

NOVARTIS AG
Form 6-K
June 06, 2008

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 5, 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:

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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:** ☒

Novartis International AG

Novartis Global Communications

CH-4002 Basel

Switzerland

<http://www.novartis.com>

- Investor Relations Release -

FDA broadens US indication for once-yearly Reclast® as only osteoporosis treatment approved for prevention of fractures after a hip fracture

- *Revised label includes data showing 35% reduction in new clinical fractures in patients treated with Reclast following recent hip fracture⁽¹⁾*
- *Few patients currently receive osteoporosis treatment following hip fracture despite high risk of morbidity and mortality⁽²⁾*
- *Safety and efficacy profile of Reclast, already approved for treatment of postmenopausal osteoporosis⁽¹⁾, reinforced in revised label*

Basel, June 5, 2008 The US Food and Drug Administration (FDA) has broadened the US indication for once-yearly Reclast® (zoledronic acid) Injection 5 mg⁽¹⁾ to include the prevention of new clinical fractures in patients who have recently had a low-trauma hip fracture⁽¹⁾.

No other osteoporosis treatment has demonstrated a reduction of new clinical fractures in patients who have recently had a low-trauma hip fracture (e.g. due to a fall from standing height or less).

The FDA decision is based on safety and efficacy data from the landmark Recurrent Fracture Trial, published in *The New England Journal of Medicine*, showing a significant 35% reduction in the risk of new clinical fractures in patients treated with Reclast⁽³⁾.

The consequences of osteoporosis can be devastating, particularly hip fractures. However, few patients actually receive treatment for the prevention of additional fractures after a hip fracture⁽²⁾, said Kenneth G. Saag, MD, MSc, Professor of Medicine and Epidemiology, Division of Clinical Immunology and Rheumatology, University of Alabama at Birmingham. In the first large-scale clinical trial of its kind, these data support an efficacious therapeutic option for patients after a hip fracture.

Osteoporosis is a condition in which the bones become weak and can break more easily⁽⁴⁾. Around 10 million people in the US are affected by osteoporosis and another 34 million are at risk from the disease, which caused an estimated 297,000 hip fractures in the US in 2005⁽⁴⁾. Of those patients who experience a hip fracture, almost a quarter of people over the age of 50 die from complications within one year⁽⁴⁾.

(1) The tradename outside the US is Aclasta®

Among those who survive a year after experiencing a hip fracture, 50% need help walking, 25% require long-term nursing care, and all remain at high risk of further fracture⁽⁵⁾. Yet few hip fracture patients are currently treated for osteoporosis⁽²⁾.

The Recurrent Fracture Trial involved more than 2,100 men and women aged 50 and older⁽³⁾ with osteoporosis who had experienced a hip fracture. Results showed that Reclast increased bone mineral density (BMD) and reduced the risk of new clinical fractures by 35% compared to patients treated with placebo⁽³⁾. The risk of new spine fractures was reduced by 46% and new non-spine fractures (e.g. hip, wrist and rib) by 27%⁽³⁾.

In the Recurrent Fracture Trial, the incidence of all-cause mortality was 9.6% in the Reclast group versus 13.3% in the placebo group⁽³⁾. This reduction in mortality is multifactorial and the groups were not randomized for risk of mortality at entry into the study⁽³⁾.

The updated US label further reinforces the safety and efficacy of Reclast, the only once-yearly treatment for postmenopausal osteoporosis approved in the US and EU (under the name Aclasta®) to reduce the risk of fractures in all key areas of the body typically affected by this disease, including the hip, spine and non-spine⁽¹⁾. Regulatory approval is also being sought for Aclasta in the European Union for the prevention of clinical fractures after a recent low-trauma hip fracture.

Unlike oral bisphosphonate therapies that are taken daily, weekly or monthly, Reclast/Aclasta is given as a once-yearly 15-minute intravenous infusion⁽¹⁾. This means with a single treatment, along with daily calcium and vitamin D supplements, a patient can receive a full year's fracture protection against the consequences of osteoporosis.

The new label reinforces the potential of Reclast/Aclasta for treating a range of osteoporosis patients, said Trevor Mundel, MD, Head of Global Development Functions at Novartis Pharma AG. These data support the clear need to treat patients after hip fracture who are at risk of the potentially devastating and life-threatening consequences of osteoporosis.

Reclast/Aclasta is already approved in more than 50 countries for the treatment of postmenopausal osteoporosis and in more than 70 countries for the treatment of Paget's disease of bone, the second most common metabolic bone disorder⁽⁶⁾.

Reclast/Aclasta has a demonstrated tolerability profile. The most common adverse events associated with Reclast/Aclasta were transient post-dose symptoms such as fever and muscle pain. Most of these symptoms occurred within the first three days following Reclast/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 Reclast/Aclasta infusion.

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

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as risk, can, potential, potentially, or similar expressions, or by express or implied discussions regarding potential future revenues from Reclast. Such forward-looking statements reflect the current views of the Company regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results with Reclast to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Reclast will achieve any particular levels of revenue in

the future. In particular, management's expectations regarding Reclast could be affected by, among other things, unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; competition in general; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; 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 growth areas in healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic pharmaceuticals, preventive vaccines and 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) Reclast® (zoledronic acid) Injection [Prescribing Information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; June 2008.
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- (3) 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.
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- (5) Edwards BJ, Perry HM III. Age-related osteoporosis. *Clin Geriatr Med*. 1994; 10:575-587.
- (6) US Department of Health and Human Services. Bone Health and Osteoporosis: A Report of the Surgeon General. 2004, p. 88.

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Novartis Media Relations

Jeffrey Lockwood

Novartis Global Media Relations

+41 61 324 7999 (direct)

+41 79 618 7748 (mobile)

jeffrey.lockwood@novartis.com

e-mail: media.relations@novartis.com

Irina Ferluga

Novartis Pharma Communications

+ 41 61 324 24 22 (direct)

+ 41 79 824 11 21 (mobile)

irina.ferluga@novartis.com

Novartis Investor Relations

Ruth Metzler-Arnold

+41 61 324 9980

Katharina Ambuehl

+41 61 324 5316

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

Central phone no:

+41 61 324 7944

Fax no:

+41 61 324 8444

e-mail: investor.relations@novartis.com

North America Office

Richard Jarvis

+1 212 830 2433

Jill Pozarek

+1 212 830 2445

Edwin Valeriano

+1 212 830 2456

Fax no:

+1 212 830 2405

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: June 5, 2008

By: /s/ MALCOLM B. CHEETHAM

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