NOVARTIS AG
Form 6-K
June 30, 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 June 24, 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

Novartis International AG

Novartis Global Communications

CH-4002 Basel

Switzerland

http://www.novartis.com

- Investor Relations Release -

Afinitor® and Sandostatin® LAR® Phase II data show advanced pancreatic NET patients remain progression-free for nearly 17 months

- *84% of patients with advanced pancreatic neuroendocrine tumors (NET) who took Afinitor® combined with Sandostatin® LAR® experienced tumor shrinkage*

- *Patients with this rare and aggressive form of cancer have limited treatment options following chemotherapy*

- *Phase III trial of Afinitor in advanced pancreatic NET underway to validate findings in this trial*

Basel, June 24, 2009 New data demonstrate that treatment with Afinitor® (everolimus) Tablets in combination with Sandostatin® LAR® (octreotide acetate suspension for injection) and Afinitor monotherapy may have the potential to control tumor growth in patients with advanced pancreatic neuroendocrine tumors (NET). These results will be presented at the 11th World Congress on Gastrointestinal Cancer in Barcelona, Spain.

RADIANT-1 (RAD001 In Advanced Neuroendocrine Tumors) is a Phase II study of 160 patients with pancreatic NET resistant to treatment with cytotoxic chemotherapy. The final analysis shows that patients who received Afinitor in combination with Sandostatin LAR, an approved treatment for symptom control in certain types of NET, remained progression-free for a median of 16.7 months, nearly four additional months since the first analysis was reported*(1),(2). In addition, 84% of patients receiving combination therapy experienced a decrease in tumor size. Patients who took Afinitor monotherapy remained progression-free for 9.7 months and nearly 60% of patients experienced a decrease in tumor size(1).

Pancreatic NET is an uncommon form of NET, a cancer formed from cells that have roles both in the endocrine and nervous systems. At time of diagnosis, nearly 60% of all patients have advanced disease, meaning the cancer has spread to other parts of the body and has become more difficult to treat. For those living with advanced pancreatic NET the median survival rate is 17 months(3).

These final results from the RADIANT-1 trial demonstrate the potential of Afinitor to stabilize tumor growth for a prolonged period of time when used in combination with Sandostatin LAR or as monotherapy, said James Yao, MD, Associate Professor of Medicine at The University of Texas M.D. Anderson Cancer Center. With limited options available to treat advanced pancreatic neuroendocrine tumors, these promising data suggest Afinitor may provide benefit in patients who experienced disease progression after chemotherapy.

Furthermore, the results of RADIANT-1 were evaluated to explore biomarkers that may help identify the patients most likely to benefit from treatment with Afinitor. An analysis of the study data showed that patients who demonstrated an early response on chromogranin A (CgA) and

neuron-specific enolase (NSE) levels experienced longer time without disease progression compared to patients who did not have an early response on CgA and NSE levels. Further evaluation is ongoing in Phase III trials to determine the potential value of these biomarkers for determining optimal treatment options for patients with NET(1).

For the past 20 years, Novartis has been committed to helping people with neuroendocrine tumors, said Alessandro Riva, MD, Executive Vice President, Global Head, Novartis Oncology Development. We hope that the biomarkers being studied in this trial will provide valuable insights into which patients are most likely to benefit from Afinitor, furthering our aim of providing the right drug for the right patients.

RADIANT-3, a Phase III trial to further investigate Afinitor as a potential treatment option for patients with pancreatic NET, has completed enrollment and is underway. The study will evaluate the potential of Afinitor plus best supportive care to extend progression-free survival (PFS) and reach overall survival (OS), as well as to examine the biomarker CgA as a secondary objective.

