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FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER

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Novartis AG

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- Investor Relations Release -

Novartis drug Tasigna® meets primary endpoint in pivotal trial against Glivec® as first-line treatment in chronic myeloid leukemia patients

- *Tasigna produced faster and deeper responses compared to Glivec as first-line treatment in Philadelphia chromosome-positive chronic myeloid leukemia*

- *First registration study using molecular response as key indicator of patient outcomes; Bcr-Abl biomarker test measures very low levels of residual disease(1),(2)*

- *Tasigna is a potent and selective inhibitor of the Bcr-Abl protein that causes production of cancer cells(3), (4)*

- *Complete results to be submitted for presentation at the American Society of Hematology (ASH) meeting in December*

Basel, October 20, 2009 Novartis announced today that Tasigna® (nilotinib) met its primary endpoint in the first head-to-head comparison with the company s groundbreaking drug Glivec® (imatinib).* Tasigna produced faster and deeper responses than Glivec when given as first-line therapy for adult patients with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase. Tasigna was well tolerated in the study(5),(6).

The Phase III clinical trial, Evaluating Nilotinib Efficacy and Safety in Clinical Trials of Newly Diagnosed Ph+ CML Patients (ENESTnd), is the largest global randomized comparison of two oral therapies ever conducted in newly diagnosed Ph+ CML patients. Designed to detect a difference in major molecular response (MMR) between Tasigna and Glivec after 12 months of treatment, it is also the first registration study in which molecular traces of a key biomarker specific to Ph+ CML have been used as a primary endpoint for regulatory review. The comparison study also met its secondary endpoint, a difference in complete cytogenetic response (CCyR) in favor of Tasigna(5),(6).

We developed Tasigna to be a potent and selective inhibitor of Bcr-Abl, with the goal of eliminating the underlying cause of Ph+ CML. We now know that Tasigna reduces the level of Bcr-Abl faster and to a lower level than Glivec, with profound implications for improving patients outcomes, said David Epstein, President and CEO of Novartis Oncology and Novartis Molecular Diagnostics. Molecular monitoring enables us to evaluate whether patients have achieved this deep level of CML residual disease, reducing the fundamental biomarker of leukemia to nearly undetectable levels.

The blood test used to determine molecular response can detect a single cell containing traces of Bcr-Abl in up to one million normal blood cells(7). In addition to being simpler and less invasive for patients, the test has a much greater sensitivity than standard cytogenetic tests, which require a sample of bone marrow to be drawn for visual detection of cells containing the Ph chromosome(1). Molecular monitoring measures the deepest level of CML residual disease(13).

In earlier clinical trials, molecular responses were found to be predictive of better patient outcomes: 100% of Ph+ CML patients who achieved MMR (defined as a thousand-fold or greater reduction in Bcr-Abl relative to standardized baseline level) in the first 12 months of treatment survived without disease progression for at least five years8. Follow up of patients in these studies is ongoing.

Details of the ENESTnd findings will be submitted as a late-breaking abstract to the 51st annual meeting of the American Society of Hematology (ASH), to take place in December, in New Orleans, Louisiana, USA.

Previous studies of Tasigna as first-line therapy for patients with newly diagnosed Ph+ CML include the Gruppo Italiano Malattie Ematologiche dell Adulto (GIMEMA) study, an ongoing, open-label, single-stage, multicenter Phase II clinical trial; and NCT00129740, an ongoing, open-label, single-center Phase II clinical trial undertaken at M.D. Anderson Cancer Center in Houston, Texas, USA. New data from the GIMEMA study presented earlier this year at the European Hematology Association (EHA) congress show that at 12 months, 85% of patients taking Tasigna achieved MMR. These data indicate a more rapid reduction in disease burden compared to that seen in previous studies with Glivec9.

Study details

ENESTnd is a Phase III randomized, open-label, multicenter study comparing the efficacy and safety of Tasigna versus Glivec in adult patients with newly diagnosed Ph+ CML in chronic phase(5),(6).

ENESTnd is being conducted at 220 global sites, with 846 patients enrolled. Patients were randomized to receive Tasigna 400 mg twice daily (n = 281), Tasigna 300 mg twice daily (n = 282) or Glivec 400 mg daily (n = 283). The primary endpoint was MMR at 12 months; the secondary endpoint was complete cytogenetic response (CCyR) by 12 months. Planned follow-up is for five years(5),(6).

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(3). Worldwide, CML is responsible for approximately 10 to 15% of all adult cases of leukemia(10), with an incidence of one to two cases per 100,000 people per year(11).

About Tasigna(4)

Tasigna has been approved in 73 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 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.

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(12)

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 to be submitted, implications, predictive, will, to take place, 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 approved for any additional indications or labeling in any market. 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 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 each of 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 99,000 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) NCCN Practice Guidelines in Oncology v.1.2010. Chronic Myelogenous Leukemia.
(2) Sessions J. Chronic Myeloid Leukemia in 2007. http://www.amcp.org/data/jmcp/pages%204-7.pdf. Accessed September 2009.
(3) National Cancer Institute. General Information About Chronic Myelogenous Leukemia (PDQ). http://www.cancer.gov/cancertopics/pdq/treatment/CML/patient/. Accessed March 2009.
(4) Tasigna (nilotinib) European Summary of Characteristics. Novartis AG. http://www.tasigna.com/en/tasigna-product-information.jsp#.
(5) Novartis data on file
(6) A Study of Imatinib Versus Nilotinib in Adult Patients With Newly Diagnosed Philadelphia Chromosome Positive (Ph+) Chronic Myelogenous Leukemia in Chronic Phase (CML-CP). http://clinicaltrials.gov/ct2/show?term=ENEST&rank=3. Accessed October 2009.
(7) Kurzrock R, Talpaz M. The molecular pathology of chronic myelogenous leukaemia. Br J Haematol. 1991 Oct; 79 Suppl 1:34-7.
(8) Druker BJ, Guilhot F, O Brien SG, et al. Five-Year Follow-up of Patients Receiving Imatinib for Chronic Myeloid Leukemia. N Engl J Med. 2006; 355(23):2408-2517.
(9) Rosti, G et al. Nilotinib for the Frontline Treatment of Ph+ Chronic Myeloid Leukemia. Blood. Published online October 12, 2009. http://bloodjournal.hematologylibrary.org/cgi/content/abstract/blood-2009-07-232595v1
(10) American Cancer Society. Detailed Guide: CML. What are the key statistics about CML? (Sept 2008 revision) Available at: http://www.cancer.org/docroot/CRI/content/CRI_2_4_1x_What_Are_the_Key_Statistics_About_Chronic_Myeloid_Leukemia_CML.asp?rnav=cri. Accessed April 2009.
(11) Central European Leukemia Study Group. About CML. [Cited 2009 Jan 13] Available from: http://www.cml-info.com/de/healthcare-professionals/about-cml.html.
(12) Glivec® (imatinib) prescribing information. Basel, Switzerland: Novartis International AG; March 2009.
(13) Jabbour E, Cortes J, Kantarjian H, et al. Molecular Monitoring in Chronic Myeloid Leukemia Response to Tyrosine Kinase Inhibitors and Prognostic Implications. Cancer. DOI10.1002/cncr.23427. Published online 17 March 2008.

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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:	October 20, 2009	By:	/s/ MALCOLM B. CHEETHAM
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		Title:	Head Group Financial Reporting and Accounting