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 December 9, 2010

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

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- Investor Relations Release -

Study shows Novartis drug Afinitor® plus hormonal therapy delays disease progression in advanced metastatic breast cancer patients

- *Randomized Phase II study shows 61% of advanced breast cancer patients on everolimus plus tamoxifen had no tumor progression at six months vs. 42% on tamoxifen alone(1)*

- *Patients on everolimus plus tamoxifen had a median time to disease progression of 8.6 months vs. 4.5 months on tamoxifen alone(1)*

- *Limited treatment options exist for hormone-receptor positive metastatic breast cancer patients with disease resistant to or progressing on standard therapy(2),(3)*

- *Novartis has initiated the Phase III BOLERO clinical trial program to further study everolimus for the treatment of metastatic breast cancer(4),(5),(6)*

Basel, December 9, 2010 A new study shows that the addition of everolimus (Afinitor® tablets) to the hormonal therapy tamoxifen in patients with hormone-receptor positive/human epidermal growth factor receptor 2-negative (HR+/HER2-) metastatic breast cancer who have been previously treated with an aromatase inhibitor (AI) delays disease progression compared to tamoxifen alone. These results were presented today at the 33rd Annual CTRC-AACR San Antonio Breast Cancer Symposium in San Antonio, Texas, US(1).

Findings from a randomized, Phase II study of 111 patients showed the proportion of metastatic breast cancer patients without tumor progression at six months was 61.1% for those taking everolimus plus tamoxifen (95% confidence interval [CI], 46.9 to 74.1) versus 42.1% for patients treated with tamoxifen alone (95% CI, 29.1 to 55.9); p=0.045(1).

Disease progression was delayed by a median of 8.6 months in patients treated with the combination versus 4.5 months in patients treated with tamoxifen alone, with everolimus in combination with tamoxifen providing a statistically significant reduction in the risk of disease progression

by 47% (hazard ratio=0.53 [95% CI, 0.35 to 0.81]; log-rank test: p=0.0026, exploratory analysis). Side effects were generally manageable in both study arms. As of October 2010, there were 25 patient deaths in the tamoxifen arm versus nine in the everolimus plus tamoxifen arm (hazard ratio=0.32 [95% CI, 0.15 to 0.68]; log-rank test: p=0.0019)(1).

This Phase II trial is conducted by the Groupe d_ Investigateurs Nationaux pour l Etude des Cancers Ovariens et du sein (the French GINECO Group).

Everolimus is an investigational agent for the treatment of patients with breast cancer. Everolimus targets mTOR in cancer cells, a protein that acts as an important regulator of tumor cell division, blood vessel growth and cell metabolism(7),(8).

The almost doubling of time to disease progression seen in the everolimus plus tamoxifen treatment arm reinforces the potential benefit of inhibiting mTOR to help overcome endocrine therapy resistance, said Thomas Bachelot, MD, from Centre Léon Bérard in Lyon, France, and principal investigator of the study. Based on these results, additional studies will evaluate the combination of everolimus with hormonal therapies as a second-line treatment for patients with HR+/HER2- metastatic breast cancer.

Breast cancer patients with advanced disease who become resistant to hormonal therapies have limited treatment options(2). Prior to these study findings, Novartis initiated a Phase III trial program called BOLERO (Breast cancer trials of OraL EveROlimus), which is the largest international Phase III clinical trial program to study an mTOR inhibitor in patients with locally advanced or metastatic breast cancer(4),(5),(6).

These results are encouraging because if everolimus is approved for this indication, it could offer physicians a new strategy to treat patients with metastatic breast cancer whose disease progresses or becomes resistant to traditional hormonal therapies, said Hervé Hoppenot, President, Novartis Oncology. Novartis has a Phase III study underway researching the potential of everolimus for this patient population, which currently has limited treatment options.

For more information about the BOLERO trials, healthcare professionals can visit www.theWIDEprogram.com.

Study Details: Abstract #S1-6

This randomized Phase II trial evaluated the efficacy and safety of everolimus in 111 patients with HR+/HER2- metastatic breast cancer with prior exposure to AI treatment (in adjuvant and/or metastatic setting). Patients were randomized 1:1 to receive everolimus plus tamoxifen (10 mg/day plus 20 mg/day, respectively) [N=54] or tamoxifen alone (20 mg/day) [N=57]. The primary endpoint was clinical benefit rate, defined as complete response, partial response and stable disease (CR+PR+SD) at six months in the everolimus plus tamoxifen arm. For the intent-to-treat analysis, a gain in clinical benefit of at least 20 percent was needed to warrant further study of the combination regimen, which was met in this trial1.

