NOVARTIS AG
Form 6-K
February 29, 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 February 28, 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

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Yes: o **No**: x

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Yes: o **No**: x

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 -

Everolimus (RAD001) significantly extends progression-free survival in advanced kidney cancer patients after failure of other targeted therapy

- *Outstanding interim results cause independent data monitoring committee to immediately share findings; patients on placebo to be offered everolimus*

- *Everolimus (RAD001) tablet, taken once daily, demonstrated highly effective anti-tumor activity through continuous targeted inhibition of mTOR*

- *Results of RECORD-1 trial address unmet medical need in renal cell cancer with worldwide regulatory filings planned for second half of 2008*

- *Complete results to be submitted as late-breaking abstract for presentation at the American Society of Clinical Oncology meeting*

Basel, February 28, 2008 An independent data monitoring committee stopped a major Phase III clinical trial of the investigational drug everolimus (RAD001) today after interim results showed significantly better progression-free survival in patients with advanced kidney cancer who received everolimus compared to placebo.

The committee stopped the trial of more than 400 patients conducted in 12 countries because the study met its primary endpoint. The interim findings are being shared with investigators to allow them to offer everolimus to patients remaining on placebo. Everolimus may fulfill an unmet medical need for patients with advanced renal cell cancer (RCC) who currently have no approved treatment options.

Everolimus is a once-daily oral therapy that offers a new approach to cancer treatment by inhibiting the mTOR protein, a central regulator of tumor cell division and blood vessel growth in cancer cells. The trial included patients who had their cancer worsen despite receiving approved treatments for RCC, such as Nexavar® (sorafenib)1 or Sutent® (sunitinib)2 or both. In addition, prior therapy with Avastin® (bevacizumab)3 and interferon was allowed.

Everolimus has the potential to greatly help patients with kidney cancer, especially in advanced stage who up to now have had no treatment options, as patients in the clinical trial on everolimus experienced a significantly longer period of time during which their cancer did not progress, said Daniel Vasella, Chairman and CEO of Novartis. Everolimus is a targeted therapy which is being studied in multiple tumor types, and could provide significant benefit to patients suffering from cancer.

This progression-free survival benefit demonstrates the possibilities of continuous mTOR inhibition as a promising target in oncology, said David Epstein, President and CEO, Novartis Oncology. These data are the first from a broad clinical research program that includes studies in patients with high unmet needs suffering from a variety of cancers. Everolimus is the first compound in our dynamic oncology late-stage pipeline with 6 compounds in registration trials to show exciting clinical data this year.

Complete results of the RECORD-1 (REnal Cell cancer treatment with Oral RAD001 given Daily) trial will be submitted as a late-breaking abstract for presentation at the American Society of Clinical Oncology annual meeting in May. Worldwide regulatory filings for this indication beginning with US and EU will occur in the second half of 2008.

RECORD-1 is the largest Phase III trial to investigate the potential of the oral mTOR inhibitor everolimus as a treatment option for patients with metastatic RCC who have failed prior targeted therapy. The randomized, double-blind multi-center Phase III study compared everolimus to placebo.

Patients in the study were randomized according to Memorial Sloan-Kettering Cancer Center (MSKCC) risk criteria and prior anti-cancer therapy. MSKCC risk criteria are standard clinical criteria to determine the prognosis of patients with RCC.

In addition to RCC, everolimus is presently being evaluated in neuroendocrine tumors, lymphoma, other cancers, and tuberous sclerosis as a single agent or in combination with existing cancer therapies.

Safety findings in the study were manageable and consistent with prior Phase II studies. Common adverse events in the study included mouth ulcers, high blood lipids, high blood sugar, skin rash, low red blood count, low phosphate levels, and inflammation of the lungs.

About Everolimus

Everolimus, an oral inhibitor of mTOR, is an investigational drug being studied in multiple tumor types. In cancer cells, everolimus inhibits mTOR, a protein that acts as a central regulator of tumor cell division, cell metabolism and blood vessel growth. Everolimus is a once-daily oral therapy that provides continuous inhibition of mTOR.

As an investigational compound, the safety and efficacy profile of everolimus has not yet been established in oncology. Access to everolimus is available only through carefully controlled and monitored clinical trials. These trials are designed to better understand the potential benefits and risks of the compound. Because of the uncertainty of clinical trials, there is no guarantee that everolimus will ever be commercially available for oncology indications anywhere in the world. Everolimus is approved under the trade-name Certican® for the prevention of organ rejection in heart and kidney transplant recipients. Certican was first approved in the EU in 2003 and is available in more than 60 countries.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as to be , planned , may , offers , potential could , possibilities , will , or similar expressions, or by express or implied discussions regarding potential future approvals for everolimus or regarding potential future revenues from everolimus. 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 everolimus to be materially different from any future results, performance or achievements expressed or implied

by such statements. There can be no guarantee that everolimus will be approved for any oncology indication. Nor can there be any guarantee that everolimus will achieve any particular levels of revenue in the future. In particular, management s expectations regarding everolimus could be affected by, among other things, unexpected clinical trial results, including unexpected new clinical data and unexpected additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; 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 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 98,200 full-time associates and operate in over 140 countries around the world. For more information, please visit http://www.novartis.com.

References

1 Nexavar is a registered trademark of Bayer.
2 Sutent is a registered trademark of Pfizer.
3 Avastin is a registered trademark of Genentech.

# # #

Novartis Media Relations

John Gilardi
Novartis Global Media Relations
+41 61 324 3018 (direct)
+41 79 596 1408 (mobile)
john.gilardi@novartis.com

Geoff Cook
Novartis Oncology Communications
+1 862 778 2675 (direct)
+1 973 652 7927 (mobile)
geoffrey.cook@novartis.com

e-mail: media.relations@novartis.com

Novartis Investor Relations

International
Ruth Metzler-Arnold
John Gilardi
Katharina Ambuehl
Pierre-Michel Bringer
Jason Hannon
Thomas Hungerbuehler
Richard Jarvis
Isabella Zinck

North America
Jill Pozarek +1 212 830 2445
Edwin Valeriano +1 212 830 2456

Central phone no: +41 61 324 7944
e-mail: investor.relations@novartis.com

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: February 28, 2008

By: /s/ MALCOLM B. CHEETHAM

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