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Novartis drug Gleevec® shows significant overall survival benefit for patients with GIST after three years of adjuvant treatment vs. one year

- *Data show 66% recurrence-free survival and 92% overall survival at five years following three years of adjuvant therapy with Gleevec in patients with resected KIT+ GIST*[1]
- *First large Phase III clinical trial to demonstrate survival benefits of extended treatment with Gleevec for three years compared to one year following surgery*[1]
- *Important finding for treatment of GIST patients who are at risk of recurrence following complete resection of primary tumor*

East Hanover, N.J., June 5, 2011 — Novartis announced new data today showing a significant improvement in both recurrence-free survival and overall survival for patients taking Gleevec® (imatinib mesylate)* tablets for three years after surgery to remove KIT (CD117)-positive gastrointestinal stromal tumors (KIT+ GIST) compared to one year of treatment. These data will be presented at the 47th American Society of Clinical Oncology (ASCO) plenary session on Sunday, June 5.

The results show that at five years 66% of patients taking Gleevec for three years remained free of cancer recurrence (primary endpoint) compared to 48% who had received Gleevec for only one year ($p<0.0001$). Moreover, 92% of patients taking Gleevec for three years were alive (secondary endpoint) compared to 82% who had received Gleevec for only one year ($p=0.019$)[1]. Median patient follow-up was 54 months.

The 400-patient Phase III trial, conducted by the Scandinavian Sarcoma Group (SSG) and the Sarcoma Group of the Arbeitsgemeinschaft Internistische Onkologie (AIO), is the first prospective multicenter clinical trial to demonstrate a survival benefit of adjuvant Gleevec therapy for KIT+ GIST with extended three years of therapy relative to one year of therapy. The side effect profile in the clinical trial was consistent with that reported in previous studies with Gleevec.

“This study confirms the hypothesis that extending the duration of Gleevec treatment for patients following surgery improves recurrence-free survival. For the first time, an effect on overall survival was found,” said Heikki Joensuu, M.D., Ph.D., Professor, Oncology, University of Helsinki and principal investigator of the study. “Results from this trial may positively impact clinical practice by helping physicians create the optimal treatment plan for patients with operable KIT+ GIST.”

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[2], which causes cells to

* Known as Glivec® (imatinib) outside the US, Canada and Israel.

grow uncontrollably and become cancerous. Patients with GIST are at risk of recurrence following complete resection of primary GIST[3].

“Over the past nine years Gleevec has provided KIT+ GIST patients with the first effective drug treatment option in the metastatic setting and later in the adjuvant setting,” said Hervé Hoppenot, President, Novartis Oncology. “Now we see exciting new data showing that by extending post-surgical treatment duration to three years, Gleevec has significant impact on overall survival in patients with KIT+ GIST. This is important news for GIST patients and the GIST community.”

Study details
The SSG XVIII clinical trial was conducted by the SSG and the Sarcoma Group of the AIO. SSG XVIII is a multicenter, prospective, randomized study for the evaluation of adjuvant treatment with Gleevec of histologically verified KIT+ GIST with a greater than 50% risk of GIST recurrence despite complete removal of all macroscopic GIST tissue at surgery[4].

The primary endpoint of the study was to compare the recurrence-free survival in GIST patients with a greater than 50% estimated risk of disease recurrence within the first five years following the diagnosis and treatment with adjuvant Gleevec for 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 Gleevec had longer overall survival (HR 0.45, 95% CI 0.22-0.89; p=0.019; five-year overall survival 92% vs. 82%, respectively). Gleevec was generally well-tolerated. The proportion of patients who discontinued Gleevec 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].

About Gleevec
Gleevec® (imatinib mesylate) tablets are indicated for the treatment of patients with KIT (CD117)–positive gastrointestinal stromal tumors (KIT+ GIST) that are cancerous, cannot be surgically removed and/or have spread to other parts of the body and use after surgery in patients that have had their KIT+ GISTs completely removed. Approval is based on survival without a return of cancer (recurrence-free survival) with a median follow-up of 14 months. Clinical benefit has not been demonstrated by a long term effect on recurrence-free survival or survival.

