

NOVARTIS AG
Form 6-K
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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 June 26, 2009

(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 -

Once-yearly Aclasta® approved in EU to treat osteoporosis caused by steroid treatment in men and postmenopausal women

- *Steroids, widely used to treat inflammatory conditions, can cause bone loss and increase risk of fractures in up to 50% of patients on long-term therapy(1)*
- *European approval based on data showing Aclasta better at increasing bone mass than oral risedronate, a current established therapy(2),(3)*
- *Clinical trial results also reaffirm efficacy and safety of Aclasta, used in more than 500,000 patients worldwide since launch in 2007(4),(5)*
- *Approval is fifth indication for once-yearly Aclasta, already approved worldwide to treat postmenopausal osteoporosis(6)*

Basel, June 26, 2009 Once-yearly Aclasta® (zoledronic acid 5 mg)(1) has been approved in the European Union to treat men and postmenopausal women with osteoporosis caused by long-term use of glucocorticoids, commonly known as steroids(6). Glucocorticoids are widely used to treat inflammatory conditions such as asthma and rheumatoid arthritis, but also cause bone loss and can increase the risk of fracture in up to 50% of patients on long-term glucocorticoid therapy(1).

The new indication for men and women with glucocorticoid-induced osteoporosis (GIO) is based on study data showing that Aclasta, given once a year as a 15-minute infusion, is more effective at treating bone loss than daily oral risedronate, a current established therapy(2),(3).

The study results, recently published in *The Lancet*, show that Aclasta produced a significantly greater increase in bone mineral density (BMD) than risedronate at six months, indicating a faster onset of efficacy(2).

Oral bisphosphonates have been used for many years for the treatment of GIO, but they are associated with poor compliance as patients frequently fail to take them as prescribed, said Professor David M. Reid, Head of the Division of Applied Medicine at the University of Aberdeen, UK. Available data show that patients who remember to take their medicines only half of the time receive little or no protection(7).

He added: The approval of Aclasta is a significant step forward, as it is more effective and faster-acting than a current established therapy for the treatment of GIO and has the advantage of year-long compliance and sustained osteoprotection.

(1) The tradename is Reclast® in the US and Aclasta® in the rest of the world.

This is the fifth indication for Aclasta, which is approved to treat osteoporosis in men and postmenopausal women, including those who have experienced a low-trauma hip fracture. Aclasta is the only bisphosphonate approved in the EU and US to reduce the risk of fractures at all key osteoporotic fracture sites, like the hip, spine, and other bones in the treatment of postmenopausal osteoporosis(8). It is also approved to treat Paget's disease of the bone.

In the US, the same medicine under the trade mark Reclast® has also been approved by the Food and Drug Administration (FDA) to treat and prevent GIO in men and women. In May it was approved in the US as the only therapy to prevent postmenopausal osteoporosis with less frequent dosing (i.e. a single dose every two years)(9).

The GIO indication is important because it is estimated that between 700,000 and 1.3 million adults in Western Europe, and between 1.5 and 2.7 million adults in the US, are receiving prolonged courses of oral glucocorticoids(10),(11). Up to 50% of patients receiving long-term glucocorticoid therapy are at increased risk of fracture, as their use is associated with side effects such as bone loss and consequently osteoporosis(1).

This European approval marks another important achievement for Aclasta by adding to the broad spectrum of patients who can now be treated with this therapy, said Trevor Mundel, MD, Global Head of Development at Novartis Pharma AG. Aclasta has a strong efficacy and safety profile established during eight years of clinical trials. Since its launch in 2007, Aclasta has been used in more than 500,000 patients, demonstrating that an annual infusion has become a valuable treatment option.

The latest approval was based on a study of 833 men and women which investigated both the prevention and treatment of GIO (288 and 545 patients respectively)(2). The study had several advantages over previous trials studying the effects of bisphosphonate drugs on GIO, including the large sample size, the inclusion of both prevention and treatment subgroups, and an excellent retention rate.