RADIANT-1 study details

RADIANT-1 is a Phase II international, multicenter, open-label, stratified study of everolimus in patients with advanced pancreatic NET who became resistant to prior treatment with cytotoxic chemotherapy. Patients enrolled in the study were divided into one of two treatment groups based on prior therapy with Sandostatin LAR. In the monotherapy treatment group, 115 patients who had not taken Sandostatin LAR received daily everolimus. In the combination treatment group, 45 patients who had taken Sandostatin LAR for at least three consecutive months at study entry continued with the addition of daily everolimus. Prior to the start of the study, patients in the combination treatment group were required to have experienced disease progression while taking Sandostatin LAR. The study was not designed to compare the two treatment groups(1).

The primary endpoint of RADIANT-1 is objective response rate (ORR) in the monotherapy group. The secondary endpoints include ORR in the combination treatment group, as well as PFS, duration of response, OS, safety and pharmacokinetics in both groups. Exploratory objectives of this trial include evaluation of biomarkers(1).

Monotherapy treatment group results

For those in the monotherapy treatment group, clinical benefit rate (ORR plus stable disease) was seen in 77% of patients. The ORR, based on central radiology review, was 9.6% (11/115; 95% confidence interval [CI], 4.9-16.5). Stable disease (SD) was noted in an additional 78 patients (67.8%) and 16 patients (13.9%) had disease progression as best overall response. Further, the median PFS in the monotherapy arm was 9.7 months (95% CI, 8.3-13.3) and median OS was reached at 24.9 months (95% CI, 20.2-27.1)(1).

The most common adverse events in patients who received everolimus monotherapy were stomatitis (45%), rash (40%), diarrhea (39%), fatigue (31%), nausea (30%), headache (22%), aphthous stomatitis (17%), vomiting (17%), asthenia (15%), edema peripheral (15%), weight decrease (15%), anemia (13%), anorexia (13%), hyperglycemia (13%) and pruritis (12%)(1).

Combination treatment group results

In the study, clinical benefit rate was seen in 84.4% of patients. The ORR, based on central radiology review, was 4.4% (2/45; 95% CI, 0.5-15.1) and SD was noted in an additional 36 patients (80%). Further, the median PFS in the combination treatment group was 16.7 months (95% CI, 11.1-NA). At time of analysis, median OS had not been reached. However, the 24-month survival rate was 54.7% (95% CI, 21.7-87.8)(1).

The most common adverse events in patients taking everolimus in combination with Sandostatin LAR were stomatitis (49%), rash (44%), diarrhea (31%), fatigue (36%), nausea (33%), aphthous stomatitis (13%), vomiting (13%), asthenia (11%), edema peripheral (13%), weight decrease

(16%), anemia (16%), anorexia (16%), hyperglycemia (13%), dysgeusia (13%), dry skin (13%), thrombocytopenia (13%), neutropenia (13%) and dyspnea (11%)(1).

About neuroendocrine tumors

There are many different types of NET, which can occur throughout the body(4). However, most are found in the digestive system and are collectively called gastroenteropancreatic neuroendocrine tumors (GEP-NET)(5),(6). Pancreatic NET, also known as pancreatic endocrine tumors or islet cell carcinomas, is a type of GEP-NET that accounts for nearly 8% of all GEP-NET(3),(4).

About Afinitor

Afinitor has been approved by the US Food and Drug Administration (FDA) as the first oral, daily therapy (5 mg and 10 mg tablets) to treat advanced kidney cancer after failure of treatment with sunitinib or sorafenib. Recently, the Committee for Medicinal Products for Human Use (CHMP) issued a positive opinion supporting EU approval of Afinitor to treat patients with advanced renal cell carcinoma whose disease has progressed on or after treatment with vascular endothelial growth factor (VEGF)-targeted therapy.

In cancer cells, Afinitor continuously targets mTOR, a protein that acts as a central regulator of tumor cell division, blood vessel growth and cell metabolism. Novartis has also filed regulatory submissions with other regulatory agencies globally for the treatment of advanced kidney cancer. Afinitor is being studied in multiple cancer types, including NET, renal cell carcinoma (RCC), breast, gastric and hepatocellular carcinoma (HCC), as well as tuberous sclerosis complex (TSC) and non-Hodgkin s lymphoma (NHL).

