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FORM 6-K

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Novartis AG

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Novartis long-term Phase III data show Ph+ CML patients on Tasigna® achieved significantly deeper molecular response versus Glivec®

- *Both newly diagnosed patients and those switching to Tasigna after long-term treatment with Glivec achieved deeper molecular response with Tasigna*

- *Data suggest correlation between early molecular response at three and six months and survival outcome for newly diagnosed patients*

- *Novartis reinforces commitment to CML with new clinical trials exploring treatment free remission in patients who achieve sustained deep molecular response*

Basel, December 10, 2012 The latest results from two Phase III clinical trials further establish the benefits of Tasigna® (nilotinib) compared to Glivec® (imatinib)* in the treatment of Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in newly diagnosed patients and in those with residual disease who switched to Tasigna after long-term treatment with Glivec.

Findings from both studies were presented in oral sessions at the 54th annual meeting of the American Society of Hematology (ASH) in Atlanta.

Two-year results from ENESTcmr showed that switching to Tasigna led to deeper molecular responses** in patients who still had evidence of residual disease after long-term therapy with Glivec(1). More than twice as many patients treated with Tasigna continued to achieve undetectable BCR-ABL versus Glivec. The difference between groups by 24 months was statistically significant (22.1% vs. 8.7%; p=0.0087) and that difference has doubled since the 12-month analysis. Significantly more patients treated with Tasigna achieved MR4.5 or undetectable BCR-ABL versus Glivec regardless of the BCR-ABL transcript level at baseline(1). In studies published to date, no patients achieving and maintaining MR4.5 have progressed to advanced stages of CML(2),(3),(4),(5),(6).

Tasigna should be considered as a leading option for frontline therapy because it allows many patients to achieve deeper responses earlier, which we have associated with improved long-term outcomes, said Timothy P. Hughes, MD, ENEST study investigator, Head of the Department of Haematology at Royal Adelaide Hospital and Clinical Professor at the University of Adelaide, Australia.

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

**In ENESTcmr, molecular response (reduction of BCR-ABL transcripts in the blood of patients) is measured at four levels, based on an international standard:

- MMR (≤ 0.1% BCR-ABL)
- MR4 (≤ 0.01% BCR-ABL)
- MR4.5 (≤ 0.0032% BCR-ABL)
- Undetectable BCR-ABL (no detectable BCR-ABL transcript level with sample sensitivity of at least 4.5 log)

Also presented at ASH are the results of a four-year landmark analysis from ENESTnd which showed that more than three times as many patients achieved early molecular response (reduction in BCR-ABL transcript levels to ≤10% at months three and six) with Tasigna as frontline therapy instead of Glivec(7). The investigators correlated early molecular response with future major molecular response (MMR) and MR4.5, as well as an increased probability of progression-free survival and overall survival(7).

In a separate four-year analysis of efficacy and safety data from ENESTnd also presented at ASH, the difference in the rates of both MR4 and MR4.5 continued to be significantly higher for Tasigna, with the difference in favor of Tasigna increasing over time (MR4: 9-14% difference by one year, 17-24% difference by four years; MR4.5: 6-10% difference by one year, 14-17% difference by four years)(7). Overall survival remained similar in all groups at four years, but fewer CML-related deaths occurred in both the Tasigna 300 mg twice daily (n=5) and 400 mg twice daily (n=4) arms versus Glivec (n=13)(7).

We are encouraged by the continued strong findings from newly-presented CML data at ASH, said Hervé Hoppenot, President, Novartis Oncology. Our dedication to ongoing research in CML over the past decades has helped to transform the disease from a fatal diagnosis to a chronic condition. We are now starting the next chapter in our commitment to helping patients with this disease by exploring in Tasigna clinical trials the idea that some patients may be able to safely stop therapy after achieving sustained and deep molecular response.

Novartis Commitment to CML

Novartis Oncology helped pioneer the transformation of Ph+ CML to a treatable, chronic condition. As an industry leader in CML, Novartis is committed to furthering the understanding of this disease and to redefining once again what is possible for the future of Ph+ CML. The company plans to initiate in early 2013 a robust clinical trial program evaluating the possibility of treatment-free remission in CML, which means sustaining deep molecular response after stopping therapy. Nine treatment-free studies are planned to be conducted in study centers across more than 50 countries.

Worldwide, CML is responsible for a little over 10% of all adult cases of leukemia, with an incidence of one to two cases per 100,000 people per year(8),(9).

