

NOVARTIS AG  
Form 6-K  
February 13, 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 February 11, 2009**

**(Commission File No. 1-15024)**

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**Novartis AG**

(Name of Registrant)

**Lichtstrasse 35**

**4056 Basel**

**Switzerland**

(Address of Principal Executive Offices)

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Yes:  No:

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**- Investor Relations Release -**

**Zometa® reduces risk of breast cancer recurrence in premenopausal women, study in *The New England Journal of Medicine* reports**

- *Adding Zometa to post-surgery hormone therapy reduced risk of breast cancer return or death by 36% more than hormone therapy alone*
- *First Phase III data to substantiate anticancer effect of Zometa*
- *Zometa is the most widely prescribed drug for prevention of bone complications due to bone metastases, with more than 2.7 million patients treated worldwide*

**Basel, February 11, 2009** A newly published study in *The New England Journal of Medicine* shows that in premenopausal women with early breast cancer administering Zometa® (zoledronic acid) along with post-surgery hormone therapy provided a reduction in risk of recurrence or death that was 36% beyond that achieved with hormone therapy alone(1).

The study, from the Austrian Breast & Colorectal Cancer Study Group (ABCSG), is the first large, randomized, Phase III clinical trial to show that Zometa offers significant protection against the return of early breast cancer in premenopausal women. Prior laboratory research suggested that Zometa might have direct anticancer effects, including helping to protect against the return and spread of cancer before it reaches an advanced stage(2).

The possible return of breast cancer is a major concern among women who ve undergone surgery to remove their tumors. We anticipate that this publication in *The New England Journal of Medicine* will provide oncologists with evidence regarding an additional treatment regimen to further help reduce the risk of breast cancer recurrence, or even death, for premenopausal women with hormone-sensitive breast cancer, said lead investigator Michael Gnant, MD, of the Medical University of Vienna.

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It is encouraging to see a significant reduction in risk of recurrence in these patients from a therapy that was also well-tolerated, said David Epstein, President and CEO of Novartis Oncology. The findings of this landmark trial substantiate the strong anticancer effect of Zometa beyond the well-established benefit of this treatment in preventing bone complications in advanced cancers.

The ABCSG Trial 12 (ABCSG-12) included more than 1,800 premenopausal women with early-stage breast cancer who, following curative surgery and goserelin treatment to suppress the ovaries, were treated with hormone therapy with or without Zometa for three years. The results demonstrated that the addition of Zometa to hormone therapy (tamoxifen or anastrozole) significantly prolonged both disease-free survival and recurrence-free survival.

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## Study details

ABCSG-12 is an open-label, multicenter, Phase III study that enrolled 1,803 premenopausal women with estrogen receptor-positive Stage I or II breast cancer, with fewer than 10 axillary lymph nodes involved. Patients were recruited for the study after curative surgery and initiation of goserelin treatment for ovarian suppression, and randomly assigned into one of four study groups: (1) anastrozole plus Zometa; (2) anastrozole alone; (3) tamoxifen plus Zometa; (4) tamoxifen alone. The treatment period was three years and the median follow-up period was 48 months(1).

The primary endpoint for all four study arms was disease-free survival. Recurrence-free survival, overall survival and bone-mineral density were secondary endpoints. Disease-free survival was defined as the length of time after randomization during which patients had no local recurrence, contralateral breast cancer, distant metastasis, secondary carcinoma and/or death from any cause. Recurrence-free survival was defined as the length of time after randomization during which patients had no local recurrence, contralateral breast cancer, distant metastasis and/or secondary carcinoma. Exploratory endpoints included bone metastasis-free survival(1).

At the median follow-up of 48 months, disease-free survival events were reduced by 36% (P=0.01) and the risk of recurrence-free survival events fell by 35% (P=0.02) with Zometa added to hormone therapy versus hormone therapy alone. Sixteen deaths had occurred among patients who received Zometa with hormone therapy versus 26 deaths in patients who received hormone therapy alone, which resulted in a non-significant reduction in the risk of death in patients who received Zometa compared with those who received hormone therapy alone (P=0.11). A similar trend was noted toward a reduction in bone metastases among patients who received Zometa compared with those who received hormone therapy alone (P=0.22). Longer follow-up and a larger number of events will be necessary to determine if any significant differences exist between the groups for overall survival and bone metastasis-free survival. Overall, treatment was generally well-tolerated and side effects were consistent with known drug safety profile(1).

