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 July 25, 2008

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

Lichtstrasse 35

4056 Basel

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:

Form 20-F: x Form 40-F: o

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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: o **No**: x

Novartis International AG

Novartis Global Communications

CH-4002 Basel

Switzerland

http://www.novartis.com

- Investor Relations Release -

Once-yearly Aclasta® recommended in EU to treat male osteoporosis and reduce risk of new fractures in patients after hip fracture

- *Male indication important as osteoporosis often neglected in men estimated one in five men aged over 50 may suffer an osteoporosis-related fracture(1)*

- *Positive opinion also expands once-yearly Aclasta indication to include osteoporosis patients who recently suffered a low-trauma hip fracture*

- *EU label to include data showing 35% reduction in new fractures and 28% reduction of all-cause mortality(2) in post-hip fracture patients treated with Aclasta*

- *Recommendation comes shortly after similar change to US label for Reclast(3)(1)*

Basel, July 25, 2008 Once-yearly Aclasta®* (zoledronic acid 5 mg) has passed another important milestone with a recommendation for European Union approval to treat osteoporosis in men who are at increased risk of fractures. Osteoporosis is an important health concern for men, with an estimated one out of five over the age of 50 experiencing an osteoporotic fracture(1).

In addition, the Committee for Medicinal Products for Human Use (CHMP) has recommended broadening the label to include data showing that Aclasta reduced the risk of new clinical fractures by 35% in men and postmenopausal women who have recently had a low-trauma hip fracture (e.g. due to a fall from standing height or less). Aclasta is the only osteoporosis treatment to demonstrate this benefit(2).

The revised label also includes data showing that in this patient population, all-cause mortality was reduced by 28% in the Aclasta-treated group compared to patients receiving placebo or dummy drug(2).

This positive opinion is an encouraging step forward for the treatment of osteoporosis in both men and women, said Steven Boonen, Professor of Medicine at the Leuven University Centre for Metabolic Bone Diseases and Division of Geriatric Medicine in Belgium. Osteoporosis in men has received little attention despite the large numbers affected. When fractures occur in men, they are associated with even higher morbidity and death than in women(1). For both men and women, hip fracture can be a potentially life-threatening consequence of osteoporosis, but unfortunately at present only a few people who experience hip fractures are treated for osteoporosis(4).

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

In 2000, approximately 1.6 million hip fractures occurred worldwide(5), and in Europe the number of hip fractures was estimated at around 179,000 for men and 611,000 for women(1). The cost of all osteoporotic fractures was around 31.5 billion(1).

The positive opinion was issued by the CHMP, which reviews medicines for the European Commission (EC). The EC generally follows the CHMP s recommendations and delivers its final decision within three months. The decision will apply in all 27 EU member states plus Iceland and Norway.

The CHMP recommendation comes shortly after the Food and Drug Administration (FDA) broadened the US label to include data showing the reduced risk of new clinical fractures in patients who have recently had a low-trauma hip fracture(3). Aclasta is available in the US under the trade-name Reclast®.

The European positive opinion is based on pivotal data from the landmark Recurrent Fracture Trial, involving more than 2,100 men and women aged 50 and older who had experienced a recent low-trauma hip fracture(2). Results showed that Aclasta reduced the risk of new clinical fractures by 35% compared to patients treated with placebo(2), and increased bone mineral density (BMD) at total hip and femoral neck. The risk of new spine fractures was reduced by 46%(2).

Furthermore, a two-year head-to-head trial comparing Aclasta with weekly oral alendronate provided additional data to support the CHMP recommendation for treatment of male osteoporosis(6). In this study involving more than 300 osteoporotic men, Aclasta was shown to preserve and improve lumbar spine BMD at 24 months(6).

We are excited about this recommendation to broaden the Aclasta label to include two important new patient populations said Trevor Mundel, MD, Global Head of Development Functions at Novartis Pharma AG. Aclasta represents a new treatment option that is administered as a once-yearly infusion, unlike daily, weekly or monthly oral bisphosphonates. Therefore Aclasta may allow osteoporotic men and women to receive a full year s bisphosphonate protection against the consequences of osteoporosis.

Aclasta, which is administered by once-yearly infusion, was approved in the EU in October 2007 for the treatment of osteoporosis in postmenopausal women. Aclasta is the only treatment for postmenopausal osteoporosis approved in the EU and US to reduce the risk of fractures at all key sites, including the hip, spine and non-spine (e.g. wrist and rib)(7). It is now approved in more than 70 countries, and in more than 80 countries for the treatment of Paget s disease of bone, the second most common metabolic bone disorder.

Aclasta has a demonstrated tolerability profile. 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 after Aclasta infusion.

Zoledronic acid, the active ingredient of Aclasta, 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 will , may , should , potential or similar expressions, or by express or implied discussions regarding potential new indications or labelling for Aclasta / Reclast or Zometa or

regarding potential future revenues from Aclasta / Reclast or Zometa. 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 / Reclast or Zometa 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 or labelling in any market. Nor can there be any guarantee that Aclasta / Reclast or Zometa will achieve any particular levels of revenue in the future. In particular, management s expectations regarding Aclasta / Reclast or Zometa a 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, 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 2007, the Group s continuing operations (excluding divestments in 2007) achieved net sales of USD 38.1 billion and net income of USD 6.5 billion. Approximately USD 6.4 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 98,000 full-time associates and operate in over 140 countries around the world. For more information, please visit http://www.novartis.com.

References

(1) International Osteoporosis Foundation. Report Osteoporosis in Men available at: www.iofbonehealth.org/download/osteofound/filemanager/publications/pdf/osteoporosis_in_men.pdf

(2) Lyles KW, Colon-Emeric CS, Magaziner JS, et al. for the HORIZON Recurrent Fracture Trial. Zoledronic acid and clinical fractures and mortality after hip fracture. N Engl J Med. 2007:537:1799-1809.

(3) Reclast® (zoledronic acid) Injection [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; June 2008.

(4) Cadarette SM, et al. Trends in drug prescribing for osteoporosis after hip fracture, 1995-2004. Journal of Rheumatology. 2007; 35:319-326.

(5) International Osteoporosis Foundation, Facts and statistics about osteoporosis and its impact, Last access July 2008, http://www.iofbonehealth.org/facts-and-statistics.html

(6) Novartis, Pharma AG, Data on file.

(7) Black DM, Delmas PD, Eastell R, et al. for the HORIZON Pivotal Fracture Trial. Once-yearly zoledronic acid for treatment of postmenopausal osteoporosis. N Engl J Med. 2007; 356: 1809-1822.

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Novartis Media Relations

Eric Althoff
Novartis Global Media Relations
+41 61 324 7999 (direct)
+41 79 593 4202 (mobile)
eric.althoff@novartis.com

Irina Ferluga
Novartis Pharma Communications
+41 61 324 2422 (direct)
+41 79 824 1121 (mobile)
irina.ferluga@novartis.com

e-mail: media.relations@novartis.com

Novartis Investor Relations

Central phone:	+41 61 324 7944
Ruth Metzler-Arnold	+41 61 324 9980
Pierre-Michel Bringer	+41 61 324 1065
John Gilardi	+41 61 324 3018
Thomas Hungerbuehler	+41 61 324 8425
Isabella Zinck	+41 61 324 7188

e-mail: investor.relations@novartis.com

North America:	
Richard Jarvis	+1 212 830 2433
Jill Pozarek	+1 212 830 2445
Edwin Valeriano	+1 212 830 2456

e-mail: investor.relations@novartis.com

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: July 25, 2008

By: /s/ MALCOLM B. CHEETHAM

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