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FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER
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Novartis AG

(Name of Registrant)

Lichtstrasse 35

4056 Basel

Switzerland

(Address of Principal Executive Offices)

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Novartis International AG

Novartis Global Communications

CH-4002 Basel

Switzerland

http://www.novartis.com

- Investor Relations Release -

Two Novartis Phase III studies show twice as many Ph+ CML patients achieve deeper levels of response with Tasigna® compared to Glivec®

- *ENESTcmr data show 23% of patients switched to Tasigna achieved undetectable levels of Bcr-Abl within 12 months compared to 11% who continued on Glivec(1)*

- *Three-year ENESTnd data show 32% of newly diagnosed patients on Tasigna reached deepest levels of molecular response measured versus 15% on Glivec(2)*

- *ENESTnd study also shows significantly fewer patients progressed to advanced stages of CML with Tasigna after three years, compared to Glivec(2)*

Basel, December 12, 2011 Phase III clinical trial data presented today contribute to the growing evidence that adult patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase who are treated with Tasigna® (nilotinib) have deeper levels of response compared to those treated with Glivec® (imatinib)*(1),(2).

The findings from the ENEST (Evaluating Nilotinib Efficacy and Safety in clinical Trials) clinical research program were presented at the 53rd Annual Meeting of the American Society of Hematology (ASH) in San Diego.

ENESTcmr is the first exploratory randomized trial to investigate the impact of switching adult patients with residual disease after a minimum of two years of treatment with Glivec to Tasigna to determine if a deeper level of response could be achieved(1).

The study showed that twice as many patients switched to Tasigna 400 mg twice a day achieved undetectable Bcr-Abl levels by 12 months compared to Glivec (23% taking Tasigna 400 mg twice daily and 11% taking Glivec 400 mg or 600 mg once daily; p= 0.0202). The primary

endpoint, which is more stringent than conventional measures, is undetectable Bcr-Abl level in two consecutive samples. Samples with any detectable level were not considered to be in complete molecular response (CMR). The lowest detected Bcr-Abl value was 0.00073%. This endpoint showed a two-fold difference in confirmed undetectable CMR for 13% of patients on Tasigna versus 6% of patients on Glivec, although statistical significance was not achieved (p=0.108). The study has a planned follow-up of four years(1).

After 36 months of follow-up, data from the Phase III ENESTnd clinical trial in adult patients with newly diagnosed Ph+ CML in chronic phase continued to show significantly more patients achieved CMR, defined in this study as at least a 4.5 log reduction from baseline or a trace amount of 0.0032% or less of Bcr-Abl compared to Glivec (32% taking Tasigna 300 mg twice daily and 15% taking Glivec 400 mg once daily). The ENESTnd study also continued to show that first-line treatment with Tasigna resulted in significantly fewer patients progressing to advanced phase and blast crisis (AP/BC) stages of disease compared to Glivec, leading to a significantly lower number of CML-related deaths in patients taking Tasigna versus Glivec (p=0.0356)(2).

Data from both ENESTnd and ENESTcmr reinforce that patients taking Tasigna have a greater chance of achieving CMR, the deepest level of response measurable today, compared to those taking Glivec, said Timothy P. Hughes, MD, ENEST study investigator and Clinical Professor at the University of Adelaide, Australia. We are encouraged by what we saw in ENESTcmr and further follow-up on both trials should help to determine if more patients can reach undetectable levels of CML over time, which could have important implications for determining criteria for future studies on discontinuation of therapy.

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 is comprised of a protein called Bcr-Abl that causes malignant white blood cells to proliferate(3). The success of treatment for CML can be measured by a test called real-time quantitative polymerase chain reaction (RQ-PCR). A molecular response means RQ-PCR shows a reduction in Bcr-Abl in the blood; a CMR means no Bcr-Abl is detected(4),(5). In recent investigator-initiated studies, select patients who achieved durable CMR have been able to cease therapy without relapse for trial periods lasting from six months to a year(6)-(8).

Data from the ENESTnd 36-month update and the ENESTcmr trial at ASH continue to reinforce the benefits of Tasigna over Glivec, and support the use of Tasigna for adult patients with chronic-phase Ph+ CML, said Hervé Hoppenot, President, Novartis Oncology. We look forward to even more progress in the future as we observe the impact of achieving deep and sustained molecular response with Tasigna for people living with this cancer.

Worldwide, CML is responsible for approximately 10% to 15% of all adult cases of leukemia, with an incidence of one to two cases per 100,000 people per year(9),(10).

