

NOVARTIS AG  
Form 6-K  
October 09, 2007

## **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 October 5, 2007**

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

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**Novartis AG**

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**- Investor Relations Release -**

**Aclasta® receives European approval as first once-yearly treatment for postmenopausal osteoporosis**

*Shown to be highly effective in strengthening bones and protecting against fractures in all key sites, including hip and spine<sup>(1)</sup>*

*Once-yearly dosing provides potential for compliance benefits and long-term anti-fracture efficacy*

*New England Journal of Medicine study in hip fracture patients shows Aclasta reduced subsequent osteoporotic fractures by 35% and mortality by 28%<sup>(2)</sup>*

*Osteoporotic fractures affect one in two women over age 50<sup>(3)</sup> and associated with increased morbidity, mortality and healthcare costs*

**Basel, October 5, 2007** Aclasta® (zoledronic acid 5 mg) has received European Union approval as the first once-yearly treatment for women with postmenopausal osteoporosis.

The announcement closely follows the recent approval in the US, where the Food and Drug Administration (FDA) approved Aclasta under the brand name Reclast® in August 2007. The European Commission decision applies to all 27 member states, Norway and Iceland.

We are very pleased to receive EU approval, especially as it comes so soon after a similar decision in the US, said James Shannon, MD, Global Head of Development at Novartis Pharma AG. This demonstrates widespread confidence in Aclasta, which provides physicians and patients with a completely new way to manage osteoporosis. The unique once-yearly dosing of this medicine has the potential for significant compliance benefits and improved quality of life for women with osteoporosis.

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Unlike oral bisphosphonate therapies taken daily, weekly or monthly, Aclasta is given as a once-yearly 15-minute intravenous (IV) infusion. This means with a single treatment, a patient can receive a full year's protection against the effects of osteoporosis. Data show that more than 70% of patients prefer a once-yearly infusion of Aclasta to a weekly tablet<sup>(4),(5)</sup>.

Osteoporosis is a long-term bone disease that causes bones to break more easily. The need for more effective treatments is based on estimates that about 200 million people worldwide suffer from this disease<sup>(6)</sup> and that one of two women over age 50 will suffer an osteoporotic fracture in their lifetime<sup>(3)</sup>.

Aclasta is the only treatment approved in the EU and US to reduce the risk of fractures in areas of the body typically affected by osteoporosis, including the hip, spine and non-spine (e.g. wrist and rib)<sup>(1)</sup>.

Aclasta is highly effective at reducing fractures and can be given once-yearly which is a significant benefit to patients and clinicians, said Steven Boonen, Professor of Medicine at the Centre for Metabolic Bone Diseases & Division of Geriatric Medicine at the Leuven University in Belgium. The convenience of a once-yearly dose should improve compliance and bone protection among patients while reducing fracture-related hospitalization and healthcare costs.

Results of the first-ever clinical study in patients with osteoporosis who had suffered a hip fracture, published in September in the *The New England Journal of Medicine*, show a once-yearly infusion of Aclasta reduced the risk of any type of subsequent osteoporotic fracture by 35% compared to patients treated with placebo. The Recurrent Fracture Trial involving more than 2,100 men and women also found the risk of death was significantly reduced by 28% in the Aclasta patient group compared to the placebo group (101 vs. 141 deaths)<sup>(2)</sup>.

The regulatory approvals were based on efficacy and safety data from another study, the three-year Pivotal Fracture Trial involving more than 7,700 women. In this study, Aclasta was shown to increase bone strength and reduce the risk of spine fractures by 70% and hip fractures by 41%. The reduction in spine fractures was sustained over three years, and bone mineral density increased significantly in the spine by 6.7% and in the hip by 6% in women on Aclasta compared to placebo<sup>(1)</sup>.

Osteoporotic fracture risk is often under-diagnosed and under-treated, resulting in sub-optimal outcomes and costs to healthcare systems<sup>(7)</sup>. Fractures can lead to reduced quality of life and loss of independence; someone with osteoporosis may also become partially disabled or immobilized, thereby requiring long-term care.

In women over age 45, osteoporosis accounts for more days spent in hospital than many other diseases, including diabetes, myocardial infarction (or heart attack) and breast cancer<sup>(8)</sup>. In 2000, the total direct costs related to osteoporotic fractures were estimated at 31.7 billion; these are forecast to increase to 76.7 billion in 2050 based on the expected changes in the demography of Europe<sup>(9)</sup>.

Aclasta is now approved in more than 30 countries for the treatment of post-menopausal osteoporosis and in more than 60 countries including the US, Canada and the EU for the treatment of Paget's disease, the second most common metabolic bone disorder. Additional studies are ongoing to examine treatment of corticosteroid-induced osteoporosis, male osteoporosis, and prevention of bone loss in osteopenic patients.

The active ingredient in Aclasta is zoledronic acid, which is also available in a different dosage under the brand name Zometa<sup>®</sup> (zoledronic acid 4 mg) Injection for use in certain oncology indications.

Aclasta was found to be generally safe and well tolerated in clinical trials. The most common adverse events associated with Aclasta were transient post-dose symptoms such as fever and muscle pain. Most of these symptoms occurred

within the first three days following Aclasta administration and resolved within three days. The incidence of post-dose symptoms can be reduced with the administration of paracetamol or ibuprofen shortly following Aclasta infusion.

In the Pivotal Fracture Trial an increased number of cases of atrial fibrillation serious adverse events were observed in women given Aclasta compared to those on placebo (1.3% vs. 0.6% respectively). However, this finding has not been observed in other clinical studies or in post-

marketing experience with over 1.5 million patients treated with zoledronic acid for oncology indications. In the Recurrent Fracture Trial, atrial fibrillation serious adverse events occurred in 1.1% of Aclasta-treated patients compared to 1.3% of placebo-treated patients. No spontaneous reports of osteonecrosis of the jaw (ONJ) a rare occurrence in the osteoporosis population treated with bisphosphonates were seen in either the Pivotal Fracture Trial or Recurrent Fracture Trial.

#### **Disclaimer**

The foregoing press release contains forward-looking statements that can be identified by the use of forward-looking terminology such as can, potential, expected, will, should, similar expressions or express or implied discussions regarding potential future regulatory submissions or approvals with respect to, or future sales of, of Aclasta, Reclast or Zometa. Such forward-looking statements reflect the current views of Novartis and involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Aclasta, Reclast or Zometa will be approved for any additional indications in the EU, US or any additional markets or that Aclasta, Reclast or Zometa will reach any particular level of sales. In particular, management's expectations regarding Aclasta, Reclast and Zometa could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results, including unexpected additional analysis of existing clinical data, and unexpected new clinical data; competition in general; government, industry, and general public pricing pressures; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; as well as the additional factors discussed in Novartis AG's Form 20-F filed 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 described herein as anticipated, believed, estimated or expected. Novartis is providing this information as of this date and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

#### **About Novartis**

Novartis AG (NYSE: NVS) is a world leader in offering medicines to protect health, cure 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. We are strengthening our medicine-based portfolio, which is focused on strategic growth platforms in innovation-driven pharmaceuticals, high-quality and low-cost generics, human vaccines and leading self-medication OTC brands. Novartis is the only company with leadership positions in these areas. In 2006, the Group's businesses achieved net sales of USD 37.0 billion and net income of USD 7.2 billion. Approximately USD 5.4 billion was invested in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ more than 100,000 associates and operate in over 140 countries around the world. For more information, please visit <http://www.novartis.com>.

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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: October 5, 2007

By: /s/ MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham  
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Reporting and Accounting