NOVARTIS AG
Form 6-K
August 21, 2009

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 August 19, 2009

(Commission File No. 1-15024)

Novartis AG

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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 -

Results in *The New England Journal of Medicine* confirm Novartis drug Femara® is superior to tamoxifen after breast cancer surgery

- *Data validate Femara alone for five years following hormone-receptor positive breast cancer surgery as an optimal first treatment vs. tamoxifen in postmenopausal women*

- *Results show long-term superiority of Femara in improving disease-free survival (P=0.03) and reducing risk of distant metastases (P=0.05) compared with tamoxifen*

- *Femara for five years following surgery is first aromatase inhibitor to suggest survival benefit versus tamoxifen; 13% reduction in risk of death (P=0.08, non-significant)*

Basel, August 19, 2009 Newly published data in *The New England Journal of Medicine* affirm five-year upfront use of Femara® (letrozole) following surgery as an optimal treatment approach versus tamoxifen for postmenopausal women with early stage breast cancer (hormone-receptor positive).

The data include an analysis from the Breast International Group (BIG) 1-98 trial that evaluated patients taking either a sequence of Femara and tamoxifen for five years or Femara alone (as monotherapy) for five years. Also included is the update of the Monotherapy Arms Analysis (MAA) conducted 10 years after initiation of the study, comparing five years of Femara alone versus five years of tamoxifen alone following surgery (adjuvant setting). The BIG 1-98 trial was conducted by the International Breast Cancer Study Group (IBCSG).

Results from the Sequential Treatments Analysis (STA) concluded that sequential treatment with tamoxifen and Femara in the first five years after breast cancer surgery did not improve disease-free survival compared with Femara alone for the same duration after surgery. In the 10-year MAA analysis, Femara monotherapy demonstrated significant long-term improvement of disease-free survival (P=0.03) and significant long-term reduction in risk of distant disease spread (metastasis) (P=0.05) compared with tamoxifen. In patients treated with Femara monotherapy, a non-statistically significant relative reduction in the risk of death of 13% versus tamoxifen (P=0.08) was observed.

The BIG 1-98 study results suggest survival benefit with five years of letrozole therapy after surgery compared to tamoxifen for the same time period following surgery, confirming the benefit of initial use of letrozole in the adjuvant breast cancer setting, said Henning T. Mouridsen, MD, PhD, Professor of Oncology, Copenhagen University Hospital and BIG 1-98 investigator. Letrozole is the only aromatase inhibitor versus tamoxifen to demonstrate early and significant reduction in the risk of distant metastases, significant improvement in disease-free survival and this suggestion in overall survival benefit in primary breast cancer patients.

Sequential Treatments Analysis (STA)

Results of the STA (median follow-up of 71 months) concluded that sequential treatment with tamoxifen did not improve disease-free survival compared with Femara alone. In the study, patients either received sequential treatment with Femara and tamoxifen (two years of Femara followed by three years of tamoxifen or two years of tamoxifen followed by three years of Femara) or five years of Femara alone. Five-year disease-free survival rates for the three groups of patients in the STA were 87.9% for those patients receiving Femara only, 86.2% for those patients receiving tamoxifen followed by Femara and 87.6% for those patients receiving Femara followed by tamoxifen.

Monotherapy Arms Analysis (MAA)

Updated results from the MAA (median follow-up of 76 months) confirm the significant long-term benefit of Femara. The data demonstrated that patients who took Femara alone for five years following surgery experienced a significant reduction in the risk of distant metastases (15%, P=0.05) with a corresponding reduction in risk of disease-free survival events (12%, P=0.03) compared with patients treated with tamoxifen alone for the same duration.

The analysis also revealed a non-significant trend towards an overall survival benefit with five years of Femara therapy following surgery (13% reduced risk of death, P=0.08) versus tamoxifen for five years following surgery. This occurred even though approximately 25% of patients in the tamoxifen arm selectively crossed over to Femara therapy after the tamoxifen arm was unblinded in 2005 due to the superiority of Femara over tamoxifen(1). This crossover confounds the evaluation of the true differences between letrozole and tamoxifen. The study group therefore, conducted a retrospective censored analysis that was not protocol-defined and in which observation times were censored at the date of crossover. Time and events beyond the crossover were ignored in patients who selectively crossed over to Femara. In this censored analysis, there was an improved survival benefit for patients receiving five years of Femara versus tamoxifen (19%; HR 0.81; 95% CI: 0.68, 0.96). According to the authors, these censored results may be an overestimate of the Femara benefit since women who had recurrent disease were not candidates for the crossover. It is likely that the most accurate assessment of the survival benefit with Femara is between these two analyses 13-19% reduction in the relative risk of death compared with tamoxifen(2).

BIG 1-98 is the only clinical trial designed to explore both a head-to-head comparison of an aromatase inhibitor versus tamoxifen monotherapy, as well as sequencing of an aromatase inhibitor and tamoxifen therapy in the first five years following breast cancer surgery, in order to determine the most effective way to minimize breast cancer recurrence. In the initial adjuvant setting, Femara is the only aromatase inhibitor to have consistently demonstrated an early significant reduction in distant metastases versus tamoxifen at a median follow-up of 26, 51 and 76 months.

