

NOVARTIS AG  
Form 6-K  
May 29, 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 May 28, 2009**

**(Commission File No. 1-15024)**

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(Name of Registrant)

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**Switzerland**

(Address of Principal Executive Offices)

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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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**- Investor Relations Release -**

**Data on more than 15 Novartis Oncology compounds at ASCO highlight progress toward targeted therapies for diverse tumor types**

- *Oral presentation on Sandostatin® LAR® Phase III data shows significant antitumor benefit in patients with advanced neuroendocrine tumors of the midgut*
- *Early data show that at eight weeks of treatment, Afinitor® stabilized or reduced tumor size in 61% of patients with advanced liver cancer*
- *New data reveal postmenopausal women with breast cancer taking Femara® experience better cognitive function than those taking tamoxifen*
- *Phase II data show potential of Glivec® in treating patients with advanced KIT-mutated melanoma; other Novartis data on advanced melanoma also presented*

**Basel, May 28, 2009** Novartis announced today that data on more than 15 compounds in its robust oncology portfolio will be included at the 2009 American Society of Clinical Oncology (ASCO) annual meeting. These studies provide new research on multiple tumor types and rare cancers.

Our strong presence at ASCO showcases our continued progress in developing innovative therapies for patients with cancer through our comprehensive discovery and development program, said David Epstein, President and CEO, Novartis Oncology, Novartis Molecular Diagnostics. We look forward to continuing to explore novel ways to help patients in need of new treatments.

**Sandostatin LAR in metastatic neuroendocrine midgut tumors**

Data from the PROMID study (abstract #4508) show Sandostatin® LAR® (octreotide acetate for injectable suspension) demonstrated a significant antitumor effect in patients with metastatic neuroendocrine tumors (NET) of the midgut(1).

Sandostatin LAR, when compared to placebo, more than doubled time without tumor growth (15.6 months vs. 5.9 months) and reduced the risk of disease progression by 67% (hazard ratio=0.33 with 95% confidence interval 0.19 to 0.55; P=0.000017)(1).

This important benefit was seen in patients with functioning tumors (i.e., tumors that are associated with carcinoid syndrome due to the secretion of various hormones that cause symptoms, such as diarrhea or flushing) and non-functioning (non-secreting) tumors. In an analysis of patients with non-functioning tumors, which affect the majority of people with NET, time to tumor progression for patients receiving Sandostatin LAR was 27.14 months versus 7.21 months for those on placebo (P=0.0008)(1).

Further, a statistically significant benefit was observed in patients with tumor load  $\leq 10\%$ , which suggests a potentially important role for treatment in the early stages of the disease. The median

time to tumor progression was 27.1 months in the patients receiving Sandostatin LAR versus 7.2 months in the placebo group ( $P < 0.0001$ )(1).

The trial, called PROMID (Placebo-controlled prospective Randomized study on the antiproliferative efficacy of Octreotide LAR in patients with metastatic neuroendocrine MIDgut tumors), is a Phase IIIb study conducted at 18 sites in Germany to evaluate the antitumor effect of Sandostatin LAR in patients with midgut NET. The study included 85 patients who were treated with either Sandostatin LAR (30 mg/month) or placebo for 18 months, or until tumor progression or death. All patients in the study were treatment-naïve, had locally inoperable or metastatic NET with the primary tumor located in the midgut, were without curative therapeutic options and had tumors that were either functioning or non-functioning. Interim results from PROMID were presented at the 2009 ASCO Gastrointestinal Cancer Symposium(1).

Neuroendocrine tumors originate from cells that have roles both in the endocrine and nervous systems. While these NET are often slow-growing, when the tumor is inoperable patients with advanced NET have limited treatment options(2).

The safety findings observed in the PROMID study were consistent with those seen in previous studies of Sandostatin LAR in patients with NET. The most frequently observed serious adverse events affected the gastrointestinal tract, hematopoietic system and other general symptoms such as fatigue and fever(1).

#### **Afinitor in patients with advanced liver cancer**

Phase I data (abstract #4587) demonstrated that 61% of patients with advanced hepatocellular carcinoma (HCC) who received daily treatment with Afinitor® (everolimus) Tablets had tumors that stabilized or reduced in size(1).

There are currently a limited number of treatment options for patients with advanced HCC, the stage when most are diagnosed(4),(5). Everolimus shows potential to help address this unmet medical need(1).

