Novartis Pharmaceuticals Corporation
One Health Plaza
East Hanover, NJ 07936-1080
http://www.pharma.us.novartis.com

NOVARTIS

MEDIA RELEASE • MEDIA RELEASE • MEDIA RELEASE

EMBARGOED UNTIL MONDAY, June 4 at 10:15 am CDT

Study shows one year of Gleevec® reduces risk of cancer returning by 82 percent following surgery for gastrointestinal stromal tumors

- *Authors suggest highly significant findings could lead to change in clinical practice recommendations*
- *Results prompted study organizers to offer Gleevec to patients on placebo*
- *Global regulatory submissions in adjuvant GIST planned for early 2008*

East Hanover, June 4, 2007 – Study results presented today show one year of treatment with Gleevec® (imatinib mesylate)* dramatically reduced the risk of cancer returning by 82 percent in patients with Kit-positive gastrointestinal stromal tumors (GIST), when given following surgery to remove primary tumors.

New data from the international clinical trial, sponsored by the US National Cancer Institute (NCI), were presented at the 43rd American Society of Clinical Oncology's annual meeting in Chicago.

Researchers found that out of 644 patients with primary resectable GISTs, 97 percent of those who received Gleevec after surgery were alive after one year with no sign of the cancer coming back, compared to 83 percent of patients who received placebo ($p<0.001$). After two years, 90 percent of Gleevec patients were alive without any sign of the cancer returning compared to 71 percent of patients receiving placebo.

"This highly significant result could prompt re-evaluation of clinical practice recommendations for management of intermediate- and high-risk primary resectable GISTs," said principal investigator Ronald DeMatteo, MD, Memorial Sloan-Kettering Cancer Center, New York, NY. "Conventional chemotherapy agents have been notoriously ineffective in GIST. This study demonstrated for the first time that targeted molecular therapy reduces the rate of recurrence after complete removal of a primary GIST."

The committee overseeing the trial halted further enrolment in April 2007 because the primary endpoint of increasing recurrence-free survival had been met. Patients in the study who were being treated with placebo were offered one year of Gleevec treatment.

Novartis expects to file global regulatory submissions for use of Gleevec as adjuvant therapy in GIST patients following surgery to remove primary tumors by early 2008.

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

Gastrointestinal stromal tumors belong to a group of cancers known as soft tissue sarcomas that usually arise from the intestinal tract, with the most common site being the stomach followed by the small intestine. Estimates of the incidence of GIST in the US vary, but experts believe there are between 1,500 and 6,000 new cases each year. Although surgery cures some patients with GIST, the recurrence rate is high.

"These results provide compelling evidence that Gleevec may dramatically improve treatment for patients across the spectrum of this disease," said Diane Young, MD, Head of Global Medical Affairs at Novartis Oncology. "In keeping with our commitment to providing useful medicines to patients with critical unmet medical needs, we are working closely with the investigators and will prepare regulatory submissions to gain approval for Gleevec as adjuvant treatment for GIST."

Patients participated through one of five NCI-sponsored North American Cooperative Oncology Groups, led by the American College of Surgeons Oncology Group and including Cancer and Leukemia Group B, Eastern Cooperative Oncology Group, Southwest Oncology Group, and the National Cancer Institute of Canada Clinical Trials Group.

Gleevec therapy was generally well tolerated by most patients in the adjuvant GIST study, with side effects similar to those observed in other GIST clinical trials with Gleevec including (but not limited to) nausea, diarrhea and swelling (edema).

Gleevec is indicated for the treatment of patients with Kit (CD117)-positive unresectable and/or metastatic malignant gastrointestinal stromal tumors. The effectiveness of Gleevec in GIST is based on objective response rate. There are no controlled trials demonstrating a clinical benefit, such as improvement in disease-related symptoms or increased survival.

Novartis supplied Gleevec for use in the study, and also provided partial funding under a Cooperative Research and Development Agreement with NCI to support the clinical development of Gleevec.

About Gleevec

Gleevec (imatinib mesylate) is indicated for the treatment of patients with KIT (CD117)-positive unresectable and/or metastatic malignant gastrointestinal stromal tumors (GIST). The effectiveness of Gleevec in GIST is based on objective response rate. There are no controlled trials demonstrating a clinical benefit, such as improvement in disease-related symptoms or increased survival.