Gleevec Important Safety Information
Gleevec can cause fetal harm when administered to a pregnant woman. Women should not become pregnant and should be advised of the potential risk to the unborn child.

Gleevec is often associated with edema (swelling) and serious fluid retention. Studies have shown that edema (swelling) tended to occur more often among patients who are 65 and older or those taking higher doses of Gleevec.

Cytopenias (reduction or lack of certain cell elements in blood circulation), such as anemia, have occurred. If the cytopenia is severe, your doctor may reduce your dose or temporarily stop your treatment with Gleevec.

Severe congestive heart failure and left ventricle dysfunction have been reported, particularly in patients with other health issues and risk factors. Patients with heart disease or risk factors will be monitored and treated for the condition.

Severe liver problems (hepatotoxicity) may occur. Cases of fatal liver failure and severe liver injury requiring liver transplants have been reported with both short-term and long-term use of Gleevec.

Bleeding may occur. Severe gastrointestinal (GI) bleeding has been reported in patients with KIT+ GIST. GI tumor sites may be the cause of this bleeding.

In patients with hypereosinophilic syndrome (a condition with increased eosinophils, which are a type of white blood cell) and heart involvement, cases of heart disease (cardiogenic shock/left ventricular dysfunction) have been associated with the initiation of Gleevec therapy.

Skin reactions, such as fluid-filled blisters, have been reported with the use of Gleevec. Clinical cases of hypothyroidism (reduction in thyroid hormones) have been reported in patients taking levothyroxine replacement with Gleevec.

Long-term use may result in potential liver, kidney and/or heart toxicities; immune system suppression may also result from long-term use.

GI perforation (small holes or tears in the walls of the stomach or intestine), in some cases fatal, has been reported.

Growth retardation has been reported in children taking Gleevec. The long-term effects of extended treatment with Gleevec on growth in children are unknown.

Cases of tumor lysis syndrome, which refers to a metabolic and electrolyte disturbance caused by the breakdown of tumor cells, have been reported and can be life-threatening in some cases.

Almost all patients with KIT+ GIST treated with Gleevec experience side effects at some time. Some common side effects you may experience are fluid retention, muscle cramps or pain and bone pain, abdominal pain, loss of appetite, vomiting, diarrhea, decreased hemoglobin, abnormal bleeding, nausea, fatigue and rash.

Gleevec is sometimes associated with stomach or intestinal irritation. Gleevec should be taken with food and a large glass of water to minimize this problem. There have been rare reports, including deaths, of stomach or intestinal perforation (a small hole or tear).

If you are experiencing any of the mentioned side effects, please be sure to speak with your doctor immediately.

Do not take any other medications without talking to your doctor or pharmacist first, including Tylenol® (acetaminophen); herbal products (St. John's wort, Hypericum perforatum); Coumadin® (warfarin sodium); rifampin; erythromycin; metoprolol; ketoconazole; and Dilantin® (phenytoin). Taking these with Gleevec may affect how they work, or affect how Gleevec works.

You should also tell your doctor if you are taking or plan to take iron supplements. Patients should also avoid grapefruit juice and other foods that may affect how Gleevec works.

Please see full Prescribing Information.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as “will,” “may,” or similar expressions, or by express or implied discussions regarding potential new indications or labeling for Gleevec or regarding potential future revenues from Gleevec. 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 Gleevec to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Gleevec will be submitted or approved for any additional indications or labeling in any market. Nor can there be any guarantee that Gleevec will achieve any particular levels of revenue in the future. In particular, management’s expectations regarding Gleevec 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; 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

Located in East Hanover, New Jersey, Novartis Pharmaceuticals Corporation is an affiliate of Novartis AG, which 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, eye care, cost-saving generic pharmaceuticals, consumer health products, preventive vaccines and diagnostic tools. Novartis is the only 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. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 119,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit http://www.us.novartis.com.

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