The trial, conducted in Taiwan by Dr Li-Tzong Chen from the National Health Research Institute, included 36 advanced HCC patients who progressed after various systemic therapies or who were no longer candidates for local therapies, including surgery, percutaneous ablation or transcatheter arterial chemoembolization. Of the 31 patients evaluable in the trial, 16 received everolimus (known as RAD001 in this study) daily. The study objective was to define the maximum tolerated dose and pharmacokinetics of everolimus(1).

The Grade 3 and 4 adverse events reported in the study included elevated bilirubin, drop in platelets count, diarrhea, bleeding, cardiac ischemia, elevated liver function tests and infection. Reactivation of Hepatitis B virus was observed in four patients as well as reactivation of Hepatitis C virus in one patient(1).

Based on these data, a global Phase III clinical trial to study the daily everolimus regimen in patients with advanced HCC is in development by Novartis.

**Femara BIG 1-98 data on cognitive function**

Impaired cognition is a concern among breast cancer patients taking hormonal therapies. Estrogen is believed to have a direct influence on cognitive function. Aromatase inhibitors reduce the level of circulating estrogen in the body. It has been suggested that reduced estrogen in the body is linked to a decline in cognitive function(6).

A new substudy (abstract #510) conducted within a subgroup of patients enrolled in the independent Breast International Group (BIG) 1-98 study (Femara® [letrozole] vs. tamoxifen) found that postmenopausal women with hormone receptor-positive early breast cancer taking

adjuvant Femara had better overall cognitive function than those taking tamoxifen, based on validated scales of cognitive function collected at the fifth year of endocrine treatment(6).

Results from this study revealed that the group of patients receiving Femara had clinically and significantly better overall cognitive function than the patients in the tamoxifen group (difference in mean composite scores =0.23, P=0.04, 95% CI: 0.02-0.54). Overall, both groups performed below age norms on most domains(6).

### Highlights in melanoma

New data highlight the potential of two Novartis products as treatments for advanced melanoma, the most serious form of skin cancer. Melanoma accounts for 41,000 deaths worldwide each year(7),(8). While melanoma is curable when diagnosed and treated in early stages, advanced melanoma is often resistant to currently available treatments(9).

New data from a Phase II study (abstract #9001) show the potential of Glivec®# (imatinib) in treating patients with advanced melanoma harboring KIT mutations. A mutation in the protein called KIT, located on the surface of normal cells, signals cells to continually grow and divide. Similar KIT mutations in GIST were shown to be treated effectively by Glivec. The preliminary data from the investigator-driven study show that five out of five patients evaluable for responses showed either partial responses to Glivec (3 out of 5) or stable disease (2 out of 5). Responses in two of the three patients are ongoing past 18 weeks. These favorable results have allowed the study to continue to a second expanded stage of enrollment(10).

Other data on advanced melanoma include preliminary results from a Phase II trial (abstract #9027) that show 72% of patients (20 out of 28) with advanced melanoma treated with everolimus in combination with bevacizumab experienced a clinical benefit (4% had a partial response and 68% had stable disease). The combination of everolimus and bevacizumab was generally well tolerated. According to the abstract, one patient withdrew from the trial due to interstitial pneumonitis, which was reversible, and one patient had a fatal heart attack, possibly bevacizumab-related. Grade 3 mucositis occurred in 13% of patients and all other grade 3 toxicities occurred in <10% of patients(11).

### Early stage development data

- *Abstract #8542*: Panobinostat + lenalidomide and dexamethasone Phase I trial in multiple myeloma (MM)
- In this first Phase I clinical trial assessing the combination of panobinostat (LBH589) in combination with lenalidomide and dexamethasone, the 5 mg and 10 mg doses of panobinostat were safe when administered to patients with multiple myeloma(12).
- *Abstract #3563*: TKI258 (dovitinib lactate) in metastatic renal cell carcinoma (mRCC) patients refractory to approved targeted therapies: a Phase I/II dose finding and biomarker study
- This study of heavily pre-treated metastatic renal cell carcinoma patients demonstrated that TKI258 500 mg/day may be an appropriate dosing schedule and showed clinical benefit in this patient population(13).

- *Abstract #3533*: Pharmacodynamics and pharmacokinetics of AUY922 in a Phase I study of solid tumor patients
- These data support the use of HSP70 as a biomarker for HSP90 inhibition. Inhibition of HSP90, a key target that regulates tumor cell survival and division, through the use of AUY922, resulted in an up regulation/increase of HSP70. The change in HSP70 observed at the highest dose of AUY922 exceeded the level needed to inhibit tumor growth in a mouse model for breast cancer(14).

