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 September 26, 2011

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

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Switzerland

(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

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Yes: o **No**: x

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Indicate by check mark whether the registrant by furnishing the information contained in this form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes: o **No**: x

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- Investor Relations Release -

Novartis drug Afinitor® helps women with advanced breast cancer live significantly longer without their disease progressing

- *Everolimus combined with hormonal therapy more than doubled time without tumor growth and reduced risk of progression by 57% vs hormonal therapy alone(1)*

- *Study shows everolimus significantly enhances benefit from hormonal therapy, representing important advance for women with postmenopausal ER+ breast cancer(1),(2)*

- *Worldwide regulatory filings planned by the end of 2011 based on these data, marking the first submission for everolimus in breast cancer*

Basel, September 26, 2011 A pivotal Phase III study shows Afinitor® (everolimus) tablets plus exemestane, a hormonal therapy, more than doubled the time women lived without tumor growth (progression-free survival; PFS) and significantly reduced the risk of cancer progression by 57% versus exemestane alone in patients with advanced breast cancer(1).

Everolimus is the first drug to show significant efficacy when combined with hormonal therapy in women with ER+HER2- advanced breast cancer, where there continues to be a critical unmet need, said Hervé Hoppenot, President, Novartis Oncology. The magnitude of benefit seen in these patients, despite their resistance to previous hormonal therapies, shows everolimus represents a potential important new treatment approach.

BOLERO-2 (Breast cancer trials of OraL EveROlimus-2) examined the safety and efficacy of everolimus in combination with exemestane versus exemestane alone in postmenopausal women with ER+HER2- advanced breast cancer who recurred or progressed while on or following previous treatment with hormonal therapies, letrozole or anastrozole(1). Findings from the trial will be presented today during a Presidential Symposium at the 2011 European Multidisciplinary Cancer Congress in Stockholm, Sweden.

At a pre-planned analysis, the trial met its primary endpoint of PFS showing treatment with everolimus improved PFS to 6.9 months compared to 2.8 months (hazard ratio 0.43 [95% confidence interval (CI): 0.35 to 0.54]; $p<0.0001$) by local investigator assessment. This significant improvement was consistent across all subgroups including number of prior therapies, presence of visceral disease, bone metastases and prior use of chemotherapy(1).

Hormonal therapy remains the cornerstone of treatment for women with advanced breast cancer but most women with metastatic disease do not respond to initial treatment with hormonal therapy, and almost all initial responders develop resistance(2),(3). Additionally, life expectancy is significantly shortened due to the worsening of the disease(3).

Everolimus targets mTOR in cancer cells, a protein that acts as an important regulator of tumor cell division, blood vessel growth and cell metabolism(4). Resistance to hormonal therapy in breast cancer has been associated with over-activation of the mTOR pathway(3).

Data from BOLERO-2 support worldwide regulatory submissions, which are planned by the end of 2011. Additional data from BOLERO-2 will be presented at upcoming medical congresses this year.

Worldwide, there are approximately 220,000 newly diagnosed cases of ER+HER2- advanced breast cancer each year(5),(6). Everolimus is also being investigated for the treatment of patients with HER2+ advanced breast cancer(7),(8).

About BOLERO-2

BOLERO-2 is a Phase III, randomized, double-blind, placebo-controlled, multicenter study. The trial was conducted at 189 sites worldwide and enrolled 724 patients(1). Patients who met the study criteria were randomized (2:1) to receive either everolimus 10 mg/day orally (n= 485), or placebo, plus oral exemestane 25 mg/day (n=239)(1).

The primary endpoint was PFS based on local investigator radiology assessment. Additional analysis by an independent central radiology review committee showed everolimus extended PFS to 10.6 months compared to 4.1 months (hazard ratio 0.36; [95% CI: 0.27 to 0.47]; p<0.0001). Other endpoints include overall survival, overall response rate, safety, patient reported outcome, clinical benefit rate and changes in markers of bone metabolism(1). These data are being evaluated and will be submitted for publication or presentation in a peer-reviewed forum.

The side effects observed were consistent with those previously reported with everolimus with the most common grade 3 or 4 adverse events including stomatitis (7.7%), anemia (5.8%), dyspnea (3.9%), hyperglycemia (4.3%), fatigue (3.7%), non-infectious pneumonitis (3.1%) and increase in liver enzymes (3.1%)(1).

About everolimus

Afinitor® (everolimus) tablets is approved in more than 70 countries and regions including the United States and the European Union in the oncology settings of advanced renal cell carcinoma (RCC) following vascular endothelial growth factor (VEGF)-targeted therapy and advanced progressive neuroendocrine tumors of pancreatic origin (pNET).

Everolimus is also available from Novartis for use in non-oncology patient populations under the brand names Votubia®, Certican® and Zortress® and is exclusively licensed to Abbott and sublicensed to Boston Scientific for use in drug-eluting stents.

Indications vary by country and 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 Afinitor (everolimus) tablets

Afinitor 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. Afinitor can affect blood cell counts, kidney and liver function, and blood sugar and cholesterol levels. Afinitor may cause fetal harm in pregnant women. Women taking Afinitor 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 and leg have been reported.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as planned, will, potential, 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 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; 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, 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 26, 2011	By:	/s/ MALCOLM B. CHEETHAM
	Name:	Malcolm B. Cheetham
	Title:	Head Group Financial Reporting and Accounting