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 December 8, 2011

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

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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

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- Investor Relations Release -

New data confirms Novartis drug Afinitor® significantly extends time women with advanced breast cancer live without tumor growth

- *Longer-term BOLERO-2 data reveal treatment with everolimus combined with hormonal therapy improved time to disease progression to 7.4 versus 3.2 months with hormonal therapy alone(1)*

- *These results presented at SABCS provide further evidence that everolimus may represent a major advance for women with ER+HER2- breast cancer(1)*

- *Published in NEJM today are previously-reported positive results of BOLERO-2, which serve as the basis for first worldwide filings planned by year end*(2)

Basel, December 8, 2011 Updated results of a Phase III study of Afinitor® (everolimus) tablets plus exemestane, a hormonal therapy, show everolimus provided additional time women with advanced breast cancer lived without their disease progressing (progression-free survival)(1).

The study findings, which represent an additional five months of follow-up, were presented at the 2011 CTRC-AACR San Antonio Breast Cancer Symposium (SABCS), abstract #S3-7(1). Simultaneously, initial results of BOLERO-2 were published today in *The New England Journal of Medicine* (*NEJM*) and were first presented at the 2011 European Multidisciplinary Cancer Congress (EMCC) (2).

These data provide longer-term evidence of the benefit of adding everolimus to hormonal therapy in patients whose disease progressed while on or following initial hormonal treatment, representing a major paradigm shift in the management of ER+HER2- breast cancer, said Gabriel Hortobagyi, MD, Chair of Breast Medical Oncology, University of Texas MD Anderson Cancer Center and lead study author. Everolimus is the first treatment to enhance the efficacy of hormonal therapy in this patient population, where there remains a significant unmet need.

Updated findings from the BOLERO-2 study presented at SABCS showed treatment with everolimus plus hormonal therapy more than doubled progression-free survival (PFS) to 7.4 months compared to 3.2 months with hormonal therapy alone (hazard ratio=0.44 [95% confidence interval (CI): 0.36 to 0.53]; $p<1x10-16$) by local investigator assessment. Twelve month estimates of patients without disease progression were 31% and 10% in the everolimus and exemestane, and exemestane-alone arms, respectively. An additional analysis based on an independent central radiology review showed everolimus extended PFS to 11.0 months compared to 4.1 months (hazard ratio=0.36 [95% CI: 0.28 to 0.45];

p<1x10-16)(1).

Response rates and clinical benefit rates (patients with complete response, partial response, or stable disease for greater than six months) were higher in the combination arms (12.0% vs. 1.3% and

50.5% vs. 25.5%; p<0.0001), respectively. The results with everolimus were favorable regardless of the presence of visceral disease, prior use of chemotherapy or number of prior therapies. In addition, patients with only bone metastases benefited from the combination. These results represent an additional five months of follow-up (median duration of follow-up of 17.5 months) and are supportive of previously presented outcomes(1).

Despite the significant progress in treating women with breast cancer, there have been no new treatment advances for women living with ER+HER2- advanced breast cancer in more than 15 years, said Hervé Hoppenot, President, Novartis Oncology. The results of BOLERO-2 are the first to show everolimus combined with hormonal therapy enabled women with this type of breast cancer to live significantly longer without their tumor progressing.

The original results published in *NEJM* today showed that at a pre-planned interim analysis, BOLERO-2 met its primary endpoint of PFS showing treatment with everolimus plus hormonal therapy extended PFS to 6.9 months compared to 2.8 months with hormonal therapy alone (hazard ratio=0.43 [95% CI: 0.35 to 0.54]; p<0.001) by local investigator 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<0.001)(2).

The side effects observed were consistent with those previously reported with everolimus with the most common Grade 3 or 4 adverse events including: stomatitis (8% vs. 1%), anemia (7% vs. 1%), hyperglycemia (5% vs. <1%), dyspnea (4% vs. 1%), fatigue (4% vs. 1%) and pneumonitis (3% vs. 0%) for the combination and exemestane-only arms, respectively(1). At the time of updated analysis, 137 patients died, constituting 17.2% of patients in the everolimus plus exemestane arm and 22.7% of those in the exemestane-only arm(3).

Hormonal therapy remains the cornerstone of treatment for women with advanced breast cancer, but almost all patients who respond eventually develop resistance(2). Everolimus targets the mTOR pathway in cancer cells. mTOR is 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(2).

Each year, around 220,000 women globally will be diagnosed with ER+HER2- advanced breast cancer(5),(6). Everolimus is also being investigated for the treatment of patients with HER2+ advanced breast cancer(7),(8).

Regulatory submissions for everolimus based on the BOLERO-2 results are planned by the end of 2011.

About BOLERO-2

BOLERO-2 (Breast cancer trials of OraL EveROlimus-2) is a Phase III, randomized, double-blind, placebo-controlled, multicenter study that 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 the hormonal therapies letrozole or anastrozole(2). The trial was conducted at 189 sites worldwide, in 24 countries and enrolled 724 patients(2). 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). Novartis provided financial support for the study(1).

The primary endpoint was PFS based on local investigator radiology assessment. Other endpoints include overall survival, overall response rate, safety, patient reported outcome, clinical benefit rate and changes in markers of bone metabolism(1).

In the data presented at SABCS, no difference in time to deterioration of quality of life was observed and everolimus increased exemestane steady-state C_{min} and C_{max} levels by 45% and

64%, respectively, with no difference in estradiol levels. Serum markers of bone resorption and bone formation increased in the exemestane arm and generally decreased in the everolimus plus exemestane arm(1).

About everolimus

Everolimus is approved as Afinitor® (everolimus) tablets in more than 80 countries including the United States and throughout the European Union in the oncology settings of advanced renal cell carcinoma (RCC) following progression on or after vascular endothelial growth factor (VEGF)-targeted therapy, and in the US and EU for locally advanced, metastatic or unresectable progressive neuroendocrine tumors of pancreatic origin (pNET).

Everolimus is also available from Novartis for use in non-oncology patient populations under the brand names Afinitor® or 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 is 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 everolimus tablets

Everolimus 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. Everolimus can affect blood cell counts, kidney and liver function, and blood sugar and cholesterol levels. Everolimus may cause fetal harm in pregnant women. Women taking everolimus should not breast feed.

The most common adverse drug reactions (incidence $\geq$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 $\geq$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 may, planned, will, potential, or simila 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, 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 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; unexpected manufacturing issues; 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 innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care, cost-saving generic pharmaceuticals, preventive vaccines and diagnostic tools, over-the-counter and animal health products. Novartis is the only global 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. 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: **December 8, 2011**

By: /s/ MALCOLM B. CHEETHAM

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