NOVARTIS AG
Form 6-K
January 20, 2012

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 January 20th 2012

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

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Switzerland

(Address of Principal Executive Offices)

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Form 20-F: x Form 40-F: o

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MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

CHMP recommends EU approval to update Novartis drug Glivec® label to include three year treatment for GIST patients after surgery

- *Opinion based on Phase III study showing 66% recurrence-free and 92% overall survival at five years after three years adjuvant Glivec in adults with KIT+ GIST*(1)

- *Glivec has helped transform treatment and outcomes in patients with KIT+ GIST since its first approval in the metastatic setting almost 10 years ago(2)*

Basel, January 20, 2012 Novartis announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion to update the Glivec® (imatinib)* label to include 36 months of treatment after surgery for adult patients with KIT (CD117)-positive gastrointestinal stromal tumors (GIST). This extended treatment regimen has been shown to improve recurrence-free survival and overall survival for KIT+ GIST patients(1).

The CHMP opinion was based on data from a multicenter, open-label, Phase III clinical trial. Results of the study, which were first presented in June 2011 at the American Society of Clinical Oncology plenary session, showed that at five years, 66% of patients taking Glivec for three years after surgery for KIT+ GIST remained free of cancer recurrence (primary endpoint), compared to 48% who had received Glivec for only one year after surgery ($p<0.0001$). In addition, at five years, 92% of patients taking Glivec for three years after surgery were alive (secondary endpoint) compared to 82% who had received Glivec for only one year after surgery ($p=0.019$)(1).

This CHMP positive opinion marks another major milestone in the evolution of GIST treatment, which began almost a decade ago with the introduction of Glivec in the metastatic setting, said Hervé Hoppenot, President, Novartis Oncology.

Gastrointestinal stromal tumors are a rare, life-threatening cancer of the gastrointestinal tract. The major cause of GIST is an abnormal form of the protein KIT which causes cells to grow uncontrollably and become cancerous(3). Patients with KIT+ GIST are at risk of recurrence following complete resection of primary GIST(4).

Applications are also underway for Glivec label updates in the United States and worldwide. In addition, in August 2011 the US National Comprehensive Cancer Network (NCCN) updated its clinical practice guidelines to recommend consideration of at least three years of adjuvant therapy with Glivec for patients with high-risk GIST.

Study details

The SSG XVIII clinical trial was conducted by the Scandinavian Sarcoma Group (SSG) and the Sarcoma Group of the Arbeitsgemeinschaft Internistische Onkologie (AIO). This trial was a multicenter, prospective, randomized study for the evaluation of adjuvant treatment with Glivec of histologically confirmed KIT+ GIST with an estimated risk of

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

GIST recurrence of greater than 50% despite complete removal of all macroscopic GIST tissue at surgery(5).

The primary endpoint of the study was to compare, within the first five years, recurrence-free survival in patients with a greater than 50% estimated risk of GIST disease recurrence, following diagnosis and treatment with adjuvant Glivec for either 12 or 36 months. The secondary endpoints included overall survival and treatment safety(1).

Four hundred patients entered the study and the median follow-up was 54 months. Recurrence-free survival was longer in the 36-month group compared to the 12-month group (HR 0.46, 95% CI 0.32-0.65; p<0.0001; five-year recurrence-free survival 66% vs. 48%, respectively). Patients assigned to 36 months of Glivec after surgery had longer overall survival (HR 0.45, 95% CI 0.22-0.89; p=0.019; five-year overall survival 92% vs. 82%, respectively). Almost all patients experienced side effects while taking Glivec. Glivec was generally well tolerated. The proportion of patients who discontinued Glivec during the assigned treatment period for reasons other than GIST recurrence was 26% over the full 3 year treatment period in the 36-month group and 13% in the 12-month group(1).

Novartis provided the study drug and supported the study financially. Additional financing was received from the Academy of Finland, Cancer Society of Finland, Sigrid Juselius Foundation and Helsinki University Research Funds.

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 recommends or similar expressions, or by express or implied discussions regarding potential new indications or labeling for Glivec or regarding potential future revenues from 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 Glivec to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Glivec will be approved for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that Glivec will achieve any particular levels of revenue in the future. In particular, management s expectations regarding 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; 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.

Novartis is on Twitter. Sign up to follow @Novartis at http://twitter.com/novartis.

References

(1) Joensuu H, et al. Twelve vs. 36 months of adjuvant imatinib (IM) as treatment of operable GIST with a high risk of recurrence: Final results of a randomized trial (SSGXVIII/AIO). 47th Annual Meeting of the American Society of Clinical Oncology. Abstract No. LBA1. June 5, 2011.

(2) National Comprehensive Cancer Network (NCCN): Clinical Practice Guidelines in Oncology: Soft Tissue.

(3) American Cancer Society. Cancer Reference Information. Detailed Guide for Gastrointestinal Stromal Tumors. http://www.cancer.org/acs/groups/cid/documents/webcontent/003103-pdf.pdf.

(4) DeMatteo RP, Lewis JJ, Leung D, Mudan SS, Woodruff JM, Brennan MF. Two hundred gastrointestinal stromal tumors: recurrence patterns and prognostic factors for survival. Ann Surg. 2000 Jan;231(1):51-8.

(5) Study Comparing 12 Months Versus 36 Months of Imatinib in the Treatment of Gastrointestinal Stromal Tumor (GIST). Available at: http://clinicaltrials.gov/show/NCT00116935. Accessed on January 9, 2012.

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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: January 20th 2012

By: /s/ MALCOLM B. CHEETHAM

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