Glivec® sets new treatment standard in chronic myeloid leukemia with high overall survival, increasing response and decreasing progression

- Nearly 90% of patients with Philadelphia chromosome-positive CML alive at five years with new analysis showing less than 5% mortality due to CML
- Response rate to Glivec increases substantially over five years in landmark IRIS study, the largest ever conducted in CML patients
- Yearly rate of progression to more advanced disease continues to drop the longer patients take Glivec, falling to 0.6% in fifth year

Basel, June 3, 2006 – Response rates to Glivec® (imatinib)* continue to increase substantially over time while the yearly risk of progression to advanced disease continues to decline the longer patients take the medicine, according to five-year data from a landmark study in patients with a form of life-threatening chronic myeloid leukemia.

Results of the International Randomized Interferon versus STI571 (IRIS) were presented today at the 2006 Annual Meeting of the American Society of Clinical Oncology.

Data from the IRIS study, the largest clinical trial to date for newly diagnosed adult patients with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase, showed the overall survival rate at five years to be 89.4% (range 86% to 92%) for patients receiving Glivec. This considers deaths from all causes, but only 4.6% of the patients died from causes related to their leukemia. Before Glivec was available, about 50% of patients progressed to the more advanced stages of Ph+ CML after only three to five years, and survival was generally short for those patients.

The results of this Phase III trial, which was started in June 2000, also showed that the number of patients with a complete cytogenetic response increased from 69% to 87% between the first and fifth years of treatment. Moreover, the yearly risk of progressing to advanced disease continued to decline — to 0.6% in the fifth year.

“Very few oncology medicines offer patients the opportunity to achieve better outcomes the longer they take the therapy,” said David Epstein, President of Novartis Oncology. “That Glivec demonstrates these significant improvements with long-term use is a good sign science will provide the path to turn lethal cancers into potentially manageable conditions with durable, well-tolerated targeted therapies.”

An estimated 93% of Glivec patients in the early, chronic phase of CML did not progress to the rapidly lethal advanced stages of the disease, and an estimated 83% survived with no evidence of disease progression at all at the five-year follow-up.

IRIS study details

* Known as Gleevec® (imatinib mesylate) tablets in the US
The International Randomized Interferon versus STI571 (IRIS) study is an open-label Phase III clinical trial enrolling 1,106 newly diagnosed patients with Ph+ CML in chronic phase in 177 centers across 16 countries. There are two arms to the study: one group of patients receiving Glivec 400 mg per day and another receiving a target dose of interferon (IFN) of 5 MIU/m2/day in combination with Ara-C 20 mg/m2/day for 10 days each month. Because of tolerability reasons or lack of response to treatment, 69% of patients in the IFN/Ara-C arm crossed over to the Glivec arm, whereas only 3% of patients in the Glivec arm crossed over to the IFN/Ara-C arm.

Cumulative best responses to Glivec treatment improved significantly between the first and fifth years of treatment. Over the period, complete hematologic responses rose from 96% to 98%, major cytogenetic responses rose from 85% to 92% and complete cytogenetic responses rose from 69% to 87%.

In a complete hematologic response, the patient’s blood cell counts return to normal. Cytogenetic response refers to the disappearance or reduction of the number of Ph+ cells detectable by standard lab methods.

Glivec continued to be generally well tolerated as initial drug therapy for Ph+ CML at the five-year follow-up. See “Glivec contraindications, warnings and adverse events” for details.

About Glivec
First launched in 2001 and now available in more than 80 countries, Gleevec is a signal transduction inhibitor approved to treat Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML). It is one of the first oncology drugs that validate rational drug design based on an understanding of how some cancer cells work. This product, known as Gleevec in the US and as Glivec in other markets, is approved in more than 90 countries including the US, EU and Japan for the treatment of all phases of Ph+ CML.

The effectiveness of Glivec is based on overall hematologic and cytogenetic response rates and progression-free survival in CML. There are no controlled trials demonstrating increased survival.

Glivec contraindications, warnings and adverse events*
The majority of patients treated with Glivec experienced adverse events at some time. Most events were of mild to moderate grade and treatment was discontinued for adverse events only in 2% of patients in chronic phase, 3% in accelerated phase and 5% in blast crisis. The most common side effects included nausea, superficial edema, muscle cramps, skin rash, vomiting, diarrhea, hemorrhage, fatigue, headache, joint pain, cough, dizziness, dyspepsia and dyspnea, as well as neutropenia and thrombocytopenia.

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.

The foregoing release contains forward-looking statements that can be identified by terminology such as “increases substantially over five years,” “Yearly rate of progression,” “increase substantially over time,” “yearly risk of progression to advanced disease,” “long-term use,” “will,” or similar expressions, or by express or implied discussions regarding potential future sales of Glivec, or regarding the long-term impact of a patient's use of Glivec. Such forward-looking statements 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 achieve any particular levels of sales. Neither can there be any guarantee regarding the long-term impact of a patient's use of Glivec. In particular, management's expectations regarding Glivec could be affected by, among other things, unexpected clinical trial results, including new clinical data, and

* Numbers indicate the range in percentages in four studies among patients with CML in blast crisis, accelerated phase and chronic phase.
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
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general public pricing pressures; and other risks and factors referred to in the Company’s current
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and net income of USD 6.1 billion. Approximately USD 4.8 billion was invested in R&D.
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