NOVARTIS AG
Form 6-K
January 16, 2009

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 January 13, 2009

(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

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- Investor Relations Release -

Afinitor® Phase II trial results positive in patients with advanced gastric cancer after failure of one or more prior treatments

- *After eight weeks of treatment Afinitor halted tumor growth in 55% of advanced gastric cancer patients previously treated with chemotherapy*

- *Based on these promising data, Novartis will initiate a Phase III trial of Afinitor for advanced gastric cancer patients*

- *Gastric cancer is the second leading cause of cancer death worldwide, with the majority of new cases occurring in East Asia*

Basel, January 13, 2009 Data released today show Afinitor® (also known as RAD001, everolimus) halted tumor growth in 55% of patients with advanced gastric cancer, a condition for which there are limited treatment options. In addition, 45% of patients in the study demonstrated some tumor shrinkage(1).

The data will be presented at the American Society of Clinical Oncology s 2009 Gastrointestinal Cancers Symposium on January 15.

The open label, single arm, multi-center Phase II study of 54 patients conducted in Japan, is designed to assess the efficacy and safety of Afinitor in patients with advanced gastric cancer whose disease progressed despite prior treatment. Patients enrolled in the trial were heavily pre-treated. All trial participants were from Japan and of Asian descent(1).

There are very limited treatment options for patients who progressed despite the standard treatment for this aggressive cancer, said Atsushi Ohtsu, MD, PhD, Director, Research Center for Innovative Oncology, National Cancer Center Hospital East, Chiba, Japan. The results from this study demonstrate that Afinitor has the potential to provide an effective new option for

these patients.

A global Phase III clinical trial program to evaluate the efficacy and safety of Afinitor monotherapy in approximately 500 advanced gastric cancer patients will begin enrollment this year.

Most advanced gastric cancer patients eventually stop responding to current therapies, demonstrating a considerable need for new treatment options, said Alessandro Riva, MD, Executive Vice President & Global Head of Development, Novartis Oncology. Early data show Afinitor may benefit these patients and provides the rationale for additional studies. Novartis is committed to further exploring the potential of Afinitor for this hard-to-treat cancer, as well as studying its role in treating other tumor types.

Gastric cancer, commonly referred to as stomach cancer, is responsible for more than 865,000 deaths each year, making it the second leading cause of cancer death worldwide(2).

This cancer is highly prevalent among people of Asian descent, with more than half of all new cases occurring in East Asia(3). It is believed that the incidence is high among this population due in part to Helicobacter pylori infection and a diet high in smoked, salted or pickled foods(4).

Study details

The proof-of-concept, Phase II study is designed to assess the efficacy and safety of Afinitor 10 mg daily in patients with advanced gastric cancer (inoperable, recurrent or metastatic gastric cancer) whose disease progressed despite prior treatment. The primary endpoint of the study is to assess disease control rate (DCR). Secondary endpoints included assessment of objective response rate (ORR), progression-free survival (PFS) and overall survival (OS), and to describe the safety profile of Afinitor.

The average duration of therapy was 57 days. There was a DCR (complete response/partial response/stable disease) of 55% at eight weeks (95% Confidence Interval: 40.4 - 68.4%). Of the 53 patients evaluated for the study s primary endpoint, 29 patients (55%) had stable disease, 22 (41%) had progressive disease and 2 (4%) had an unknown response. The ORR was zero. The median PFS was 83 days (95% Confidence Interval: 50 91 days), with 29.6% of patients estimated to still be progression-free at four months. Median overall survival was not attained at the time of evaluation.

The most commonly reported adverse events (all grades; >10% patients) in the study included stomatitis, anorexia, fatigue, rash, nausea, edema peripheral, thrombocytopenia, diarrhea, pruritus, anemia, dysgeusia, vomiting, pyrexia, pneumonitis, constipation and insomnia. Serious adverse events (grade 3 or 4; >3% of patients) included anemia, hyponatremia, raised liver function, fatigue, stomatitis, anorexia, hyperglycemia, hypophosphatemia, ileus and lymphopenia.

About Afinitor

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

Afinitor is being studied in multiple cancer types including advanced kidney, breast and neuroendocrine tumors and lymphoma. Currently, Afinitor is under regulatory review in the US and Europe for the treatment of advanced renal cell carcinoma.

The safety and efficacy profile of Afinitor has not yet been established in oncology and there is no guarantee that Afinitor will become commercially available for oncology indications. The active ingredient in Afinitor is everolimus, which is available in different dosage strengths 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.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as promising, will, potential, may, committed, exploring, believed, estimated, anticipated, or similar expressions, or by express or implied discussions regarding potential regulatory filings or marketing approvals for Afinitor or regarding potential future revenues from Afinitor. 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 Afinitor to be

materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Afinitor will be approved for sale for any oncology indication in any market. Nor can there be any guarantee that Afinitor will achieve any particular levels of revenue in the future. In particular, management s expectations regarding Afinitor 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; 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 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 97,000 full-time associates and operate in over 140 countries around the world. For more information, please visit http://www.novartis.com.

References

(1) Ohtsu, A et al. Multicenter phase II study of RAD001 for previously treated metastatic gastric cancer. Presented at the American Society of Clinical Oncology s 2009 Gastrointestinal Cancers Symposium, January 15, 2008.

(2) World Health Organization. Cancer. http://www.who.int/mediacentre/factsheets/fs297/en/. Accessed on December 23, 2008.

(3) Ohtsu, A. Chemotherapy for metastatic gastric cancer: past, present, and future. J Gastroenterol 2008; 43:256 264.

(4) American Cancer Society. Overview: Stomach Cancer. Available at: http://www.cancer.org/docroot/CRI/content/CRI_2_2_2X_What_causes_stomach_cancer_40.asp?sitearea=. Accessed on December 23, 2008.

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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: January 13, 2009

By: /s/ MALCOLM B. CHEETHAM

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