**About the Novartis Oncology pipeline**

The Novartis Oncology pipeline features 18 new molecular entities. These compounds are being studied in more than 40 different cancer types in approximately 15,000 patients. The pipeline portfolio encompasses a broad array of therapeutic strategies for fighting cancer, including novel



targeted agents, monoclonal antibodies, deacetylase (DAC) inhibitors, multiligand somatostatin analogs and novel cytotoxics.

### **Sandostatin LAR important safety information**

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.

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 ( $\geq 1/1000, \leq 1/100$ ) 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.

### **Afinitor important safety information**

Afinitor is approved in the US as the first oral, daily therapy (5 mg and 10 mg tablets) to treat patients with advanced renal cell carcinoma after failure of treatment with sunitinib or sorafenib. 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.

#### **Femara important safety information**

Femara should not be taken by women who have previously had any unusual or allergic reactions to letrozole or any of its ingredients. Femara should not be taken by women who are pregnant or breastfeeding. Only women who are of postmenopausal endocrine status should take Femara. Patients with severe liver impairment should be monitored closely. The use of Femara in patients with significantly impaired kidney function warrants careful consideration.

The most common side effects of Femara are hot flushes, fatigue, joint pain and nausea. Other common side effects are anorexia, appetite increase, peripheral edema, headache, dizziness, vomiting, dyspepsia, constipation, diarrhea, hair loss, increased sweating, rash, muscle pain, bone pain, arthritis, osteoporosis, bone fractures, weight increase, hypercholesterolemia and depression. Other rare, but potentially serious adverse events include leukopenia, cataract, cerebrovascular accident or infarction, thrombophlebitis, pulmonary embolism, arterial thrombosis and ischemic cardiovascular disease.

#### **Glivec important safety information**

The majority of patients treated with Glivec in clinical trials experienced adverse events at some time. Most events were of mild to moderate grade and treatment discontinuation was not necessary in the majority of cases.

The safety profile of Glivec was similar in all indications. The most common side effects included nausea, superficial edema, muscle cramps, skin rash, vomiting, diarrhea, abdominal pain, myalgia, arthralgia, hemorrhage, fatigue, headache, joint pain, cough, dizziness, dyspepsia and dyspnea, dermatitis, eczema and fluid retention, as well as neutropenia, thrombocytopenia and anemia. Glivec was generally well tolerated in all of the studies that were performed, either as monotherapy or in combination with chemotherapy, with the exception of a transient liver toxicity in the form of transaminase elevation and hyperbilirubinemia observed when Glivec was combined with high dose chemotherapy.

Rare/serious adverse reactions include: sepsis, pneumonia, depression, convulsions, cardiac failure, thrombosis/embolism, ileus, pancreatitis, hepatic failure, exfoliative dermatitis, angioedema, Stevens-Johnson syndrome, renal failure, fluid retention, edema (including brain, eye, pericardium, abdomen and lung), hemorrhage (including brain, eye, kidney and gastrointestinal tract), diverticulitis, gastrointestinal perforation, tumor hemorrhage/necrosis and hip osteonecrosis/avascular necrosis.

Patients with cardiac disease or risk factors for cardiac failure should be monitored carefully and any patient with signs or symptoms consistent with cardiac failure should be evaluated and treated. Cardiac screening should be considered in patients with HES/CEL and patients with MDS/MPD with high level of eosinophils (echocardiogram, serum troponin level).

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Glivec is contraindicated in patients with known hypersensitivity to imatinib or any of its excipients. Women of childbearing potential should be advised to avoid becoming pregnant while taking Glivec.

## Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as progress toward, potential, will, look forward to, risk, suggests, potentially, in development, may, pipeline, being studied, strategies, or similar expressions, or by expressions of discussions regarding potential future marketing approvals for compounds in development, potential new indications or labeling for existing products, or regarding potential future revenues from such compounds or products. 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 to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that any such development compounds will be approved for sale in any market. Nor can there be any guarantee that any of the existing products referred to in this release will be approved for any additional indications or labeling in any market. Neither can there be any guarantee that any of these compounds or products will achieve any particular levels of revenue in the future. In particular, management's expectations regarding compounds and products 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>.

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\* Updated data from these abstracts may be presented at the ASCO annual meeting

# Known as Gleevec® (imatinib mesylate) tablets in the US, Canada and Israel

**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: May 28, 2009

By: /s/ MALCOLM B. CHEETHAM

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