NOVARTIS AG
Form 6-K
July 30, 2012

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 July 30, 2012

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

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(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

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MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

Novartis drug Afinitor® approved by European Commission to treat patients with the most common form of advanced breast cancer

- *In combination with exemestane, Afinitor is approved for use in women with HR+/HER2- advanced breast cancer after progressing on an aromatase inhibitor*(1)

- *Approval is based on Phase III trial of more than 700 patients showing those treated with Afinitor lived significantly longer before their disease progressed*

- *Afinitor is first major advance in HR+ advanced breast cancer in more than 15 years and the first mTOR inhibitor approved to treat women with this disease(2)*

Basel, July 30, 2012 The European Commission has approved Afinitor® (everolimus) tablets* for the treatment of hormone receptor-positive (HR+), HER2/neu-negative (HER2-) advanced breast cancer (HR+ advanced breast cancer), in combination with exemestane, in postmenopausal women without symptomatic visceral disease after recurrence or progression following a non-steroidal aromatase inhibitor(1).

The approval of Afinitor is an important milestone marking the first major advance for women in the European Union with hormone receptor-positive advanced breast cancer since the introduction of aromatase inhibitors more than 15 years ago, said Hervé Hoppenot, President, Novartis Oncology. Treatment with Afinitor gives women a new option in the battle against this advanced form of breast cancer, where there remains a significant unmet need.

The approval was based on the Phase III BOLERO-2 (Breast cancer trials of OraL EveROlimus-2) trial(1). The randomized, double-blind, placebo-controlled, multi-center study of 724 patients found that treatment with Afinitor plus exemestane more than doubled median progression-free survival (PFS) to 7.8 months, compared to 3.2 months with exemestane alone (hazard ratio=0.45 [95% Cl: 0.38 to 0.54]; p<0.0001), by local investigator assessment(3). An additional analysis based on an independent central radiology review showed Afinitor extended median PFS to 11.0 months compared to 4.1 months (hazard ratio=0.38 [95% CI: 0.31 to 0.48]; p<0.0001)(3). The most common grade 3-4 adverse reactions (incidence ≥ 2%) were stomatitis, infections, hyperglycemia, fatigue, dyspnea, pneumonitis and diarrhea(3).

By boosting the effectiveness of endocrine therapy, Afinitor significantly extends the time women with hormone receptor-positive advanced breast cancer live without tumor progression, said Jose Baselga, MD, PhD, Chief, Hematology/Oncology, Massachusetts General Hospital and co-lead investigator of the BOLERO-2 trial. Afinitor, the first mTOR inhibitor to be approved for this disease, has the potential to redefine the way this common form of advanced breast cancer is treated.

Each year, an estimated 220,000 women globally will be diagnosed with HR+ advanced breast cancer(1),(4). For these women, endocrine therapy remains the cornerstone of treatment, but most will eventually develop resistance to therapy(5). This therapeutic resistance has been

associated with overactivation of the PI3K/AKT/mTOR pathway(5). Afinitor works to target the mTOR pathway in cells. mTOR is a protein that acts as an important regulator of tumor cell division, blood vessel growth and cell metabolism(5).

The European Commission decision follows the positive opinion adopted by the Committee for Medicinal Products for Human Use on June 21, 2012 for Afinitor for the treatment of HR+ advanced breast cancer and applies to all 27 EU member states, plus Iceland and Norway(6). On July 20, 2012, the US Food and Drug Administration approved Afinitor in combination with exemestane in the HR+/HER2- population after failure of letrozole or anastrazole(7). Additional regulatory submissions for Afinitor in advanced breast cancer are under way worldwide. Afinitor is also being studied in HER2-positive breast cancer in two ongoing Phase III trials.

About Advanced Breast Cancer

Advanced breast cancer is comprised of metastatic breast cancer (stage IV) and locally advanced breast cancer (stage III)(8). Metastatic breast cancer is the most serious form of the disease and occurs when the cancer has spread to other parts of the body, such as the bones or liver(8). Locally advanced breast cancer occurs when the cancer has spread to lymph nodes and/or other tissue in the area of the breast, but not to distant sites in the body(8).

It is estimated that women with metastatic breast cancer have a life expectancy of approximately 18-36 months after diagnosis and median survival for women with stage III disease is less than five years(9),(10).

HR+ advanced breast cancer is characterized by hormone receptor-positive tumors, a group of cancers that express receptors for certain hormones such as estrogen and progesterone. Cancer cell growth can be driven by these hormones(8). The presence of estrogen receptor (ER) and/or progesterone receptor (PgR) is one of the most important predictive and prognostic markers in human breast cancers, and is collectively referred to as hormone receptor-positive(8).

About Afinitor (everolimus)

Afinitor® (everolimus) is approved in the European Union for the treatment of hormone receptor-positive (HR+), HER2/neu-negative (HER2-) advanced breast cancer, in combination with exemestane, in postmenopausal women without symptomatic visceral disease after recurrence or progression following a non-steroidal aromatase inhibitor. In the United States, Afinitor is approved for the treatment of postmenopausal women with advanced hormone receptor-positive, HER2-negative breast cancer (advanced HR+ breast cancer) in combination with exemestane after failure of treatment with letrozole or anastrozole.

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

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. 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.

Afinitor® Important Safety Information

Afinitor®/Votubia® 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/Votubia can affect blood cell counts, kidney and liver function, and blood sugar and cholesterol levels. Afinitor/Votubia may cause fetal harm in pregnant women. Highly effective contraception is recommended for women of child-bearing potential while receiving Afinitor/Votubia and for up to eight weeks after ending treatment. Women taking Afinitor/Votubia 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, diabetes and amenorrhea. Cases of hepatitis B reactivation and blood clots in the lung and leg have been reported.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as potential, will, under way, being studied, 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 submitted or 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; government, industry and general public pricing pressures; competition in general; 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 2011, the Group achieved net sales of USD 58.6 billion, while approximately USD 9.6 billion (USD 9.2 billion excluding impairment and amortization charges) was invested in R&D throughout the Group. Novartis Group companies employ approximately

126,000 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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*Known as Votubia® (everolimus) tablets for certain patients with SEGA associated with TSC in the EU and Switzerland.

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(10) Eniua A, Palmierib F and Perez E. Weekly Administration of Docetaxel and Paclitaxel in Metastatic or Advanced Breast Cancer. The Oncologist, 2005.

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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:	July 30, 2012	By:	/s/ MALCOLM B. CHEETHAM
		Name:	Malcolm B. Cheetham
		Title:	Head Group Financial Reporting and Accounting