ENESTcmr study details

ENESTcmr is an open-label, randomized, prospective, multi-center Phase III study of Tasigna 400 mg twice daily versus standard-dose Glivec (400 mg or 600 mg once daily) comparing kinetics of CMR for patients with Ph+ CML in chronic phase who had achieved complete cytogenetic response (CCyR) but were still Bcr-Abl positive (i.e., had evidence of residual leukemia) after at least two years of treatment with Glivec. The study enrolled 207 patients. The patients were randomized into one of two treatment arms: Tasigna 400 mg twice daily versus continuing Glivec 400 mg or 600 mg once daily (same dose as at study entry)(1).

The primary endpoint was the rate of confirmed best cumulative CMR by 12 months of study therapy with Tasigna or Glivec. Samples with any detectable level were considered not to be in CMR. The lowest detected Bcr-Abl value was 0.00073%. Secondary objectives included the kinetics of CMR, duration of CMR, progression-free survival and overall survival in both arms. CMR was defined at three levels: CMR (CMR ≥4.5-log, undetectable Bcr-Abl by RQ-PCR at a sensitivity of less than 0.0032%), CMR4 (CMR ≥4-log, undetectable Bcr-Abl by RQ-PCR at a sensitivity of 0.01% or less) and CMR4.5 (CMR ≥4.5-log, undetectable Bcr-Abl by RQ-PCR at a sensitivity of 0.0032% or less)(1).

These data showed that 23% of patients taking Tasigna achieved undetectable disease (24 patients) by 12 months compared to 11% (11 patients) taking Glivec(1).

A majority of patients in both treatment arms received prior Glivec treatment for at least three years before entering the trial. Patients randomized to receive Tasigna were given a new treatment while the others continued to receive a therapy that they had been taking for a minimum of two years(1).

During this study, discontinuation due to adverse events occurred in 8.9% and 1% for Tasigna- and Glivec-treated patients, respectively. The majority of these were asymptomatic laboratory adverse events. The adverse events seen in ENESTcmr were similar to other studies for patients switched from chronic Glivec therapy to Tasigna(1).

ENESTnd study details

ENESTnd is a Phase III randomized, open-label, multicenter trial comparing the efficacy and safety of Tasigna versus Glivec in adult patients with newly diagnosed Ph+ CML in chronic phase. It is the largest global randomized comparison of two oral therapies ever conducted in newly diagnosed Ph+ CML patients(2).

The study is being conducted at 217 global sites with 846 patients enrolled. Patients were randomized to receive Tasigna 300 mg twice daily (n=282), Tasigna 400 mg twice daily (n=281) or Glivec 400 mg once daily (n=283). The primary endpoint was major molecular response (MMR) at 12 months; the key secondary endpoint was durable MMR at 24 months (patients having MMR when evaluated at both 12 and 24 months). MMR was defined in this study as 0.1% or less of Bcr-Abl as measured by RQ-PCR. Planned follow-up is for five years. Patients on the Glivec treatment arm who had suboptimal response or treatment failure were allowed to escalate dose and/or switch to Tasigna in a separate extension study. These data, presented at ASH, were the 36-month minimum follow-up(2).

Results showed that fewer patients in the core treatment group progressed to accelerated phase or blast crisis while on treatment with Tasigna at 300 mg twice daily (n=2) and 400 mg twice daily (n=3) versus Glivec at 400 mg once daily (n=12) with 36 months of minimum follow-up. Analysis of the broader study group, including patients followed after discontinuation of the study, showed 9 patients on Tasigna 300 mg twice daily, 6 patients on Tasigna 400 mg twice daily and 19 patients on Glivec progressed(2).

Over the past three years a total of 38 patients (5%) died during the ENESTnd study (17 patients taking Glivec, 13 taking Tasigna 300 mg twice daily and 8 taking Tasigna 400 mg twice daily). Tasigna treatment was also associated with significantly lower rates of CML-related deaths (5 patients taking Tasigna 300 mg twice daily, 4 patients taking Tasigna 400 mg twice daily and 14 patients taking Glivec) consistent with the significant improvement observed with progression to AP/BC. Since the last data cut-off there were a total of five CML related deaths (4 with

Glivec 400 mg once daily and 1 with Tasigna 400 mg twice daily)(2).

The median follow-up for this study was 36 months. Overall, 90% and 88% of patients remained in the study on Tasigna 300 mg twice daily and Glivec 400 mg once daily, respectively(2).

Rates of discontinuation due to adverse events or laboratory abnormalities continued to be lowest for Tasigna 300 mg twice daily (10%) compared to Tasigna 400 mg twice daily (14%) and Glivec 400 mg once daily (11%).