## About Zometa

Zometa is indicated for the treatment or prevention of skeletal related events (pathological fractures, spinal compression, radiation or surgery to bone, or tumor-induced hypercalcemia) in patients with advanced malignancies involving bone. Zometa is approved and indicated for the treatment of patients with multiple myeloma and patients with documented bone metastases from solid tumors, in conjunction with standard antineoplastic therapy. An intravenous bisphosphonate, Zometa is the only therapy to demonstrate efficacy in reducing or delaying bone complications across a broad range of tumor types such as breast, prostate, lung and renal cell cancers, in patients with metastatic disease when administered monthly. Zometa offers patients, nurses and clinicians a convenient 4 mg, 15-minute infusion.

Zometa is the world's leading treatment for the prevention or delay of skeletal-related events (SREs) in patients with advanced malignancies involving bone across a broad range of tumors. Laboratory research has suggested that Zometa may also help protect patients from the spread of cancer to other parts of the body (distant metastatic sites) and help keep patients recurrence-free.

Zometa slows the bone-destroying effect that occurs with bone metastases by fighting abnormal activation of osteoclasts, cells that normally break down old bone, and osteoblasts, cells that normally build new bone. Growth factors produced by cancer cells overstimulate osteoclasts and osteoblasts, causing excessive erosion of bone and/or the abnormal buildup of new but unstable bone.

## Important safety information

In clinical studies, the safety profile with Zometa was similar to that of pamidronate. Zometa has been associated with reports of renal insufficiency. Patients should have serum creatinine



assessed prior to receiving each dose of Zometa. Caution is advised when Zometa is used in aspirin-sensitive patients, or with aminoglycosides, loop diuretics and other potentially nephrotoxic drugs. Due to the risk of clinically significant deterioration in renal function, single doses of Zometa should not exceed 4 mg and the duration of infusion should be no less than 15 minutes in 100 ml of diluent.

In clinical trials in patients with bone metastases and hypercalcemia of malignancy (HCM), Zometa had a safety profile similar to other intravenous bisphosphonates. The most commonly reported adverse events included flu-like syndrome (fever, arthralgias, myalgias, skeletal pain), fatigue, gastrointestinal reactions, anemia, weakness, cough, dyspnea and edema. Zometa should not be used during pregnancy. Zometa is contraindicated in patients with clinically significant hypersensitivity to zoledronic acid or other bisphosphonates, or any of the excipients in the formulation of Zometa.

Osteonecrosis of the Jaw (ONJ): ONJ has been reported in patients with cancer receiving treatment including bisphosphonates, chemotherapy, and/or corticosteroids. The majority of reported cases have been associated with dental procedures such as tooth extraction. A dental examination with appropriate preventive dentistry should be considered prior to treatment with bisphosphonates in patients with concomitant risk factors. While on treatment, these patients should avoid invasive dental procedures if possible. No data are available to suggest whether discontinuation of bisphosphonate therapy reduces the risk of ONJ in patients requiring dental procedures.

Please see full Prescribing Information.

#### **Disclaimer**

The foregoing release contains forward-looking statements that can be identified by terminology such as anticipate, will, might, encouraging, may or similar expressions, or by express or implied discussions regarding potential new indications or labeling for Zometa or regarding potential future revenues from Zometa. 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 Zometa to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Zometa will be approved for any additional indications or labeling in any market. Nor can there be any guarantee that Zometa will achieve any particular levels of revenue in the future. In particular, management's expectations regarding Zometa 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; 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**

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Novartis AG 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

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needs: innovative medicines, preventive vaccines, diagnostic tools, cost-saving generic pharmaceuticals, 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 96,700 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit <http://www.novartis.com>.

#### For more information

Additional information regarding Zometa and Novartis Oncology can be found on the websites <http://www.novartisoncologyvpo.com/zometa>, [www.zometa.com](http://www.zometa.com) and [www.novartisoncology.com](http://www.novartisoncology.com).

#### References

- (1) Gnant, M. et al. Adjuvant Endocrine Therapy Plus Zoledronic Acid in Premenopausal Women With Early Breast Cancer: First Efficacy Results from ABCSG-12. *N Engl J Med*. 2009 Feb 12; VOLUME / PAGE
- (2) Mundy, GR, et al. Metastases to bone: causes, consequences and therapeutic opportunities. *Nat Rev Cancer* 2002;2:584-593.

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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: February 11, 2009

By: /s/ MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham

Title: Head Group Financial Reporting and Accounting

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