

NOVARTIS AG  
Form 6-K  
February 19, 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 February 19, 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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**Form 20-F:**       Form 40-F:

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:       **No:**

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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 -**

**Novartis drug Tasigna® receives FDA priority review for newly diagnosed patients with early-stage chronic myeloid leukemia**

- *Study results show Tasigna exceeds Glivec® in every measure of efficacy in the trial including prevention of disease progression at 12 months(1)*
- *Regulatory applications underway worldwide for Tasigna in the first-line indication with submissions now filed in the US, EU and Japan*
- *Tasigna, if approved, will be first treatment since Glivec for newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia patients in chronic phase*

**Basel, February 19, 2010** Novartis announced today that Tasigna® (nilotinib) has been granted priority review by the US Food and Drug Administration (FDA) for the treatment of adult patients with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase.

FDA priority review status is granted to therapies that offer major advances in treatment or provide a treatment where no adequate therapy exists. This status accelerates the standard review time from 10 to six months. Tasigna demonstrated that significantly fewer patients progressed to more advanced stages of the disease than the standard of care Glivec® (imatinib)\* at 12 months. Tasigna also showed a statistically significant improvement over Glivec in every other measure of efficacy in the trial, including major molecular response (MMR) and complete cytogenetic response (CCyR) at 12 months(1).

In addition to the US, regulatory submissions have been filed in the EU and Japan. All filings are based on data showing superior efficacy for Tasigna in the first head-to-head comparison of the drug against the standard of care Glivec in newly diagnosed Ph+ CML patients. If approved for the first-line indication, Tasigna will be the first drug for newly diagnosed patients to become available since the approval of Glivec in 2002.

Recently presented data showed that Tasigna surpassed Glivec in every measure of treatment efficacy designated in the study including prevention of disease progression at 12 months, said David Epstein, CEO of the Novartis Pharmaceuticals Division. Now this priority review designation brings us one step closer to offering patients who are newly diagnosed with Ph+ CML in the chronic phase a promising new

treatment option.

The regulatory submissions are based on data from the ENESTnd (Evaluating Nilotinib Efficacy and Safety in Clinical Trials of Newly Diagnosed Ph+ CML Patients) Phase III clinical trial. This randomized, open-label, multicenter trial compared the efficacy and safety of Tasigna versus Glivec in adult patients with newly diagnosed Ph+ CML in chronic phase(1). It is the largest global randomized comparison of two oral therapies ever conducted in newly diagnosed Ph+ CML patients.

In the ENESTnd clinical trial, significantly fewer patients at 12 months progressed to accelerated or blastic phase on Tasigna 300 mg twice daily than on Glivec 400 mg once daily (2 patients vs. 11 patients)(1), demonstrating a significant improvement in disease control. Fewer patients discontinued due to adverse events from the Tasigna 300 mg twice daily arm of the study compared to the Glivec 400 mg once daily arm. No patients in the study had a prolongation of the QT interval >500 milliseconds(1). In addition, no sudden deaths occurred with either treatment(2).

Tasigna is a potent and selective inhibitor of the Bcr-Abl protein that causes production of cancer cells in Ph+ CML(2),(3). The first clinical trials of Tasigna began 21 months after its discovery, with the drug receiving its first regulatory approval in the second-line indication in 2007(3).

### **About Ph+ CML**

CML is a disease in which the body produces cancerous white blood cells. Almost all patients with CML have an abnormality known as the Philadelphia chromosome, which produces a protein called Bcr-Abl. Bcr-Abl causes malignant white blood cells to proliferate(4). Worldwide, CML is responsible for approximately 10 to 15% of all adult cases of leukemia(5), with an incidence of one to two cases per 100,000 people per year(6).

### **About Tasigna(3)**

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 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 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.

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(7)**

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.





## Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as "priority review," "will," "promising," or similar expressions, or by express or implied discussions regarding potential approvals of new indications or labeling for Tasigna, or the potential timing of such approvals, or regarding potential future revenues from Tasigna or Glivec. 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 Tasigna or Glivec to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Tasigna will be approved for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that Tasigna or Glivec will achieve any particular levels of revenue in the future. In particular, management's expectations regarding Tasigna and Glivec 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 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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- (2) Novartis data on file.
- (3) Tasigna (nilotinib) European Summary of Characteristics. Novartis AG. <http://www.tasigna.com/en/tasigna-product-information.jsp#>.
- (4) National Cancer Institute. General Information About Chronic Myelogenous Leukemia (PDQ). <http://www.cancer.gov/cancertopics/pdq/treatment/CML/patient/>. Accessed March 2009.

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- (6) Central European Leukemia Study Group. About CML. Available from: <http://www.cml-info.com/de/healthcare-professionals/about-cml.html>. Accessed Nov 2009.
- (7) Glivec® (imatinib) prescribing information. Basel, Switzerland: Novartis International AG; March 2009.

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Media materials can be accessed at: <http://www.novartisoncology.com/media>

**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 19, 2010

By: /s/ MALCOLM B. CHEETHAM

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