

NOVARTIS AG
Form 6-K
October 18, 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 October 16, 2010

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

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Switzerland

(Address of Principal Executive Offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

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Yes: ☐ **No:** ☒

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- Investor Relations Release -

Long-term data show Novartis once-yearly Aclasta preserves bone mass and provides fracture protection in postmenopausal osteoporosis

- *Aclasta reduced the risk of new spine fractures by 52% over six years versus patients who stopped treatment after three years(1)*
- *New data from six-year study validate Aclasta safety profile and support long-term use of annual infusions in patients with postmenopausal osteoporosis(1)*
- *More than one million Aclasta infusions administered worldwide(2) for the treatment of early to advanced bone loss(3)*

Basel, October 16, 2010 Novartis announced today that new six-year data reinforce the long-term efficacy and safety profile of once-yearly Aclasta(1) (zoledronic acid 5 mg) in postmenopausal women with osteoporosis(1). The study of more than 1,200 women was presented at the annual meeting of the American Society for Bone and Mineral Research (ASBMR) in Toronto, Canada.

The study showed that Aclasta preserved bone mass in postmenopausal osteoporotic patients who received annual infusions for six years(1). In patients who stopped Aclasta treatment after three years, the bone mineral density (BMD) decreased but remained well above the levels measured at the beginning of the study (difference between the two groups at six years: 1.04%, $p=0.0009$)(1).

Patients who stayed on Aclasta therapy for six years reduced their risk of new morphometric spine fractures by 52%, compared to those who stopped treatment at three years ($p=0.04$)(1), the study also showed. Morphometric fractures can occur unaccompanied by pain and therefore may not be diagnosed and treated(4). Over time patients can experience these fractures in the form of back pain, loss of height, or stooped posture(4).

These new findings show that continued treatment with zoledronic acid for six years continues to maintain bone mass and reduces vertebral fractures risk with no change to its favorable safety profile compared to discontinuation of treatment after three years, said Dennis Black, PhD, the study's lead author and Professor of Epidemiology and Biostatistics at the University of California, San Francisco. These new long-term data reconfirm Aclasta as an important therapeutic option for doctors when considering an osteoporosis medicine for their patients.

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In both study groups, the bone markers were maintained over six years within the normal premenopausal range(1). In patients who discontinued Aclasta after three years, there was no evidence of accelerated bone loss(1). This builds upon existing data from extensive clinical studies

(1) The tradename in the US is Reclast®

and confirms that Aclasta helps preserve bone turnover, the balanced process by which the bone is constantly renewed and remodeled throughout adult life.

Aclasta is highly effective at protecting patients against osteoporotic fractures for a long period of time and its once-yearly dosing represents an important improvement for patients and doctors in terms of compliance for an entire year, said Trevor Mundel, MD, Global Head of Development at Novartis AG. These long-term data affirm our confidence in the efficacy and safety profile of this medicine.

Osteoporosis is a condition in which bones become weak and break more easily(4). According to the International Osteoporosis Foundation (IOF), an estimated 75 million people in Europe, USA, and Japan are affected by this disease(5) and one in three women over the age of 50 as well as one in five men will suffer an osteoporotic fracture in their lifetime(5).

This long-term study, which extended the HORIZON (Health Outcomes and Reduced Incidence with Zoledronic Acid Once Yearly) Pivotal Fracture Trial by three years, is a multi-center, double-blind, randomized, placebo-controlled study to evaluate the long-term efficacy and safety of Aclasta in the treatment of postmenopausal osteoporosis(1). The extension study evaluated more than 1,200 women aged 68 years or older(1). After three years of therapy, participants were randomized to either receive an Aclasta infusion (n=616) or an annual placebo infusion (n=617) for additional three years(1).

The primary endpoint of the study was the percentage change in the BMD at the femoral neck at year six vs. year three(1). Secondary endpoints included evaluation of BMD at other sites, fractures, changes in bone turnover markers and overall safety(1). The incidence of adverse events was comparable between groups(1). There was no long-term effect on renal function or increase in risk of osteonecrosis of the jaw or atrial fibrillation(1).

Aclasta provides year-long bisphosphonate compliance with a single infusion. Aclasta is the only yearly treatment approved in US and EU 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)(6). Additionally, it is also the only proven therapy to reduce new clinical fracture and all-cause mortality (28% reduction in death) after a recent low trauma hip fracture(7).

Approved in more than 90 countries, Aclasta is approved for up to six indications to treat a broad spectrum of patients, from the newly diagnosed to those with more severe forms of osteoporosis(2). These include treatment of postmenopausal osteoporosis, prevention of postmenopausal osteoporosis, prevention of subsequent fractures after a low-trauma fracture, increase in bone mass in men with osteoporosis, treatment and prevention of glucocorticoid-induced osteoporosis in men and women, and treatment of Paget's disease of bone in men and women(2).

Aclasta is generally well tolerated. Given as an infusion, it by-passes the gastrointestinal tract and avoids the potential side-effects like upper gastrointestinal irritation. The most common adverse events associated with Aclasta are transient post-dose symptoms such as fever and muscle pain. Most of these symptoms occur within the first three days following Aclasta administration and usually resolve within three days. The incidence of such post-dose symptoms can be reduced with the administration of paracetamol or ibuprofen shortly after Aclasta infusion. These data are based on one of the most extensive osteoporosis clinical trial programs involving over 14,000 men and women.

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Zoledronic acid, the active ingredient in Aclasta, is also available in a different dosage under the trade-name Zometa for use in certain oncology indications.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as confidence, will, potential, or similar expressions, or by express or implied discussions regarding potential new indications or labeling for Aclasta or regarding potential future revenues from Aclasta. 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 Aclasta to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Aclasta will be submitted or approved for any additional indications or labeling in any market. Nor can there be any guarantee that Aclasta will achieve any particular levels of revenue in the future. In particular, management's expectations regarding Aclasta could be affected by, among other things, 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; unexpected regulatory actions or delays or government regulation generally; 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

- (1) Black DM, et al. The Effect of 3 versus 6 Years of Zoledronic Acid Treatment in Osteoporosis: a Randomized Extension to the HORIZON-Pivotal Fracture Trial (PFT). American Society for Bone and Mineral Research (ASBMR) Annual Meeting. October 16, 2010.
- (2) Novartis, IMS MIDAS Quarterly data, June 2010.
- (3) Reclast (zoledronic acid) Injection Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation. January 2010.
- (4) National Osteoporosis Foundation. Fast Facts on Osteoporosis brochure. February 2008.
- (5) International Osteoporosis Foundation fact sheet Facts and Statistics about Osteoporosis and its Impact. September 10, 2010 at <http://www.iofbonehealth.org/facts-and-statistics.html#factsheet-category-17>.
- (6) Black DM et al. Once Yearly Zoledronic Acid for Treatment of Postmenopausal Osteoporosis. NEJM 2007; 356:1809 - 1822.
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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 16, 2010

By: /s/ MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham

Title: Head Group Financial
Reporting and Accounting