NOVARTIS AG
Form 6-K
May 24, 2013

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 May 24, 2013

(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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Novartis drug Afinitor® significantly extended time without disease progression in women with HER2 positive advanced breast cancer

- *Everolimus plus trastuzumab and vinorelbine met primary endpoint of extending PFS compared to placebo plus trastuzumab and vinorelbine after prior therapy(1)*

- *Results of Phase III trial, BOLERO-3, first to show potential benefit of everolimus in HER2 positive advanced breast cancer, an aggressive form of the disease(1)*

- *Detailed data will be presented at the upcoming ASCO Annual Meeting and shared with regulatory authorities worldwide*

Basel, May 17, 2013 Results of a pivotal Phase III trial in women with HER2 positive (HER2+) advanced breast cancer showed that Afinitor® (everolimus) tablets in combination with trastuzumab (Herceptin®*) and vinorelbine significantly extended progression-free survival (PFS) after prior therapy when compared to treatment with placebo plus trastuzumab and vinorelbine, meeting the study s primary endpoint(1).

Efficacy and safety data from the BOLERO-3 (Breast cancer trials of OraL EveROlimus-3) trial were assessed as part of a prospectively planned analysis. These results will be presented on June 2 at the American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, Illinois(2), as well as at future medical congresses, and shared with regulatory authorities worldwide.

We are encouraged by the BOLERO-3 results and are committed to helping improve treatment options for the HER2 positive patient population where there remains an unmet need, said Alessandro Riva, Global Head, Oncology Development & Medical Affairs, Novartis Oncology. Everolimus works differently than any currently available treatment for HER2 positive breast cancer, and these results support its potential expanded role in advanced breast cancer.

Everolimus targets the PI3K/AKT/mTOR pathway, which is hyperactivated in many types of cancers(3). mTOR is a protein that acts as an important regulator of cell division, blood vessel growth and cell metabolism(4). Data confirm that blocking mTOR is a proven approach to maximize the benefit of existing advanced breast cancer treatments(4).

Everolimus is approved as Afinitor in more than 65 countries including the United States and the countries of the European Union to treat postmenopausal women with hormone receptor-positive, HER2 negative (HR+/HER2 negative) advanced breast cancer in combination with exemestane, after recurrence or progression following a non-steroidal aromatase inhibitor(1). The specific indications vary by country(1). HR+/HER2 negative advanced breast cancer is the most common form of the disease(5). Approximately 70% of all invasive breast cancers are positive for HR expression at the time of diagnosis(6).

* Herceptin® is a registered trademark of Genentech, Inc.

Study design

BOLERO-3 is a Phase III, randomized, double-blind study of everolimus plus trastuzumab and vinorelbine conducted at 159 clinical trial sites globally(1). The trial included 569 women with HER2 positive locally advanced or metastatic breast cancer who were previously treated with a taxane and were resistant to trastuzumab(1). Participants were randomized 1:1 to receive either everolimus 5 mg/day orally or placebo, plus weekly vinorelbine 25 mg/m(2) IV and weekly trastuzumab 2 mg/kg IV following loading dose of 4 mg/kg(1).

The primary endpoint of the trial is PFS(1). Secondary endpoints include overall survival, objective response rate, time to deterioration of performance status, changes in quality-of-life scores over time, clinical benefit rate, duration of response, time to response, safety and pharmacokinetics(1).

About advanced breast cancer

Advanced breast cancer comprises metastatic breast cancer (stage IV) and locally advanced breast cancer (stage III)(7). 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 brain, bones or liver(7). 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(7).

Overactivation of the PI3K/AKT/mTOR pathway has been associated with disease progression in women with advanced breast cancer(4). Eighty percent of advanced breast cancer is either hormone receptor-positive (HR+) and/or human epidermal growth factor receptor-2 positive (HER2 positive)(1),(8).

HR+ advanced breast cancer is the most common type of advanced breast cancer, with an estimated 220,000 women diagnosed globally each year(1). 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(9).

In HER2 positive advanced breast cancer, overexpression of the HER2 gene activates signaling pathways, such as the mTOR pathway, leading to the uncontrolled growth and division of cancer cells(1),(10). Globally, an estimated 140,000 women are living with HER2 positive advanced breast cancer(1).

About Afinitor® (everolimus)

Everolimus is approved as Afinitor® in the European Union for the treatment of hormone receptor-positive, HER2 negative (HR+/HER2 negative) 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+/HER2 negative breast cancer)

in combination with exemestane after failure of treatment with letrozole or anastrozole.

Afinitor (everolimus) tablets is approved in more than 95 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 certain 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 (everolimus) tablets

Afinitor/Votubia can cause serious side effects including lung or breathing problems, infections (including sepsis), and kidney 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, cholesterol, and triglyceride 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. Fertility in women and men may be affected by treatment with Afinitor/Votubia.

The most common adverse drug reactions (incidence ≥10 percent) are mouth ulcers, skin rash, feeling tired or weak, diarrhea, nausea, decreased appetite, infections (including upper respiratory tract infection), low level of red blood cells, abnormal taste, inflammation of lung tissue, weight loss, swelling of extremities or other parts of the body, nose bleeds, itching, vomiting, high level of blood cholesterol, headache, high level of blood sugar, cough, spontaneous bleeding or bruising, and breathlessness. The most common Grade 3-4 adverse drug reactions (incidence ≥2 percent) are mouth ulcers, feeling tired or weak, infections, inflammation of lung tissue, diarrhea, spontaneous bleeding or bruising, low white blood cells (a type of blood cell that fights infection), and breathlessness. Cases of hepatitis B reactivation, blood clots in the lung or legs, and menstruation disorders such as absence of periods have been reported. Abnormalities were observed in hematology and clinical chemistry laboratory tests.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as potential, will, upcoming, may, committed, 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 new 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 2012, the Group achieved net sales of USD 56.7 billion, while R&D throughout the Group amounted to approximately USD 9.3 billion (USD 9.1 billion excluding impairment and amortization charges). Novartis Group companies employ approximately 129,000 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:	May 24, 2013	By:	/s/ MALCOLM B. CHEETHAM
		Name:	Malcolm B. Cheetham
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