ENESTcmr study details

ENESTcmr (Evaluating Nilotinib Efficacy and Safety in Clinical Trials Complete Molecular Response) 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 molecular response 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 complete molecular response by 12 months of study therapy with Tasigna or Glivec. Secondary objectives included the kinetics of molecular response, duration of molecular response, progression-free survival and overall survival in both arms. These data, presented at ASH, were the 24-month follow-up(1).

More than twice as many patients treated with Tasigna continued to achieve undetectable BCR-ABL versus Glivec. The difference between groups by 24 months was statistically significant (22.1% vs. 8.7%; p=0.0087). Compared to the 12-month analysis, the difference between the treatment arms doubled over time from 6.7% to 13.4%. Among patients without documented MR4.5 at baseline, cumulative incidence of MR4.5

was over twice as high in Tasigna-treated patients versus those who stayed on Glivec (42.9% vs. 20.8%; p=0.0006) and the difference increased over time from 12 to 24 months. Significantly more patients treated with Tasigna achieved MR4.5 versus Glivec regardless of the BCR-ABL transcript level at baseline. In patients without documented MMR, MR4 and MR4.5 at baseline, the differences were superior in all subsets (29.2% vs. 3.6%; p=0.016; 31.1% vs. 11.5%; p=0.003 and 42.9% vs. 20.8%; p=0.0006, respectively)(1).

ENESTnd study details

ENESTnd (Evaluating Nilotinib Efficacy and Safety in Clinical Trials Newly Diagnosed Patients) 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(7),(10),(11).

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 48-month minimum follow-up(7),(10),(11).

The ENESTnd landmark analysis was based on BCR-ABL transcript levels at three and six months using data with a minimum follow-up of four years. The Tasigna 300 mg BID (n=282) and Glivec 400 mg QD (n=283) treatment arms were used for the analysis. Rates of MMR, MR4.5, progression-free survival and overall survival were evaluated among patients grouped according to their BCR-ABL transcript levels of ≤1%, >1% to ≤10%, and >10% at three and six months. Among evaluable patients at three months, 9% of patients (n=24) in the Tasigna arm versus 33% (n=88) in the Glivec arm had BCR-ABL transcript levels of >10%. Patients with a BCR-ABL transcript level of >10% had a significantly lower probability of future MMR or MR4.5 as well as poorer progression-free survival and overall survival compared with patients who had BCR-ABL transcript levels ≤10% at three months. Fewer patients in the Tasigna arm versus the Glivec arm had BCR-ABL transcript levels >10% at three and six months. Early molecular response at three and six months correlated with future MMR and MR4.5 as well as an increased probability of progression-free survival and overall survival(7).

The four-year ENESTnd update found continued significantly higher rates of MMR, MR4 and MR4.5 by three years were achieved in Tasigna versus Glivec-treated patients. The difference in the rates of both MR4 and MR4.5 continued to be significantly higher for Tasigna, with the difference in favor of Tasigna increasing from year one to year four (MR4: 9-14% difference by one year, 17-24% difference by four years; MR4.5: 6-10% difference by one year, 14-17% difference by four years). Among patients who achieved MMR, more patients achieved MR4 or MR4.5 on Tasigna 300 mg twice daily (68%) and Tasigna 400 mg twice daily (62%) compared with Glivec (49%). No patient in any arm progressed after achieving MR4.5. Significantly fewer patients progressed to accelerated phase/blast crisis on Tasigna versus Glivec. Nearly twice as many patients had emergent mutations on Glivec (n=21) versus either Tasigna arm (n=11 in each arm), with five patients overall developing mutations between two and three years. Overall survival remained similar in all groups at three years, but fewer CML-related deaths occurred in both the Tasigna 300 mg twice daily (n=5) and 400 mg twice daily (n=4) arms versus Glivec (n=14). Both drugs were well tolerated. Few new adverse events (AEs) and laboratory abnormalities were observed between two and three years. Rates of

discontinuation due to AEs were 10%, 14%, and 11% in the Tasigna 300 mg BID, Tasigna 400 mg BID, and Glivec arms, respectively(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. Take twice daily 12 hours apart. Do not take with food. No food to be consumed for 2 hours before or one hour after dosing. 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 suggest, commitment, exploring, should, encouraged, committed, plans, planned, or similar expressions, or by express or implied discussions regarding potential new indicati 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 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 and Glivec will achieve any particular levels of revenue in the future. In particular, management s expectations 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; 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 2011, the Group s continuing operations achieved net sales of USD 58.6 billion, while approximately USD 9.6 billion (USD 9.2 billion excluding impairment and amortization charges) was invested in R&D throughout the Group. Novartis Group companies employ approximately 127,000 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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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 10, 2012	By:	/s/ MALCOLM B. CHEETHAM
		Name:	Malcolm B. Cheetham
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