About Tasigna (nilotinib)

Tasigna® (nilotinib) is approved in more than 90 countries for the treatment of chronic phase and accelerated phase Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML) in adult patients resistant or intolerant to at least one prior therapy, including Glivec, and for the treatment of adult patients with newly diagnosed Ph+ CML in chronic phase. Tasigna should be taken twice daily 12 hours apart. Tasigna should not be taken with food and no food should be consumed for two hours after dosing. Patients taking Tasigna should avoid grapefruit juice and CYP3A4 inhibitors.

Tasigna Important Safety Information

Use with caution in patients with uncontrolled or significant cardiac disease and in patients who have or may develop prolongation of QTc. Low levels of potassium or magnesium must be corrected prior to Tasigna administration. Monitor closely for an effect on the QTc interval. Baseline ECG is recommended prior to initiating therapy and as clinically indicated. Uncommon cases (0.1 to 1%) of sudden death have been reported in clinical studies in patients with significant risk factors.

Use with caution in patients with liver impairment, with a history of pancreatitis and with total gastrectomy. Patients with rare hereditary problems of galactose intolerance, severe lactase deficiency or glucose-galactose malabsorption should not use Tasigna. Tasigna may cause fetal harm in pregnant women. Women taking Tasigna should not breastfeed.

The most frequent Grade 3 or 4 adverse events are hematological (neutropenia and thrombocytopenia) which are generally reversible and usually managed by withholding Tasigna temporarily or dose reduction. Monitor blood counts regularly. Pancreatitis has been reported. The most frequent non-hematologic adverse events were rash, pruritus, nausea, fatigue, headache, alopecia, myalgia, constipation and diarrhea. Most of these adverse events were mild to moderate in severity.

Please see full Prescribing Information.

About Glivec (imatinib)

Glivec® (imatinib) is approved in more than 110 countries for the treatment of all phases of Ph+ CML, for the treatment of adult patients with KIT (CD117)-positive gastrointestinal stromal tumors (GIST), which cannot be surgically removed and/or have metastasized and for the treatment of adult patients following complete surgical removal of KIT+ GIST. Take with food and a large glass of water.

Glivec Important Safety Information

Glivec can cause fetal harm in pregnant woman. Glivec has been associated with severe edema (swelling) and serious fluid retention. Cytopenias (anemia, neutropenia, thrombocytopenia) are common, generally reversible and usually managed by withholding Glivec or dose reduction. Monitor blood counts regularly. Severe congestive heart failure and left ventricle dysfunction, severe liver problems including cases of fatal liver failure and severe liver injury requiring liver transplants have been reported. Use caution in patients with cardiac dysfunction and hepatic dysfunction. Monitor carefully.

Bleeding may occur. Severe gastrointestinal (GI) bleeding has been reported in patients with KIT+ GIST. Skin reactions, hypothyroidism in patients taking levothyroxine replacement, GI perforation, in some cases fatal and tumor lysis syndrome, which can be life threatening, have also been reported with Glivec. Correct dehydration and high uric acid levels prior to treatment. Long-term use may result in potential liver, kidney, and/or heart toxicities; immune system suppression may also result from long-term use. In patients with hypereosinophilic syndrome and heart involvement, cases of heart disease have been associated with the initiation of Glivec therapy. Growth retardation has been reported in children taking Glivec. The long-term effects of extended treatment with Glivec on growth in children are unknown.

The most common side effects include fluid retention, muscle cramps or pain and bone pain, abdominal pain, loss of appetite, vomiting, diarrhea, decreased hemoglobin, abnormal bleeding, nausea, fatigue and rash.

Please see full Prescribing Information.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as should, could, look forward to, or similar expressions, or by express or implied discussions regarding potential new indications or labeling for Tasigna 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 submitted or 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 or 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 protection; 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; unexpected manufacturing issues; 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 innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, eye care, cost-saving generic pharmaceuticals, preventive vaccines and diagnostic tools, over-the-counter and animal health products. Novartis is the only global company with leading positions in these areas. In 2010, the Group s continuing operations achieved net sales of USD 50.6 billion, while approximately USD 9.1 billion (USD 8.1 billion excluding impairment and amortization charges) was invested in R&D throughout the Group. Novartis Group companies employ approximately 121,000 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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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

Amy Vinci

Novartis Oncology

+1 862 778 6309 (direct)

+1 917 535 2602 (mobile)

amy.vinci@novartis.com

e-mail: media.relations@novartis.com

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For questions about the site or required registration, please contact: journalisthelp@thenewsmarket.com.

Novartis Investor Relations

Central phone:	+41 61 324 7944
Susanne Schaffert	+41 61 324 7944
Pierre-Michel Bringer	+41 61 324 1065
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: December 12, 2011

By: /s/ MALCOLM B. CHEETHAM

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