NOVARTIS AG
Form 6-K
June 22, 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 June 22, 2012

(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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MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

CHMP recommends Novartis drug Afinitor® for EU approval marking major milestone in the treatment of advanced breast cancer

- *Upon approval, Afinitor will provide a new treatment approach for women with HR+ advanced breast cancer, where there remains a significant unmet need(1)*

- *In a Phase III trial, women taking Afinitor with exemestane lived more than twice as long without their cancer progressing compared to exemestane alone(2)*

- *Worldwide regulatory submissions in HR+ advanced breast cancer are underway and if approved, will represent the fifth indication for Afinitor, an mTOR inhibitor*

Basel, June 22, 2012 Novartis announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion for Afinitor® (everolimus) tablets*, in combination with exemestane, for the treatment of hormone receptor-positive (HR+), HER2/neu-negative (HER2-) advanced breast cancer, in postmenopausal women without symptomatic visceral disease after recurrence or progression following a non-steroidal aromatase inhibitor(1).

Afinitor represents the first major innovation in HR+/HER2- advanced breast cancer since aromatase inhibitors were introduced more than 15 years ago, said Hervé Hoppenot, President, Novartis Oncology. The Committee s support of Afinitor brings us one step closer to providing an important new option for women living with this disease.

The European Commission generally follows the recommendations of the CHMP and usually delivers its final decision within three months of the CHMP recommendation. The decision will be applicable to all 27 European Union member states plus Iceland and Norway.

The CHMP opinion was based on pivotal Phase III data from the randomized, double-blind, placebo-controlled, multi-center BOLERO-2 (Breast cancer trials of OraL EveROlimus-2) trial(3). The study evaluated 724 patients with HR+/HER2- advanced breast cancer and 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(2). 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)(2).

Each year, an estimated 220,000 women globally will be diagnosed with HR+/HER2- advanced breast cancer(3). Women with advanced breast cancer have a life expectancy of approximately 18-36 months after diagnosis(4). Endocrine therapy remains the cornerstone of treatment for these women, but most will eventually develop treatment resistance(5). Therapeutic resistance has been associated with overactivation of the PI3K/AKT/mTOR pathway(5). Afinitor 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(5).

Afinitor is currently being considered in this patient population for approval by the US Food and Drug Administration, the Swiss Agency for Therapeutic Products (Swissmedic) and by health authorities worldwide. Afinitor is also being studied in HER2-positive breast cancer in two Phase III trials.

About Advanced Breast Cancer

Hormone receptor-positive (HR+) advanced breast cancer is characterized by hormone receptor tumors, a group of cancers that express receptors for certain hormones such as estrogen and progesterone. Cancer cell growth is driven by these hormones(6). 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 HR+. Approximately 70 percent of all invasive breast cancers are positive for HR expressions at the time of diagnosis(7).

Metastatic breast cancer, or stage IV 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(6). Advanced stage III breast cancer (also called locally advanced) occurs when the cancer has spread to lymph nodes and/or other tissue in the area of the breast and cannot be cured by surgery or radiation treatment, but not to distant sites in the body(6).

About Afinitor (everolimus)

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 (RCC) 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 (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. 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®

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 percent) 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 percent) 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 recommends, will, underway, positive opinion, recommendations, recommendation, is currently being considered, or similar expressions, or by express or implied discussions regarding potential submissions or approvals for new indications or labeling for everolimus, or regarding the timing of any such submission or approval, 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 s continuing operations 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 124,000 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.

References

(1) Novartis Data on File.

(2) Piccart M et al. Everolimus for Postmenopausal Women with Advanced Breast Cancer: Updated Results of the BOLERO-2 Phase III Trial. Abstract #559. American Society of Clinical Oncology 2012 Annual Meeting, Chicago, IL.

(3) Novartis Data on File.
(4) J. O Shaughnessy. Extending Survival with Chemotherapy in Metastatic Breast Cancer. Oncology 2005, 10: 20-29.
(5) Baselga, J. Everolimus in Postmenopausal Hormone-Receptor-Positive Advanced Breast Cancer. New England Journal of Medicine. February 9, 2012.
(6) National Cancer Institute. What You Need to Know About Advanced Breast Cancer. Available at: http://www.cancer.gov/cancertopics/wyntk/breast/WYNTK_breast.pdf. Accessed on March 8, 2012.
(7) Dobrescu, Andrei. Study of Estrogen Receptor and Progesterone Receptor Expression in Breast Ductal Carcinoma In Situ by Immunohistochemical Staining in ER/PgR-Negative Invasive Breast Cancer. May 9, 2011. Available at: http://www.isrn.com/journals/oncology/2011/673790/. Accessed on April 9, 2012.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, Novartis AG has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

NOVARTIS AG

Date: June 22, 2012

By: /s/ MALCOLM CHEETHAM

Name: Malcolm Cheetham
Title: *Head Group Financial Reporting and Accounting*