

NOVARTIS AG  
Form 6-K  
June 02, 2010

## 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 2nd, 2010

(Commission File No. 1-15024)

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**Novartis AG**

(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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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):

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Yes:  No:

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:

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**- Investor Relations Release -**

**Data at ASCO show promise of Novartis drugs for patients with life-threatening diseases like CML, multiple myeloma and breast cancer**

- *Eighteen-month results for Tasigna® in first-line treatment for patients with newly diagnosed chronic myeloid leukemia*
- *Two separate Phase III studies with Zometa® in multiple myeloma and adjuvant breast cancer*
- *Phase II data with Afinitor® in SEGA brain tumors associated with tuberous sclerosis in children and adults*
- *Pipeline data, including panobinostat (LBH589), PI3K Inhibitors BEZ235 and BKM120, and LDE225, underscore strength of the Novartis Oncology pipeline*

**Basel, June 2, 2010** Novartis today announced that nearly 170 abstracts highlighting investigational uses of current therapies and investigational agents in the Novartis Oncology portfolio will be presented at the 46th Annual Meeting of the American Society of Clinical Oncology (ASCO) from June 4 through June 8 in Chicago, IL(1). These data include results with Tasigna® (nilotinib), Zometa® (zoledronic acid), Afinitor® (everolimus) tablets, panobinostat (LBH589) and targeted pipeline therapies that underscore the Company's dedication to improving treatment for cancer patients around the world by developing therapies based on the molecular pathways of various cancers and tumor types.

Our scientific presence at ASCO speaks to our commitment to improve cancer treatment by discovering, developing and making available individualized therapies for diseases where there is unmet medical need, said Herve Hoppenot, President, Novartis Oncology. Through our robust discovery and development program, we will continue to be a leader in the oncology community, working to bring forth significant treatment advances that strive to improve the lives of patients suffering from cancer.

Notable data with Novartis treatments include the following oral presentations.

- *Abstract #6501: 18-month (median follow-up) study results with Tasigna in adult patients with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase(2).*

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- *Abstract #8021:* Results from a large, Phase III study evaluating the addition of Zometa to chemotherapy versus oral clodronate plus chemotherapy in patients with newly diagnosed multiple myeloma(3).
  - *Abstract #2004:* Findings on everolimus in patients with subependymal giant cell astrocytomas (SEGAs) associated with tuberous sclerosis (TS), a genetic disorder which causes tumors to form in many vital organs, including the brain(4),(5). There are currently no FDA-approved treatments, although invasive brain surgery can be used to remove tumors(4).
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- Two oral presentations will highlight panobinostat (LBH589) in Hodgkin lymphoma and multiple myeloma. Interim results from a Phase II study (*abstract #8007*) of panobinostat in heavily pre-treated patients with relapsed/refractory Hodgkin lymphoma and updated data from a Phase Ib study (*abstract #8001*) of oral panobinostat in combination with bortezomib in patients with relapsed or relapsed and refractory multiple myeloma will be presented(6),(7). Also, Novartis will present PANORAMA-2, a new Phase II study (*abstract #TPS308*) on panobinostat in bortezomib-refractory multiple myeloma patients(8).

Data from the Novartis Oncology pipeline include innovative, targeted therapies in various solid tumor types.

- *Abstract #3005*: Results from the first-in-human Phase I study of the oral PI3K inhibitor BEZ235 in patients with advanced solid tumors(9).
- *Abstract #3003*: Phase I dose-escalation study of BKM120, an oral pan-class I PI3K inhibitor, in advanced solid tumors(10).
- *Abstract #2500*: Phase I dose-escalation study of LDE225, a smoothed antagonist, in solid tumors(11).

Other key studies being presented at ASCO underscore Novartis Oncology's commitment to exploring the potential of currently approved products in areas of unmet patient need, including(1):

- *Abstract #6515*: 24-month update of the GIMEMA Phase II trial will reveal the efficacy and safety results of Tasigna 800 mg daily in early chronic phase Ph+ CML(12).
- *Abstract #533*: Data from a five-year update of the ABCSG-12 study evaluating the addition of Zometa to hormonal therapy following surgery on disease-free survival in premenopausal women with ER-positive early breast cancer(13).
- *Abstract #1013*: Interim results from a Phase II trial that evaluated progression-free survival data when everolimus is added to paclitaxel and trastuzumab in patients with human epidermal growth factor receptor 2 positive (HER2+) metastatic breast cancer with prior resistance to trastuzumab and taxanes(14). Based on earlier results of these data, a Phase III trial BOLERO-1 is currently underway to evaluate the potential of everolimus in women with HER2+ breast cancer.

### **About Tasigna**

Tasigna has been approved in more than 80 countries for the treatment of chronic phase and accelerated phase Ph+ CML in adult patients resistant or intolerant to at least one prior therapy, including Glivec. The effectiveness of Tasigna for this indication is based on confirmed hematologic and unconfirmed cytogenetic response rates. There are no controlled trials demonstrating a clinical benefit, such as improvement in disease-related symptoms or increased survival.