The study showed that over one year, a single intravenous infusion of Aclasta produced increases in BMD of the lumbar spine and femoral neck, trochanter and total hip that were significantly greater than those seen with once-daily oral risedronate (Actonel®)(2).

The greater efficacy of Aclasta was evident at six months in both the treatment group (Aclasta 4.03%, risedronate 2.70%; $P=0.0002$) and prevention group (Aclasta 2.34%, risedronate 0.36%; $P<0.0001$)(2). Aclasta was better than risedronate at increasing lumbar spine BMD at 12 months in both the treatment group (Aclasta 4.1%, risedronate 2.7%; $P=0.0001$) and prevention group (Aclasta 2.6%, risedronate 0.6%; $P<0.0001$)(2).

Results from the study showed that Aclasta is generally safe and well tolerated(2), supporting previous clinical trial evidence from more than 14,000 patients(4). The most common adverse events associated with Aclasta were transient post-dose symptoms such as fever and muscle pain. Most of these symptoms occurred in the first three days after Aclasta administration and resolved within the same period of time. Post-dose symptoms can be reduced by taking paracetamol or ibuprofen shortly after the Aclasta infusion(2),(6),(8).

In this trial there were no cases of osteonecrosis of the jaw or delayed fracture healing, and no evidence of an increased risk of atrial fibrillation(2).

Zoledronic acid, the active ingredient in Aclasta/Reclast, is also available under the trade name Zometa® for use in oncology indications.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as can, risk, estimated, 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 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 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

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 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 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 98,000 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) Sambrook PN. Corticosteroid Osteoporosis: Practical Implications of Recent Trials. JBMR 2000; 15:1645-1649.
- (2) Reid DM, Devogelaer J-P, Saag K, Roux C, et al. Zoledronic acid and risedronate in the prevention and treatment of glucocorticoid-induced osteoporosis (HORIZON): a multicenter, double-blind, double-dummy, randomized controlled trial. Lancet 2009; 373: 1253-63.
- (3) Actonel 5mg Film Coated Tablets SPV. Available at: <http://emc.medicines.org.uk/document.aspx?documentId=3340>. Last accessed June 8, 2009.
- (4) Novartis data on file. Novartis Pharma AG; June, 2009.
- (5) Novartis - NPMR, May 2009, based on vials sold (retreatments taken into account).
- (6) Aclasta Summary of Product Characteristics. West Sussex, United Kingdom: Novartis Europharm Limited, 2009.
- (7) Siris SE, Harris ST, Rosen CT et al. Adherence to Bisphosphonate Therapy and Fracture Rates in Osteoporotic Women: Relationship to Vertebral and Nonvertebral Fractures From 2 US Claims Databases. Mayo Clin Proc., August 2006;81(8):1013-1022.
- (8) Black D, Delmas S, Eastell R et al for the HORIZON Pivotal Fracture Trial Group. Once-Yearly Zoledronic Acid for Treatment of Postmenopausal Osteoporosis. NEJM 2007; 356(18): 1809-22.
- (9) Reclast® (zoledronic acid) Injection [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; May 2009.
- (10) Gluck O, Colic G. Recognizing and Treating Glucocorticoid-Induced Osteoporosis in Patients with Pulmonary Diseases. CHEST 2004; 125: 1859 1876.
- (11) United Nations. Department of Economic and Social Affairs. Population Division. The 2008 Revision. Western Europe and United States of America Population Statistics. Available at: <http://esa.un.org/unpp>. Last accessed 30 March, 2009. The estimated figures for glucocorticoid use in Western Europe and the US were calculated by extrapolating the percentage of UK adults receiving oral glucocorticoids at any given time (between 0.5% and 0.9% of the adult population) to the populations of Western Europe (145 million adults) and the US (300 million adults).

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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: June 26, 2009

By: /s/ MALCOLM B. CHEETHAM

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