

NOVARTIS AG  
Form 6-K  
December 06, 2010

# 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 December 6 2010**

(Commission File No. 1-15024)

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(Name of Registrant)

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(Address of Principal Executive Offices)

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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:**  **Form 40-F:**

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:  No:

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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:  No:

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**- Investor Relations Release -**

*This press release is not intended for United Kingdom news media*

**Phase III data published in *Lancet* show Novartis drug Zometa® improves overall survival in newly diagnosed multiple myeloma patients**

- *Regimen including Zometa significantly improved both progression-free survival and overall survival when compared to regimen including oral clodronate*
- *Zometa provided significant clinical anticancer benefit independent of and in addition to significant reduction in skeletal-related events, compared to clodronate*
- *Initially presented at ASCO, these data add to the growing body of clinical evidence suggesting potential anticancer activity of Zometa in multiple cancer types*

**Basel, December 4, 2010** A newly published study in the *Lancet* suggested that a first-line treatment regimen including Zometa® (zoledronic acid) significantly improved overall survival (OS) and progression-free survival (PFS) in newly diagnosed multiple myeloma patients compared with a regimen that included oral clodronate. The impact on survival was independent of the effect of Zometa on bone complications (also known as skeletal-related events or SREs)(1),(2).

The published results are from Medical Research Council (MRC) Myeloma IX, a large, randomized, Phase III clinical trial of nearly 2,000 patients with multiple myeloma(1). These results were initially reported at the 46th Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago, IL, in June 2010.

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At a median follow-up of 3.7 years, Zometa significantly reduced the risk for death by 16% (hazard ratio [HR] 0.842; 95% confidence interval [CI] 0.74-0.96; P=0.0118) and the relative risk for PFS events by 12% (HR 0.88; 0.80-0.98; P=0.0179) compared with oral clodronate. In addition to demonstrating superiority to clodronate on survival endpoints, Zometa was significantly superior to clodronate in the prevention of SREs associated with multiple myeloma, regardless of SRE history at baseline(1).

More than 750,000 cases of multiple myeloma are diagnosed each year worldwide, with a median overall survival of three to five years(3). Nearly 95% of advanced stage multiple myeloma patients have bone disease and half of them will experience SREs (e.g., pathologic fractures, radiation or surgery to bone, spinal cord compression) if not treated(4),(5).

As a hematologist who treats patients with multiple myeloma, the survival benefit demonstrated by Zometa in this study is very encouraging, said Professor Gareth Morgan, Head of Haemato-oncology at The Royal Marsden and The Institute of Cancer Research, UK and one of the study's lead investigators. We have long known that Zometa is effective in the reduction of SREs, but these results suggest that there is a new role for Zometa in the treatment of multiple myeloma that may extend the life of patients battling this disease.

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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 (HCM). It is the most widely used bisphosphonate in the oncology setting and has been used to treat more than 3.9 million patients worldwide.

It is encouraging to see the improvement in both overall and progression-free survival in these patients with multiple myeloma, said Hervé Hoppenot, President, Novartis Oncology. The findings of this large-scale trial add to the growing body of evidence that supports the potential anticancer effect of Zometa in multiple cancer types.

#### **MRC Myeloma IX study details(1),(6)**

The Medical Research Council (MRC) Myeloma IX is a Phase III, prospective, multicenter, randomized, controlled study to compare intravenous (IV) Zometa (4 mg every 3-4 weeks) with oral clodronate (1600 mg daily) based on the severity of bone disease and in improving survival. A total of 1,960 evaluable patients from the United Kingdom and New Zealand with newly diagnosed International Staging System (ISS) Stage I, II or III multiple myeloma entered either an intensive or non-intensive treatment pathway, determined on the basis of performance status, informed decision and consent. Patients were randomized for type of bisphosphonate therapy and first-line therapy (induction chemotherapy) on a 1:1 basis.

The primary study endpoints were OS, PFS and response. Overall survival was defined as the length of time from randomization to death due to any cause. Progression-free survival was defined as the length of time from randomization to disease progression or death. Secondary endpoints included SREs (including bone fractures, radiation to bone, surgery to bone, bone lesions and/or spinal cord compression) and safety.

At a median follow-up of 3.7 years, Zometa reduced the relative risk for death by 16% (HR 0.842; 95% CI 0.74-0.96; P=0.0118) and the relative risk for PFS events by 12% (HR 0.88; 0.80-0.98; P=0.0179) compared with oral clodronate. The proportion of patients who experienced an SRE on study was reduced by 24% in patients receiving Zometa versus clodronate (27.0% versus 35.0%, respectively; P=0.0004). The survival advantage demonstrated by Zometa was observed in patients with Stage I, II or III newly diagnosed multiple myeloma. This survival advantage was also observed in addition to and independently of the drug's benefit on SREs. In an exploratory Cox model including first SRE as a time-dependent covariate, the adjusted improvement in OS with Zometa versus clodronate remained statistically significant. The adjusted result indicated that there was a 15% (HR 0.85; CI 0.74-0.97; P=0.018) reduced risk for death with Zometa compared to clodronate treatment independent of the benefit on SREs. In addition, Zometa reduced the development of new bone lesions regardless of whether a patient had bone lesions when entering the study.

The tolerability profile of Zometa is well-established and results from this study were found to be consistent with the known profile. The incidence of confirmed osteonecrosis of the jaw (ONJ) in the Zometa and clodronate treatment arms was 4.0% and less than 1.0%, respectively. Renal deterioration was reported to be similar between treatment groups.

#### **About ZOMETETA**

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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 therapy to demonstrate efficacy in reducing or delaying bone complications in multiple myeloma, as well as 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 4 mg, 15-minute infusion.

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Zometa is the number one prescribed treatment for the prevention or delay of skeletal-related events (SREs) in patients with advanced malignancies involving bone across a broad range of tumors.

### **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 diluent. 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, encouraging, suggest, 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

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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 100,000 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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## References

- (1) Morgan G., et al. First-Line and Ongoing Treatment with Zoledronic Acid Improves Overall Survival in Patients with Multiple Myeloma: Results of the MRC Myeloma IX Randomised Controlled Trial. *Lancet*. Published Online. December 4, 2010.
- (2) Morgan, G., et al. Evaluating the Effects of Zoledronic Acid (ZOL) on Overall Survival (OS) in Patients (Pts) with Multiple Myeloma (MM): Results of the Medical Research Council (MRC) Myeloma IX study. Abstract #8021. American Society of Clinical Oncology 2010 Annual Meeting.
- (3) Podar K., et al. Emerging Therapies for Multiple Myeloma. *Expert Opin Emerg Drugs*. 2009;14(1):99-127.
- (4) Coleman R. E. Skeletal Complications of Malignancy. *Cancer*. 1997;Supp 1. 1588-1594.
- (5) Berenson J.R. Recommendations for Zoledronic Acid Treatment for Patients with Bone Metastases. *The Oncologist*. 2005;10:52-62.
- (6) Morgan G., et al. MM IX Protocol. Version 3.0.

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## Novartis Media Relations

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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 6, 2010

By: */s/ MALCOLM B. CHEETHAM*

Name: Malcolm B. Cheetham

Title: Head Group Financial Reporting and Accounting

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