Tasigna is not approved for the treatment of newly diagnosed Ph+ CML-CP.

### **Tasigna important safety information**

Because taking Tasigna with food may increase the amount of drug in the blood, Tasigna should not be taken with food and patients should wait at least two hours after a meal before taking Tasigna. In addition, no food should be consumed for at least one hour after the dose is taken.

The most frequent Grade 3 or 4 adverse events for Tasigna were primarily hematological in nature and included neutropenia and thrombocytopenia. Elevations seen in bilirubin, liver function tests, lipase enzymes and blood sugar, were mostly transient and resolved over time. These cases were easily managed and rarely led to discontinuation of treatment. Pancreatitis was reported in less than 1% of cases. The most frequent non-hematologic drug-related adverse events were rash, pruritus, nausea, fatigue, headache, constipation and diarrhea. Most of these adverse events were mild to moderate in severity.

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Tasigna should be used with caution in patients with uncontrolled or significant cardiac disease (e.g., recent heart attack, congestive heart failure, unstable angina or clinically significant bradycardia), as well as in patients who have or may develop prolongation of QTc. These include patients with abnormally low potassium or magnesium levels, patients with congenital long QT syndrome, patients taking anti-arrhythmic medicines or other drugs that may lead to QT prolongation. Low levels of potassium or magnesium must be corrected prior to Tasigna administration. Close monitoring for an effect on the QTc interval is advisable and a baseline echocardiogram is recommended prior to initiating therapy with Tasigna and as clinically indicated.

### **About Glivec**

Glivec is approved in more than 90 countries, including the US, EU and Japan, for the treatment of all phases of Ph+ CML. Glivec is also approved in the US, EU and other countries for the treatment of patients with Kit (CD117)-positive gastrointestinal tumors (GIST), which cannot be surgically removed and/or have already spread to other parts of the body (metastasized). In the US and EU, Glivec is now approved for the post-surgery treatment of adult patients following complete surgical removal of Kit (CD117)-positive gastrointestinal stromal tumors. In the EU, Glivec is also approved for the treatment of adult patients with newly diagnosed Ph+ acute lymphoblastic leukemia (Ph+ ALL) in combination with chemotherapy and as a single agent for patients with relapsed or refractory Ph+ ALL. Glivec is also approved for the treatment of adult patients with unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP) who are not eligible for surgery. Glivec is also approved for the treatment of patients with myelodysplastic/myeloproliferative diseases (MDS/MPD). Glivec is also approved for hypereosinophilic syndrome and/or chronic eosinophilic leukemia (HES/CEL).

The effectiveness of Glivec is based on overall hematological and cytogenetic response rates and progression-free survival in CML, on hematological and cytogenetic response rates in Ph+ ALL, MDS/MPD, on hematological response rates in systemic mastocytosis (SM), HES/CEL, on objective response rates and progression-free survival in unresectable and/or metastatic GIST, on recurrence free survival in adjuvant GIST and on objective response rates in DFSP. Increased survival in controlled trials has been demonstrated only in newly diagnosed chronic phase CML and GIST.

Not all indications are available in every country.

### **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).

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.

### **About Zometa**

Zometa is indicated for the prevention of skeletal related events (pathological fractures, spinal compression, radiation or surgery to bone, or tumor-induced hypercalcemia) in patients with advanced malignancies involving bone. An intravenous bisphosphonate, Zometa is the only therapy to demonstrate efficacy in reducing or delaying bone complications across a broad range of tumor types such as breast, prostate, lung and renal cell cancers, in patients with metastatic disease when administered monthly. Zometa offers patients, nurses and clinicians a 4 mg, 15-minute infusion.

Zometa is the world's leading treatment for the prevention or delay of skeletal-related events (SREs) in patients with advanced malignancies involving bone across a broad range of tumors. Laboratory research has suggested that Zometa may also help protect patients from the spread of cancer to other parts of the body (distant metastatic sites) and help keep patients recurrence-free.

### **Zometa important safety information**

Zometa has been associated with reports of renal insufficiency. Patients should be adequately rehydrated and have their serum creatinine assessed prior to receiving each dose of Zometa. Due to the risk of clinically significant deterioration in renal function, single doses of Zometa should not exceed 4 mg and the duration of infusion should be no less than 15 minutes in 100 ml of diluent. Severe and occasionally incapacitating bone, joint, and/or muscle pain has been reported in patients taking bisphosphonates including Zometa. Caution is advised when Zometa is used in aspirin-sensitive patients, or with aminoglycosides, loop diuretics and other potentially nephrotoxic drugs. Zometa contains the same active ingredient (zoledronic acid) as found in Aclasta. Patients being treated with Zometa should not be treated with Aclasta concomitantly.

In clinical trials, the most commonly reported adverse events included flu-like syndrome (fever, arthralgias, myalgias, skeletal pain), fatigue, gastrointestinal reactions, anemia, weakness, cough, dyspnea and edema. Zometa should not be used during pregnancy. Zometa is contraindicated in patients with clinically significant hypersensitivity to zoledronic acid or other bisphosphonates, or any of the excipients in the formulation of Zometa.

