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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 October 30, 2010

(Commission File No. 1-15024)

Novartis AG

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

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- Investor Relations Release -

Novartis drug Afinitor® approved by FDA as first medication for children and adults with a benign brain tumor associated with tuberous sclerosis

- *Subependymal giant cell astrocytoma (SEGA) is a benign brain tumor associated with tuberous sclerosis (TS)*(1)
- *Prior to the approval of Afinitor, brain surgery was the only treatment option for patients with growing SEGAs*(1)
- *Worldwide regulatory submissions underway, including applications filed in the EU and Switzerland*

Basel, October 30, 2010 Novartis announced, that the US Food and Drug Administration (FDA) has approved Afinitor® (everolimus) tablets for patients with subependymal giant cell astrocytoma (SEGA), a benign brain tumor associated with tuberous sclerosis (TS), who require therapeutic intervention but are not candidates for curative surgical resection(2).

This accelerated approval of Afinitor is based on an open-label, single-arm, 28-patient study conducted by Cincinnati Children s Hospital Medical Center(2). The effectiveness of Afinitor is based on an analysis of change in SEGA volume. A Phase III study is underway that compares Afinitor to placebo to explore the clinical benefits of Afinitor for the treatment of patients with SEGA associated with TS(3).

Prior to this FDA approval, the only treatment option for growing SEGAs, which primarily affect children and adolescents, was brain surgery(1),(4),(5). Tuberous sclerosis is a genetic disorder affecting approximately 25,000 to 40,000 people in the US that may cause benign tumors to form in vital organs(6). SEGAs, benign brain tumors, occur in up to 20% of patients with TS(1).

Today s FDA decision is an important milestone for the children and adults living with SEGA associated with tuberous sclerosis, said Hervé Hoppenot, President of Novartis Oncology. We are committed to furthering research for patients with tuberous sclerosis and will continue to work towards addressing their unmet medical needs.

In this study, nearly one-third of patients (32%) experienced a reduction of 50% or greater in the size of their largest SEGA at six months relative to baseline. None of the patients developed a new SEGA while receiving Afinitor(2).

SEGAs can be challenging for individuals with tuberous sclerosis and for the whole family, which is why we are encouraged to see ongoing research and new treatment options like Afinitor for these individuals, said Vicky Whittemore, Vice President and Chief Scientific Officer of the patient advocacy group the Tuberous Sclerosis Alliance.

For the treatment of patients with SEGA associated with TS, Afinitor received FDA priority review status, which is granted to drugs that offer major advances in treatment. This indication was approved under the FDA s accelerated approval program, which provides patients access to a treatment where previously there was an unmet medical need even though clinical benefit has yet to be confirmed(7). Novartis is continuing to study the efficacy and clinical benefit of Afinitor for patients with SEGA associated with TS in a Phase III trial(3).

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®.

About the study

In an 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/m2. As of March 8, 2010, the median duration of treatment was 24.4 months (range 4.7-37.3 months)(2).

In the study, 32% of patients experienced a reduction of 50% or greater in the size of their largest SEGA at six months relative to baseline. None of the patients developed a new SEGA while receiving Afinitor(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 the open-label, single-arm trial were mouth sores, upper respiratory tract infections, sinusitis, middle ear infections and fever(2).

All data from the study reported in this press release are based on the cut-off date of March 8, 2010.

About the EXIST-1 Phase III trial

EXIST-1, a Phase III randomized, placebo-controlled trial aimed at evaluating the results of the open-label, single-arm trial, is examining everolimus treatment in patients with SEGAs associated with TS. Endpoints include SEGA response, seizure rate and skin lesion response rate. The trial has completed accrual and patients continue to be followed(3).

The trial involves patients in 10 countries, including Australia, Belgium, Canada, Germany, Italy, the Netherlands, Poland, Russia, the UK and the US(3).

About Afinitor (everolimus)

Afinitor® (everolimus) tablets is now 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.

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. 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. 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 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.

Patients should 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 to explore, committed, will, can, encouraged, 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 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: October 30, 2010	By:	/s/ MALCOLM B. CHEETHAM
	Name:	Malcolm B. Cheetham
	Title:	Head Group Financial Reporting and Accounting