NOVARTIS AG
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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 27, 2012

(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

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MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

European Commission approves new label for Novartis drug Glivec® extending adjuvant therapy to three years for certain GIST patients

- *Approval based on Phase III study showing significant recurrence-free and overall survival after three years of adjuvant Glivec in adults with KIT+ GIST(1)*

- *Adults with KIT+ GIST are at risk of recurrence following surgical removal of the primary tumor; extended treatment may delay onset of recurrence(2)*

- *Glivec is the only available therapy in the EU for the treatment of post-surgical KIT+ GIST*

Basel, February 27, 2012 Novartis announced today that the European Commission (EC) has approved an update to the Glivec® (imatinib)* label to include 36 months of treatment after surgery for adults with KIT (CD117)-positive gastrointestinal stromal tumors (GIST) who met the inclusion criteria of the pivotal study. This extended treatment regimen has been shown to improve recurrence-free survival and overall survival for these patients with KIT+ GIST compared to patients who received 12 months of treatment after surgery(3).

Adults with KIT+ GIST are at risk of recurrence following surgical removal of the primary tumor. Although complete surgical removal is possible in most patients with KIT+ GIST, many patients develop tumor recurrence or metastasis following surgery and survival following recurrence is poor*(2)*. The newly updated label states that treatment with Glivec beyond 36 months may delay the onset of tumor recurrences further, while noting that an effect on overall survival has not been determined.

The EC decision follows a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) and applies in all 27 European Union (EU) member states, plus Norway and Iceland. Approval was based on data from an international, multicenter, open-label, Phase III clinical trial first presented at the 47th Annual Meeting of the American Society of Clinical Oncology (ASCO) plenary session in June 2011(1).

Results of the study showed that at five years, 66% of patients taking Glivec for three years after surgery for KIT+ GIST remained free of cancer recurrence 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 compared to 82% who had received Glivec for only one year after surgery ($p=0.0187$)(3).

This approval marks a key milestone in advancing the post-surgical treatment of GIST for certain patients in Europe, where Glivec is the only available therapy in this setting, said Hervé Hoppenot, President, Novartis Oncology. With this clinical evidence, physicians now have a strong basis for recommending three years of treatment for these patients with KIT+ GIST after surgery.

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

Gastrointestinal stromal tumors, or GIST, are a rare, life-threatening cancer of the gastrointestinal tract. They are often difficult to diagnose and to treat because they may not cause any physical symptoms(4). In the EU, the incidence of GIST is estimated to be more than 5,000 cases each year(5),(6).

Study details

This multicenter, prospective, randomized study for the evaluation of adjuvant treatment with Glivec of histologically confirmed KIT+ GIST was conducted by the Scandinavian Sarcoma Group (SSG) and the Sarcoma Group of the Arbeitsgemeinschaft Internistische Onkologie (AIO)(5).

The primary endpoint 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). Inclusion criteria for risk of recurrence was defined as tumor diameter >5.0 cm and mitotic count >5/50 high power fields (HPFs); or tumor diameter >10.0 cm, any mitotic count; or tumor of any size with a mitotic count >10/50 HPFs; or tumors ruptured into the peritoneal cavity.

Three hundred ninety-seven patients entered the study and the median follow-up was 54 months, from date of randomization to data cut-off. Recurrence-free survival was significantly 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 had significantly longer overall survival (HR 0.45, 95% CI 0.22-0.89; p=0.0187; 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% in the 36-month group and 13% in the 12-month group(1).

Novartis provided the study drug and supported the study financially. Additional funding 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.

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. Glivec should be taken with food and a large glass of water.

Please see full Prescribing Information.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as may, recommending, 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 additional markets. 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; government, industry and general public pricing pressures; competition in general; 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 124,000 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. Version 2, 2011.

(3) Glivec (imatinib) prescribing information. Basel, Switzerland: Novartis International AG.

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

(5) The World Factbook. European Union Population. CIA.gov; July 2010. Available from: https://www.cia.gov/library/publications/the-world-factbook/geos/ee.html. Accessed February 2012.

(6) Joensuu H. Current perspectives on the epidemiology of gastrointestinal stromal tumors. European Journal of Cancer Supplements. March 2006; Volume 4, Issue 3: 4-9.

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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: February 27, 2012

By: /s/ MALCOLM B. CHEETHAM

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