For patients receiving everolimus plus tamoxifen, time to disease progression, a secondary endpoint, was almost twice as long as it was for patients receiving tamoxifen alone (8.6 months in patients treated with the combination versus 4.5 months in patients treated with tamoxifen alone). Everolimus in combination with tamoxifen provided a statistically significant reduction in the risk of disease progression by 47% (hazard ratio=0.53 [95% CI, 0.35 to 0.81]; log-rank test: p=0.0026, exploratory analysis)1.

Side effects were generally manageable in both arms of the study. Everolimus had to be decreased for 15 patients (28%). Treatment was stopped due to toxicities in three patients in the everolimus plus tamoxifen arm and in four patients in the tamoxifen-only arm. Grade 3-4 adverse events (>10%) were stomatitis (11% in the everolimus plus tamoxifen arm and 0% in the tamoxifen-only arm), pain (9% in the everolimus plus tamoxifen arm and 19% in the tamoxifen-only arm) and fatigue (6% in the everolimus plus tamoxifen arm and 11% in the tamoxifen-only arm)1.

Novartis Pharmaceuticals Corporation provided drug and financial support for this study.

About Breast Cancer

Breast cancer is the most prevalent cancer in women worldwide and is increasing in developing countries where the majority of cases are diagnosed in late stages(9). Data has shown that approximately 30% of women with breast cancer will eventually develop metastatic or advanced disease(2). In 2008, breast cancer caused approximately 460,000 deaths worldwide(10).

Breast cancer can originate in lobes, milk-producing ducts and other tissue within the breast. In these cases, some of the cells in the breast begin growing abnormally and uncontrollably. This quick division of cells may cause the cancer to spread through the breast to other parts of the body(11). The process of finding out how widespread the cancer is at initial time of diagnosis is called staging The stage of breast cancer is one of the most important factors in determining treatment options(3).

There are several standard treatment options for people diagnosed with breast cancer, which are based on the advancement and type of an individual s breast cancer, as well as their general health(3). For patients with advanced or metastatic breast cancer who become resistant or progress on standard therapies, treatment options are limited(2).

About Afinitor (everolimus)

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.

Afinitor is also approved in the US to treat patients with subependymal giant cell astrocytoma (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.

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.

Everolimus is exclusively licensed for use in drug-eluting stents to Abbott for the XIENCE V® and XIENCE PRIME Everolimus Eluting Coronary Stent System*, and sublicensed to Boston Scientific for the PROMUS and PROMUSElement Everolimus Eluting Coronary Stent System**.

Not all indications are available in every country. As an investigational compound the safety and efficacy profile of everolimus has not yet been established in breast cancer. 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. Because of the uncertainty of clinical trials, there is no guarantee that everolimus will become commercially available for breast cancer or any additional indications anywhere 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.

Hypersensitivity reactions have been observed.

Mouth ulcers, stomatitis and oral mucositis have been seen. Topical treatments are recommended; alcohol- or peroxide-containing mouthwashes should be avoided.

Monitoring of renal function, blood glucose and complete blood counts is recommended prior to initiation and periodically during treatment. Cases of renal failure, some fatal, have been observed.

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. Male fertility may be compromised by Afinitor.

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, renal failure, hemoptysis and exacerbation of diabetes mellitus. Uncommon adverse reactions (<1%) include ageusia, congestive cardiac failure, new-onset diabetes mellitus, impaired wound healing, and grade 1 hemorrhage.

Cases of hepatitis B reactivation and pulmonary embolism have been reported

In patients with SEGA, the most common adverse reactions (≥10%) include infections, hypertriglyceridaemia, cough, stomatitis, diarrhoea, acneiform dermatitis, acne, pyrexia, and decreased white blood cell count. Common adverse reactions (≥1 to <10%) include pharyngeal inflammation, gastritis, vomiting, mucosal inflammation, increased blood triglycerides, anxiety, somnolence, hypertension, respiratory disorders,

dry skin, pityriasis rosea, proteinuria, fatigue, peripheral oedema, ocular hyperaemia, and decreased blood immunoglobulin G.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as investigational, potential, will, could, 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 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; 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.

About GINECO

Groupe d Investigateurs Nationaux pour l Etude des Cancers Ovariens et du sein (GINECO) is a French cooperative trial group of clinicians dedicated to metastatic breast and gynecological cancers. GINECO includes 100 oncology sites (public and private) and 600 investigators. Main GINECO objectives are to promote top-level clinical research and to contribute to define a national policy to fight against cancer, for the sake of patient and society, through a better use of resources. For more information, please visit http://www.arcagy.org.

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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: December 9, 2010

By: /s/ MALCOLM B. CHEETHAM

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