NOVARTIS AG
Form 6-K
March 24, 2006

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 March 24, 2006

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

Lichtstrasse 35

4056 Basel

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: ý 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**: ý

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Yes: o **No**: ý

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**: ý

Investor Relations

Novartis International AG
CH-4002 Basel
Switzerland

Novartis Corporation
608 Fifth Avenue
New York, NY 10020
USA

- Investor Relations Release -

Femara® approved in Germany as initial therapy for postmenopausal women with early breast cancer after surgery

Approvals in other European countries expected in the near future - new indication already approved in the US, UK and Japan

Benefit of Femara is most evident in women with higher risk of their breast cancer coming back

New global 4,000 patient head-to-head trial comparing Femara to anastrozole launched first comparative study of these two aromatase inhibitors in post-surgery setting

Basel, March 20, 2006 Novartis announced today that Femara® (letrozole) has received approval in Germany for use after surgery in postmenopausal women with hormone-sensitive early breast cancer (adjuvant setting). This is the first major European market approval for this additional indication under the European mutual recognition procedure.

The approval was based on results from the BIG 1-98 study, a comparison of Femara versus tamoxifen, which demonstrated that Femara reduced the risk of breast cancer recurrence by an additional 19% (p=0.003). The benefit of Femara was most evident in women with a higher risk of their breast cancer coming back, i.e. those whose breast cancer has already spread to the lymph nodes (node-positive) and/or those who have received chemotherapy.

To better define the optimal adjuvant treatment for these patients at higher risk, Novartis has initiated the FACE (Femara vs. Anastrozole Clinical Evaluation) trial. This is the first comparative study of these two aromatase inhibitors in the post-surgery setting and is expected to enroll 4,000 women worldwide. The trial will evaluate the efficacy of the two drugs in reducing the risk of breast cancer coming back.

This new approval of Femara offers these women an effective treatment after surgery to help protect them from their cancer returning, said David Epstein, President and CEO, Novartis Oncology. The superior efficacy of aromatase inhibitors over tamoxifen has led physicians and patients to ask which drug in this class is the most effective in the adjuvant setting. This is why Novartis has made a significant commitment to sponsor the FACE trial.

Femara is the only medicine in its class that women with hormone-related breast cancer can use as either initial treat-ment immediately after surgery or after they have completed five years of tamoxifen therapy (extended adjuvant setting). Femara is the first aromatase inhibitor to demonstrate greater benefit in women at increased risk of breast cancer recurrence.

About the BIG 1-98 study

BIG 1-98 is the only clinical trial that incor-porates both a head-to-head comparison and a sequencing of Femara and tamoxifen as adjuvant treatment. The results of the head-to-head comparison were published in the December 29, 2005, issue of *The New England Journal of Medicine*.

Femara reduced the risk of breast cancer recurrence by an additional 19% with even further reduction in women at high risk. In women whose breast cancer had already spread to the lymph nodes at the time of diagnosis (node positive), Femara reduced the risk of recurrence by 29% (results of women with node negative disease did not yet show statistical significance). In women who received prior chemotherapy, the reduction in risk of recurrence was 28%.

In addition, Femara reduced the risk of cancer spreading to distant parts of the body by 27% (metastasis). This is considered especially important because distant disease free survival (DDFS) is considered a surrogate for overall survival. Cancer that spreads to other parts of the body increases the likelihood that a woman will die from the disease.

After surgery, many of these women take a hormonal therapy to lower the risk that their cancer may come back. We are very pleased that just one year after the presentation of the first results, Femara is now available to women with breast cancer, said Professor Dr. Beat Thürlimann, St. Gallen, Switzerland, and the BIG 1-98 Trial Study Chair.

About the FACE trial

The FACE trial is a global Phase III randomized multi-center study involving more than 250 sites comparing the efficacy and safety of Femara to anastrazole in 4,000 postmenopausal women with node-positive hormone-sensitive early breast cancer. This is an important study because women with node-positive disease have an increased risk of breast cancer recurrence. This condition, in turn, can raise their chance of dying from the disease. About half (46%) of postmenopausal women with hormone-sensitive early breast cancer are node-positive at diagnosis.

