NOVARTIS AG
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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 December 9, 2010

(Commission File No. 1-15024)

Novartis AG

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- Investor Relations Release -

Study of Novartis drug Zometa for potential new use in early breast cancer did not meet primary endpoint in overall study population

- *Interim results of AZURE trial report Zometa added to standard adjuvant therapy did not show disease free survival advantage compared to standard therapy alone(1)*

- *In subgroup of women with well-established menopause, an improvement in disease free survival and overall survival was shown in Zometa arm(1)*

- *Current applications in the US and EU for adjuvant treatment in early breast cancer will be withdrawn; Novartis to evaluate future plans based on these new data*

- *Study results do not impact the current indications for Zometa in preventing SREs in patients with advanced cancers involving bone and multiple myeloma and treating HCM*

Basel, December 9, 2010 Results from the second interim analysis of the Phase III AZURE (Adjuvant Zoledronic acid to reduce REcurrence) trial show that Zometa® (zoledronic acid) did not demonstrate a disease-free survival (DFS) advantage when added to standard adjuvant (post-surgery) chemotherapy and/or hormonal therapy in pre- and postmenopausal women with early breast cancer. In a preplanned analysis based on menopausal status, a benefit in disease free survival and overall survival was seen in women with well-established menopause in the Zometa arm(1).

The AZURE trial was conducted to determine if Zometa as adjuvant therapy had a benefit in preventing recurrences in premenopausal and postmenopausal women with early breast cancer. The results were presented today at the 33rd Annual CTRC-AACR San Antonio Breast Cancer Symposium in San Antonio, Texas, US(1).

Zometa is currently approved for the reduction or delay of bone complications (skeletal-related events, or SREs) across a broad range of metastatic cancers (breast, prostate, lung and other solid tumors) involving bone and multiple myeloma, as well as for the treatment of hypercalcemia of malignancy (HCM) and is the most widely used bisphosphonate in the oncology setting.

These trial results do not impact the current usage of Zometa, which continues to be a critical treatment for many patients with a broad range of metastatic cancers and multiple myeloma, said Hervé Hoppenot, President, Novartis Oncology. Although we did not see an overall disease free survival advantage for early breast cancer patients receiving Zometa in the adjuvant setting, we re encouraged that a subset of postmenopausal patients in the trial experienced an improvement.

The potential anticancer benefit of Zometa was previously observed in a large, randomized, Phase III study from the Austrian Breast & Colorectal Cancer Study Group (ABCSG-12 study), which included more than 1,800 premenopausal women with hormone receptor-positive (HR+) early-stage breast cancer who, following curative surgery and hormone therapy, including

goserelin treatment to suppress ovarian function and induce menopause, were treated with or without Zometa for three years(2). The trial showed that the addition of three years of Zometa therapy to hormonal therapy following surgery improved disease-free survival by 32% (hazard ratio=0.68 [95% confidence interval 0.51-0.91], P=0.009)(3).

Last year, Novartis filed supplemental marketing authorization applications for the adjuvant treatment of premenopausal women with HR+ early breast cancer in conjunction with hormonal therapy in the US and European Union (EU) based on the results of ABSCG-12. Novartis is currently reviewing the data from the AZURE trial results, which were expected to be added to the submission. In the meantime, Novartis will withdraw the current marketing applications and discuss next steps with health authorities.

Zometa is approved in more than 100 countries for the reduction or delay of bone complications in multiple myeloma and across a broad range of metastatic cancers (breast, prostate, lung and other solid tumors) involving bone, as well as for the treatment of hypercalcemia of malignancy. It is the most widely used bisphosphonate in the oncology setting and has been used to treat more than 3.9 million patients worldwide.

AZURE study details

AZURE is a randomized, open-label, multicenter, parallel group trial that enrolled 3,360 women from 174 centers in seven countries(4),(1). The study is run by the National Cancer Research Network in the United Kingdom with input from an international collaborative group(4). Patients participate in a five-year treatment phase and a subsequent five-year follow-up phase(4). A small subset of patients also received neo-adjuvant (pre-surgery) therapy(4).

The primary endpoint of DFS was to be determined after 940 disease events(4). The data presented at SABCS are from a second interim analysis performed when at least 75% (752) of the final events had occurred(1). Secondary endpoints included invasive DFS, overall survival, bone metastasis free survival safety, and other translational endpoints(4). After a median follow up of 59 months (interquartile range 53-61), the hazard ratio (HR) for DFS in Zometa-treated (n=1681) compared to control patients (n=1678) was 0.98 (95% confidence interval [CI] [0.85-1.13], P=0.79), thus there was no clinically significant benefit between the treatment groups(1). The trend toward improved overall survival in patients on the Zometa arm was not statistically significant (HR=0.85 [95% CI 0.72-1.01], P=0.0726) (1).

In a preplanned analysis of women based on menopausal status, a benefit of disease free survival and overall survival was seen in women with well-established menopause in the Zometa arm(1). An adjusted analysis for imbalances in prognostic factors (estrogen receptor, lymph node status and tumor stage) showed this benefit was statistically significant (29% improvement in overall survival (HR=0.71 [95% CI 0.54-0.94]; P=0.017)(1). No benefit was seen in premenopausal women(1).

The tolerability profile of Zometa is well-established and results from this study were found to be consistent with the known profile(1). Generally, serious adverse events (SAE) were similar in both treatment arms(1). There were 17 cases of osteonecrosis of the jaw confirmed in the Zometa arm(1). This represents a rate of 1.16%, which is consistent with what has been seen in other well controlled trials(6).

About ZOMETA

Zometa is indicated for the prevention of skeletal related events (pathological fractures, spinal compression, radiation or surgery to bone, or tumor-induced hypercalcemia) in patients with multiple myeloma and advanced malignancies involving bone. An intravenous bisphosphonate, Zometa is the only approved therapy to demonstrate efficacy in reducing or delaying bone complications in multiple myeloma and across a

broad range of malignancies such as breast,

prostate, lung and renal cell cancers in patients with metastatic disease when administered monthly. Zometa offers patients, nurses and clinicians a 4 mg, 15-minute infusion.

Important Safety Information

Zometa has been associated with reports of renal insufficiency. Patients should be adequately rehydrated and have their serum creatinine assessed prior to receiving each dose of Zometa. 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 dilutent. The risk of renal adverse events may be greater in patients with renal insufficiency. Zometa is not recommended for treatment of patients with severe renal impairment. Severe and occasionally incapacitating bone, joint, and/or muscle pain has been reported in patients taking bisphosphonates including Zometa. Caution is advised when Zometa is used in aspirin-sensitive patients, or with aminoglycosides, loop diuretics and other potentially nephrotoxic drugs. Zometa contains the same active ingredient (zoledronic acid) as found in Aclasta. Patients being treated with Zometa should not be treated with Aclasta concomitantly. Zometa should not be used in patients who are pregnant, or plan to become pregnant, or who are breast-feeding.

In clinical trials, 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. A causal relationship between bisphosphonate use and ONJ has not been established.

Please see full Prescribing Information.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as potential, will, to evaluate, encouraged, expected, 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 submitted or 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 clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; 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; 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 2009, the Group s continuing operations achieved net sales of USD 44.3 billion, while approximately USD 7.5 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 102,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit http://www.novartis.com.

References

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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: December 9, 2010

By: /s/ MALCOLM B. CHEETHAM

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