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.

Afinitor important safety information

Afinitor is contraindicated in patients with hypersensitivity to everolimus, to other rapamycin derivatives or to any of the excipients. Potentially serious adverse reactions include non-infectious pneumonitis and infections for which patients should be monitored carefully and treated as needed. In addition, non-infectious pneumonitis may require temporary dose reduction and/or interruption or discontinuation. Patients with systemic invasive fungal infections should not receive Afinitor. Oral ulceration is a common side effect with Afinitor. Renal function, blood glucose, lipids and hematological parameters should be evaluated prior to the start of therapy with Afinitor and periodically thereafter. Strong or moderate CYP3A4 or P-glycoprotein inhibitors should be avoided. An increase in the dose of Afinitor is recommended when co-administered with a strong CYP3A4 inducer. Live vaccinations and close contact with those who have received live vaccines should be avoided by patients taking Afinitor. Afinitor should not be used in patients with severe hepatic impairment. Afinitor may cause fetal harm in pregnant women.

The most common adverse reactions irrespective of causality (incidence $\geq$ 30%) were stomatitis, infections, asthenia, fatigue, cough and diarrhea. The most common grade 3/4 adverse reactions irrespective of causality (incidence $\geq$ 3%) were infections, dyspnea, fatigue, stomatitis, dehydration, pneumonitis, abdominal pain and asthenia. The most common laboratory abnormalities (incidence $\geq$ 50%) were anemia, hypercholesterolemia, hypertriglyceridemia, hyperglycemia, lymphopenia and increased creatinine. The most common grade 3/4 laboratory abnormalities (incidence $\geq$ 3%) were lymphopenia, hyperglycemia, anemia, hypophosphatemia and hypercholesterolemia. Deaths due to acute respiratory failure (0.7%), infection (0.7%) and acute renal failure (0.4%) were observed in patients receiving Afinitor.

About Sandostatin LAR

Sandostatin LAR is a long-acting, injectable depot formulation of octreotide acetate that is indicated for the treatment of acromegaly; for patients in whom surgery or radiotherapy is

inappropriate or ineffective; for patients until radiotherapy becomes fully effective; and, for the relief of symptoms associated with functional GEP-NET. Octreotide has been used to treat the clinical syndromes associated with NET and substantially reduces, and in many cases can control, growth hormone and/or normalize IGF-1 levels in patients with acromegaly, a disease caused by a GH-secreting pituitary adenoma.

Sandostatin LAR was first approved in France in June 1995 and is currently approved in 85 countries. For more than a decade, Sandostatin LAR has achieved a long-standing track record of sustained efficacy with a well-established safety profile.

Not all indications are approved in every country.

Sandostatin LAR important safety information

Patients who have a known hypersensitivity to octreotide or to any of the excipients should not take Sandostatin LAR. Dose adjustments of drugs, such as beta-blockers, calcium channel blockers or agents to control fluid and electrolyte balance may be necessary. Caution should be used in patients with insulinomas; patients with diabetes mellitus thyroid function should be monitored if receiving prolonged treatment with octreotide. Patients receiving Sandostatin LAR should receive periodic examination of the gallbladder; and patients who have a history of vitamin B12 deprivation should have their vitamin B12 levels monitored. Caution should be used in patients with pregnancy; patients should be advised to use adequate contraception, if necessary. Patients should not breast feed during Sandostatin LAR treatment. The use of Sandostatin LAR may increase the bioavailability of bromocriptine, impair intestinal absorption of cyclosporin and delay that of cimetidine. Drugs mainly metabolized by CYP3A4 and that have a low therapeutic index should be used with caution.