Osteonecrosis of the Jaw (ONJ): ONJ has been reported in patients with cancer receiving treatment including bisphosphonates, chemotherapy, and/or corticosteroids. The majority of reported cases have been associated with dental procedures such as tooth extraction. A dental examination with appropriate preventive dentistry should be considered prior to treatment with bisphosphonates in patients with concomitant risk factors. While on treatment, these patients should avoid invasive dental procedures if possible. No data are available to suggest whether discontinuation of bisphosphonate therapy reduces the risk of ONJ in patients requiring dental procedures. A causal relationship between bisphosphonate use and ONJ has not been established.

Please see full Prescribing Information.

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### **About everolimus**

In the European Union (EU), everolimus is approved under the trade name Afinitor® (everolimus) tablets for the treatment of patients with advanced renal cell carcinoma (RCC) whose disease has progressed on or after treatment with vascular endothelial growth factor (VEGF)-targeted therapy. In the US, Afinitor is approved for the treatment of patients with advanced RCC after failure of treatment with sunitinib or sorafenib.

In the EU, everolimus is available in different dosage strengths under the trade name Certican® for the prevention of organ rejection in heart and kidney transplant recipients. In the US, everolimus is available in different dosage strengths under the trade name Zortress® for the prophylaxis of organ rejection in adult patients at low-moderate immunologic risk receiving a kidney transplant.

As an investigational compound, the safety and efficacy profile of everolimus has not yet been established in cancer and tumor types outside of the approved advanced renal cell carcinoma indication. Access to everolimus for cancer and tumor types is available through carefully controlled and monitored clinical trials. These trials are designed to better understand the potential benefits and risks of the compound. For more information about everolimus clinical trials, healthcare professionals can visit [www.theWIDEprogram.com](http://www.theWIDEprogram.com). Because of the uncertainty of clinical trials, there is no guarantee that everolimus will become commercially available for cancer and tumor types anywhere in the world.

### **Afinitor (everolimus) tablets important safety information**

Afinitor is contraindicated in patients with hypersensitivity to everolimus, to other rapamycin derivatives or to any of the excipients.

Cases of non-infectious pneumonitis have been described; some of these have been severe and occasionally fatal. Management of pneumonitis may require dose adjustment and/or interruption, or discontinuation of treatment and/or addition of corticosteroid therapy.

Afinitor is immunosuppressive. Localized and systemic bacterial, fungal, viral or protozoal infections (e.g. pneumonia, aspergillosis, candidiasis, hepatitis B reactivation) have been described; some of these have been severe and occasionally fatal. Pre-existing infections should be treated prior to starting treatment. Patients should be vigilant for symptoms and signs of infection; in case of emergent infections, appropriate treatment should be promptly instituted and interruption or discontinuation of Afinitor should be considered. Patients with systemic invasive fungal infections should not receive Afinitor.

Mouth ulcers, stomatitis and oral mucositis have been seen in patients treated with Afinitor. Monitoring of renal function, blood glucose and complete blood counts is recommended prior to initiation and periodically during treatment.

Afinitor is not recommended in patients with severe hepatic impairment. Use of live vaccines should be avoided. Afinitor is not recommended during pregnancy or for women of childbearing potential not using contraception. Afinitor may cause fetal harm in pregnant women. Women taking Afinitor should not breast feed.

Avoid concurrent treatment with strong CYP3A4 and PgP inhibitors and use caution with moderate inhibitors. Avoid concurrent treatment with strong CYP3A4 or PgP inducers.

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The most common adverse reactions (=10%) include stomatitis, rash, fatigue, asthenia, diarrhea, anorexia, nausea, mucosal inflammation, vomiting, cough, infections, peripheral edema, dry skin, epistaxis, pneumonitis, pruritus, dyspnea and dysgeusia. Common adverse reactions (=1 to <10%) include headache, dry mouth, pyrexia, weight decreased, hand-foot syndrome, abdominal pain, erythema, insomnia, dyspepsia, dysphagia, hypertension, increased daytime urination,

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dehydration, chest pain, hemoptysis and exacerbation of diabetes mellitus. Uncommon adverse reactions (<1%) include ageusia, congestive cardiac failure, new-onset diabetes mellitus, impaired wound healing, grade 1 hemorrhage and hepatitis B reactivation.

## Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as promise, pipeline, will, dedication, commitment, potential, or similar expressions, or by express or implied discussions regarding potential new indications or labeling, or potential marketing approvals for the products described in this release, or regarding potential future revenues from such 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 of the products or additional indications or labeling described in this release will be submitted for approval or approved for sale in any market. Nor can there be any guarantee that any of these products or indications will achieve any particular levels of revenue in the future. In particular, management's expectations regarding these products and indications 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 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 2009, the Group's continuing operations achieved net sales of USD 44.3 billion, while approximately USD 7.5 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 100,000 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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## References

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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: June 2nd, 2010

By: /s/ MALCOLM B. CHEETHAM

Name: Malcolm B. Cheetham

Title: Head Group Financial Reporting and Accounting

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