About Femara

Femara is a leading once-a-day oral aromatase inhibitor available in more than 90 countries, including the US, Europe, and Japan. Femara is approved for use as adjuvant treatment of postmenopausal women with hormone-receptor-positive early breast cancer, as extended adjuvant treatment of hormone-dependent early breast cancer in postmenopausal women who have received prior standard adjuvant tamoxifen therapy for five years, as first-line treatment in postmenopausal women with hormone-dependent advanced breast cancer and for advanced breast cancer in women with natural or artificially induced postmenopausal status after relapse or disease progression who have previously been treated with antiestrogens. Not all indications are available in each country.

Safety Profile

The most common side effects of Femara are hot flushes (34.4%), increased sweating (14.4%), fatigue (5.5%) and joint pain (20.2%). Other common side effects are anorexia, appetite increase, peripheral oedema, headache, dizziness, nausea, vomiting, dyspepsia, constipation, diarrhea, hair loss, rash, muscle pain, bone pain, osteoporosis, bone fractures, weight increase, hypercholesterolemia, malaise and depression.

Other rare but potentially serious adverse reactions include leucopenia, cataract, cerebro-vascular accident or infarction, thrombophlebitis, pulmonary embolism, arterial thrombosis, ischemic cardiac events.

Femara should not be taken if patients have previously had any unusual or allergic reactions to letrozole or any of its ingredients. Femara should not be taken by women who are pregnant or breastfeeding. Femara should be taken only by women who are postmenopausal. Patients with severe liver impairment should be monitored closely. The use of Femara in patients with significantly impaired kidney function warrants careful consideration.

The foregoing release contains forward-looking statements that can be identified by terminology such as expected, significant commitment, or similar expressions, or by express or implied discussions regarding potential new indications, marketing approvals, or future sales of Femara. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results with Femara to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Femara will be approved for any additional indications in any market, nor that it will reach any particular sales levels. In particular, management s expectations regarding commercialization of Femara could be affected by, among other things, additional analysis of Femara clinical data; new clinical data; unexpected clinical trial results; unexpected regulatory actions or delays or government regulation generally; the company s ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; increased government, industry, and general public pricing pressures; and other risks and factors referred to in the Company s current Form 20-F on file with the U.S. 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.

For more information

Additional information regarding Femara or Novartis Oncology can be found on the websites www.femarainfo.com or www.novartisoncology.com.

About Novartis

Novartis AG (NYSE: NVS) is a world leader in offering medicines to protect health, treat disease and improve well-being. Our goal is to discover, develop and successfully market innovative products to treat patients, ease suffering and enhance the quality of life. Novartis is the only company with leadership positions in both patented and generic pharmaceuticals. We are strengthening our medicine-based portfolio, which is focused on strategic growth platforms in innovation-driven pharmaceuticals, high-quality and low-cost generics and leading

self-medication OTC brands. In 2005, the Group s businesses achieved net sales of USD 32.2 billion and net income of USD 6.1 billion. Approximately USD 4.8 billion was invested in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 91,000 people and

operate in over 140 countries around the world. For more information, please visit http://www.novartis.com.

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Novartis Global Investor Relations

Karen J. Huebscher, Ph.D. +41 61 324 84 33

International office

Katharina Ambühl	+41 61 324 53 16
Nafida Bendali	+41 61 324 35 14
Richard Jarvis	+41 61 324 43 53
Silke Zentner	+41 61 324 86 12

e-mail: investor.relations@novartis.com

Fax: +41 61 324 84 44
www.novartis.com

North American office

Ronen Tamir	+1 212 830 24 33
Jill Pozarek	+1 212 830 24 45

e-mail: investor.relations@novartis.com

Fax: +1 212 830 24 05
www.novartis.com

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: March 24, 2006

By: /s/ MALCOLM B. CHEETHAM

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