The most common ($\geq$ 1/10) adverse drug reactions in clinical studies with Sandostatin LAR were diarrhea, abdominal pain, nausea, constipation, flatulence, headache, cholelithiasis, hyperglycemia and injection-site localized pain. Common ($\geq$ 1/100, < 1/10) adverse drug reactions were dyspepsia, vomiting, abdominal bloating, steatorrhea, loose stools, discoloration of feces, dizziness, hypothyroidism, thyroid dysfunction (e.g., decreased thyroid stimulating hormone, decreased Total T4 and decreased Free T4), cholecystitis, biliary sludge, hyperbilirubinemia, hypoglycemia, impairment of glucose tolerance, anorexia, elevated transaminase levels, pruritus, rash, alopecia, dyspnea and bradycardia.

The uncommon ($\geq$ 1/1000, <1/100) adverse drug reactions were dehydration and tachycardia. The following adverse reactions have been reported postmarketing: anaphylaxis, allergy/hypersensitivity reactions, urticaria, acute pancreatitis, acute hepatitis without cholestasis, cholestatic hepatitis, cholestasis, jaundice, cholestatic jaundice, arrhythmia, increased alkaline phosphatase levels and increased gamma glutamyl transferase levels.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as may, potential, to explore, further evaluation is ongoing, committed, will, or similar expressions, or by express or implied discussions regarding potential future regulatory filings or marketing approvals for Afinitor, potential new indications or labeling for Sandostatin LAR or regarding potential future revenues from Afinitor and/or Sandostatin LAR. 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 and/or Sandostatin LAR 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 in any additional market, or for any additional indication or labeling. Nor can there be any guarantee that Sandostatin LAR will be approved for any additional indications or labeling in any market. Neither can there be any guarantee that Afinitor or Sandostatin LAR will achieve any particular

5

levels of revenue in the future. In particular, management s expectations regarding Afinitor and Sandostatin LAR 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; 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) Yao, et al. Daily Oral Everolimus Activity in Patients with Metastatic Pancreatic Neuroendocrine Tumors After Failure of Cytotoxic Chemotherapy: A Phase II Trial. 11th World Congress on Gastrointestinal Cancer, Barcelona, Spain.

(2) Yao, et al. A Phase II Trial of Daily Oral RAD001 (Everolimus) in Patients With Metastatic Pancreatic Neuroendocrine Tumors (NET) After Failure of Cytotoxic Chemotherapy. 33rd European Society for Medical Oncology Congress, Stockholm, Sweden.

(3) Halfdanarson, et al. Pancreatic neuroendocrine tumors (PNETs): incidence, prognosis and recent trend toward improved survival. Annals of Onc 19: 1727-1733, 2008.

(4) Yao, J. One Hundred Years After Carcinoid: Epidemiology of and Prognostic Factors for Neuroendocrine Tumors in 35,825 Cases in the United States. Journal of Clinical Oncology. June 20 2009; vol. 26, number 18.

(5) American Cancer Society. What are the Key Statistics about Gastrointestinal Carcinoid Tumors? Available at: http://www.cancer.org/docroot/CRI/content/CRI_2_4_1X_What_are_the_key_statistics_for_gastrointestinal_carcinoid_tumors_14.asp?rnav=cri. Accessed May 2009.

(6) Gunter K, Perren A, Heitz PU The Gastroenteropancreatic Neuroendocrine Cell System and Its Tumors: The WHO Classification. Ann. of the New York Acad of Sci. 2006 Jan 16 2005;1014:13-27

**Presented in part at the 33rd European Society for Medical Oncology Congress in 2008 and ASCO 2009 Gastrointestinal Cancers Symposium*

# # #

Novartis Media Relations

Central media line : +41 61 324 2200
Eric Althoff
Novartis Global Media Relations
+41 61 324 7999 (direct)
+41 79 593 4202 (mobile)
eric.althoff@novartis.com

Denise Brashear
Novartis Oncology
+1 862 778 7336 (direct)
denise.brashear@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: June 24, 2009

By: /s/ MALCOLM B. CHEETHAM

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