Femara is the only aromatase inhibitor to demonstrate consistent, early and significant reduction in risk of distant metastases, said Alessandro Riva, MD, Global Head Oncology Development, Novartis Oncology. Based on these results, starting with Femara monotherapy for five years in the adjuvant setting instead of tamoxifen may offer breast cancer patients the opportunity for a better outcome.

Study details

This Phase III, randomized, double-blind, controlled clinical trial enrolled more than 8,000 postmenopausal women with early breast cancer in 27 countries2.

Patients were randomly assigned one of four treatment regimens: (1) five years of tamoxifen only; (2) five years of Femara only; (3) two years of tamoxifen followed by three years of Femara; (4) two years of Femara followed by three years of tamoxifen.

The primary endpoint of the study was disease-free survival, defined as the time from randomization to the first of any of the following events: recurrence at local, regional, or distant sites; a new invasive cancer in the contralateral breast; any second, non-breast cancer; or death without a previous cancer event. Other endpoints included time to breast cancer recurrence, time to distant breast cancer recurrence and overall survival.

In 2005, following initial results showing superiority of Femara monotherapy over tamoxifen monotherapy in improving disease-free survival and reducing the risk of recurrence, the tamoxifen-only treatment arm was unblinded and approximately one quarter of those patients selectively crossed over to Femara treatment. The other three treatment arms remained blinded. Subsequent analyses were designed to estimate the extent to which the crossover affected the comparative benefit of Femara.

With the long-term follow-up in the analysis conducted more than 10 years after the start of the study, adverse events for Femara and tamoxifen were found to be consistent with the known safety profiles of both drugs. Patients will be monitored for the rest of their lives to track disease status, safety and overall survival. The long-term BIG 1-98 findings add to the large body of clinical evidence regarding the established safety profile of Femara.

About Femara

Femara is a leading once-daily oral aromatase inhibitor available in more than 100 countries, including the US, major European countries and Japan. It is approved for a number of indications:

- Adjuvant treatment of postmenopausal women with hormone receptor-positive early breast cancer*
- Extended adjuvant treatment of hormone-dependent early breast cancer in postmenopausal women who have had prior standard adjuvant tamoxifen therapy for five years**
- First-line treatment in postmenopausal women with hormone-dependent advanced breast cancer
- Advanced breast cancer in women with natural or artificially induced postmenopausal status after relapse or disease progression who have been treated with antiestrogens
- Pre-operative therapy in postmenopausal women with localized hormone receptor-positive breast cancer which allows subsequent breast-conserving surgery in patients not originally considered suitable for this type of surgery.

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* Femara is also approved as neo-adjuvant (pre-operative) therapy in Japan, and in some countries for patients with metastatic disease.

** Not all indications are approved in every country.

Important Safety Information

Femara should not be taken by women who 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. Only women who are of postmenopausal endocrine status should take Femara. Patients with severe liver impairment should be monitored closely. The use of Femara in patients with significantly impaired kidney function warrants careful consideration.

The most frequent adverse reactions of Femara are hot flushes, nausea, fatigue and arthralgia. Other common side effects are anorexia, appetite increase, peripheral oedema, headache, dizziness, malaise, vomiting, dyspepsia, constipation, diarrhea, alopecia, increased sweating, rash, myalgia, bone pain, osteoporosis, bone fractures, weight increase, hypercholesterolemia and depression. Other rare, but potentially serious adverse events include leukopenia, cataract, cerebrovascular accident or infarction, thrombophlebitis, pulmonary embolism, arterial thrombosis, general edema, ischemic cardiovascular disease, angioedema, anaphylactic reaction, hepatitis, toxic epidermal necrolysis and erythema multiforme.

This press release is not intended for UK media.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as long-term, risk, suggest, suggestion, will, may, likely, designed to explore, or similar expressions, or by express or implied discussions regarding potential new indications or labeling for Femara or regarding potential future revenues from Femara. 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 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 submitted or approved for any additional indications or labeling in any market. Nor can there be any guarantee that Femara will achieve any particular levels of revenue in the future. In particular, management s expectations regarding Femara could be affected by, among other things, the company s ability to obtain or maintain patent or other proprietary intellectual property protection; competition in general; 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; government, industry and general public pricing pressures; 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 healthcare solutions that address the evolving needs of patients and societies. Focused solely on healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic pharmaceuticals, preventive vaccines, diagnostic tools and consumer health products. Novartis is the only company with leading positions in these areas. In 2008, the Group s continuing operations achieved net sales of USD 41.5 billion and net income of USD 8.2 billion. Approximately USD 7.2 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 99,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit http://www.novartis.com.

References

(1) Thürlimann B et al. A Comparison of Letrozole and Tamoxifen in Postmenopausal Women with Early Breast Cancer. N Engl J Med. 2005 Dec 29; 353(26); 2807-9.

(2) Mouridsen H for the BIG 1-98 Collaborative Group. Letrozole Alone or in Sequence with Tamoxifen for Postmenopausal Women with Breast Cancer. N Engl J Med. 2009 Aug 20; 361(8); 22-32.

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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: August 19, 2009	By:	/s/ MALCOLM B. CHEETHAM
	Name:	Malcolm B. Cheetham
	Title:	Head Group Financial Reporting and Accounting