from baseline to six months in overall frequency of seizures per 24 hour video electroencephalograms (EEG) (n=16; median change -1 seizure, p=0.022). Additionally, no patients required surgery or developed a new SEGA while receiving everolimus(2).

Everolimus was recently approved in the US under the FDA s accelerated approval program as Afinitor for patients with SEGA associated with TS 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(3). A Phase III study is underway that compares everolimus to placebo to explore the clinical benefits of Afinitor for the treatment of patients with SEGA associated with TS(7).

The most common adverse reactions observed (incidence ≥30%) in this trial were mouth sores, upper respiratory tract infections, sinusitis, middle ear infections and fever(2).

This is the first clinical trial to show that a drug has the potential to provide patients with growing SEGAs, many of whom are children, another treatment option besides brain surgery, said David Franz, MD, Director, Tuberous Sclerosis Clinic at Cincinnati Children s Hospital Medical Center and principal investigator of the study. In addition to decreasing the size of the brain tumors, everolimus was associated with a significant reduction in the frequency of seizures, which occur in 90% of affected individuals.

About the study published in NEJM

In this Phase I/II 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) once-daily or on an alternate day regimen. Doses were subsequently adjusted subject to tolerability to attain a trough concentration of 5-15 ng/mL(2).

The study met its primary efficacy endpoint of change in primary SEGA lesion volume from baseline to six months (or at the last available assessment if a patient discontinued treatment prior to month six [one patient discontinued the trial before six months]). Everolimus was associated with a statistically significant reduction in primary SEGA volume at six months relative to baseline on independent central review ($p<0.001$). As of December 9, 2009, the median duration of treatment was 21.5 months(2).

Study findings also showed that everolimus was associated with a clinically relevant reduction from baseline to six months in overall frequency of seizures per 24 hour EEG (n=16; median change -1.0 seizure, p=0.022). Of 16 patients with seizures at the start of the study for whom EEGs were available, nine experienced decreases in seizure frequency, six reported no change and one experienced an increase at six months(2).

The reliability of the frequency of adverse reactions and laboratory abnormalities reported in this trial is limited because of the small number of patients. The most common adverse reactions reported (incidence ≥30%) in this trial were mouth sores, upper respiratory tract infections, sinusitis, middle ear infections and fever(2).

All data reported in this study published in NEJM are based on the cut-off date of December 9, 2009(2).

About the EXIST-1 Phase III trial

EXIST-1, a Phase III randomized, placebo-controlled trial aimed at evaluating the results of the Phase I/II study, is examining everolimus treatment in patients with SEGAs associated with TS. Endpoints include SEGA response rate, seizure rate, skin lesion response rate and safety. The trial has completed accrual and patients continue to be followed(7).

The trial involves patients in 10 countries, including Australia, Belgium, Canada, Germany, Italy, the Netherlands, Poland, Russia, the UK and the US(7).

About Afinitor (everolimus)

Afinitor® (everolimus) tablets is approved in the US to treat patients with 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. Improvement in disease-related symptoms or increase in survival has not been shown.

Novartis has submitted marketing applications for everolimus to the European Medicines Agency (EMA) and the Swiss Agency for Therapeutic Products (Swissmedic), and additional regulatory submissions are underway worldwide. If approved in the European Union (EU) for this indication, everolimus will be made available under the trade name Votubia®.

There is no guarantee that everolimus will become commercially available for SEGA anywhere else in the world. As an investigational compound, the safety and efficacy profile of everolimus has not yet been established outside the US in patients with SEGA associated with TS.

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 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.

Not all indications are available in every country.

Important Safety Information about Afinitor (everolimus) tablets

Afinitor is contraindicated in patients with hypersensitivity to everolimus, to other rapamycin derivatives or to any of the excipients.

Cases of non-infectious pneumonitis have been described; some of these have been severe and occasionally fatal. Management of pneumonitis may require dose adjustment and/or interruption, or discontinuation of treatment and/or addition of corticosteroid therapy.

Afinitor is immunosuppressive. Localized and systemic bacterial, fungal, viral or protozoal infections (e.g., pneumonia, aspergillosis, candidiasis, hepatitis B reactivation) have been described; some of these have been severe and occasionally fatal. Pre-existing infections should be treated prior to starting treatment. Patients and physicians should be vigilant for symptoms and signs of infection; in case of emergent infections, appropriate treatment should be promptly instituted and interruption or discontinuation of Afinitor should be considered. Patients with systemic invasive fungal infections should not receive Afinitor.

Mouth ulcers, stomatitis and oral mucositis have been seen in patients treated with Afinitor. Monitoring of renal function, blood glucose and complete blood counts is recommended prior to initiation and periodically during treatment.

Afinitor is not recommended in patients with severe hepatic impairment. Use of live vaccines should be avoided. Afinitor is not recommended during pregnancy or for women of childbearing potential not using contraception. Afinitor may cause fetal harm in pregnant women. Women taking Afinitor should not breast feed.

Avoid concurrent treatment with strong CYP3A4 and PgP inhibitors and use caution with moderate inhibitors. Avoid concurrent treatment with strong CYP3A4 or PgP inducers.

In advanced RCC, the most common adverse reactions (≥10%) include stomatitis, rash, fatigue, asthenia, diarrhea, anorexia, nausea, mucosal inflammation, vomiting, cough, infections,

peripheral edema, dry skin, epistaxis, pneumonitis, pruritus, and dyspnea. Common adverse reactions (≥1 to <10%) include headache, dysgeusia, dry mouth, pyrexia, weight loss, hand-foot syndrome, abdominal pain, erythema, insomnia, dyspepsia, dysphagia, hypertension, increased daytime urination, dehydration, chest pain, hemoptysis and exacerbation of diabetes mellitus. Uncommon adverse reactions (<1%) include ageusia, congestive cardiac failure, new-onset diabetes mellitus, impaired wound healing, grade 1 hemorrhage and hepatitis B reactivation.

In the SEGA study, the most common adverse reactions (≥10%, all grades) irrespective of relationship to the drug reported among the 28 patients with evidence of established SEGA growth included: stomatitis or mouth sores, upper respiratory tract infection, sinusitis, middle ear infection, fever, convulsion, acne-like skin inflammation, diarrhea, cellulitis or acute infection of the deep tissues of skin or muscle, vomiting, cough, body tinea or fungal infection, headache, personality change, rash, skin infection, dry skin, gastroenteritis or inflammation of the gastrointestinal tract, contact dermatitis, dizziness, external ear infection, allergic rhinitis or inflammation of nasal passages, gastric infection, nasal congestion, excoriation or skin abrasion, acne, constipation, abdominal pain and pharyngitis or inflammation of the pharynx.

Grade three adverse reactions irrespective of relationship to the study drug included convulsion, infections (single cases of sinusitis, pneumonia, tooth infection and viral bronchitis) and single cases of stomatitis, aspiration, cyclic neutropenia, sleep apnea syndrome, vomiting, dizziness, white blood cell count decreased and neutrophil count decreased. A grade four convulsion was reported.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as may, potential, will, aimed at, or simil 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 submitted or approved for any additional indications or labeling in any market. 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; the company s ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; 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, cost-saving generic pharmaceuticals, preventive vaccines, diagnostic tools and consumer health products. Novartis is the only company with leading positions in these areas. In 2009, the Group s continuing operations achieved net sales of USD 44.3 billion, while approximately USD 7.5 billion was invested in R&D activities throughout the Group. Headquartered

in Basel, Switzerland, Novartis Group companies employ approximately 100.000 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: November 3, 2010

By: /s/ MALCOLM B. CHEETHAM

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