Gleevec contraindications, warnings and adverse events

Severe (NCI Grades 3/4) lab abnormalities (400 mg/day; 600 mg/day)—including neutropenia (10%; 11%), anemia (3%; 9%), thrombocytopenia (0%; 1%), and hepatotoxicity (6%; 8%)—and severe adverse experiences (NCI Grades 3/4), including severe fluid retention (eg, pleural effusion or ascites; 3%; 8%) and superficial edema (6%; 5%), hemorrhage (6%; 11%), abdominal pain (11%; 4%), nausea (6%; 4%), diarrhea (3%; 7%), and musculoskeletal pain (6%; 1%) were reported among patients receiving Gleevec.

Some patients (5%) were reported to have severe gastrointestinal (GI) bleeds and/or intratumoral bleeds. GI tumor sites may have been the source of GI bleeds.

Patients should be weighed and monitored regularly for signs and symptoms of edema, which can be serious or life-threatening. There have also been reports, including fatalities, of cardiac tamponade, cerebral edema, increased intracranial pressure, papilledema, and gastrointestinal (GI) perforation.

Severe congestive heart failure and left ventricular dysfunction have occasionally been reported. Most of the patients with reported cardiac events have had other comorbidities and risk factors, including advanced age and previous medical history of cardiac disease. Patients with cardiac disease or risk factors for cardiac failure should be monitored carefully, and any patient with signs or symptoms consistent with cardiac failure should be evaluated and treated.

Bullous dermatologic reactions (eg, erythema multiforme and Stevens-Johnson syndrome) have also been reported. In some cases, the reaction recurred upon rechallenge. Several postmarketing reports describe patients able to tolerate the reintroduction of Gleevec at a lower dose with or without concomitant corticosteroids or antihistamines following resolution or improvement of the bullous reaction.

Dose adjustments may be necessary due to hepatotoxicity, other nonhematologic adverse events, or hematologic adverse events. Therapy with Gleevec was discontinued for adverse events in 5% of patients at both dose levels studied.

Patients with severe hepatic impairment should be treated at a starting dose of 300 mg/day and should be closely monitored.

Gleevec is metabolized by the CYP3A4 isoenzyme and is an inhibitor of CYP3A4, CYP2D6, and CYP2C9. Dosage of Gleevec should increase by at least 50%, and clinical response should be carefully monitored, in patients receiving Gleevec with a potent CYP3A4 inducer such as rifampin or phenytoin. Examples of commonly used drugs that may significantly interact with Gleevec include acetaminophen, warfarin, erythromycin, and phenytoin. (Please see full Prescribing Information for other potential drug interactions).

For daily dosing of 800 mg and above, dosing should be accomplished using the 400 mg tablet to reduce exposure to iron.

Use of Gleevec tablets is contraindicated in patients with hypersensitivity to imatinib or to any other component of Gleevec tablets.

Women of childbearing potential should be advised to avoid becoming pregnant while taking Gleevec tablets and should be advised to avoid breast-feeding while taking Gleevec tablets because of the potential for serious adverse reactions in nursing infants.

Common Side Effects of Gleevec Tablets

The majority of patients who received Gleevec in the GIST study experienced adverse events at some time. Most adverse events were mild to moderate in severity. The most frequently reported adverse events (400 mg/day; 600 mg/day) (all Grades) were superficial edema (81%; 77%), nausea (63%; 74%), muscle cramps (47%; 58%), diarrhea (59%; 70%), fatigue (48%; 53%), abdominal pain (40%; 37%), rash and related terms (38%; 53%), vomiting (38%; 35%) musculoskeletal pain (37%; 30%), and hemorrhage (26%; 34%).[*]

Supportive care may help management of some mild to moderate adverse events so that the prescribed dose can be maintained whenever possible. However, in some cases, either a dose reduction or interruption of treatment with Gleevec may be necessary.

Gleevec tablets should be taken with food and a large glass of water to minimize GI irritation. Gleevec tablets should not be taken with grapefruit juice.

[*] For more detailed study information please see full Prescribing Information.

Disclaimer

The foregoing release contains forward-looking statements that can be identified by terminology such as “suggest,” “could,” “planned,” “expects,” “usually,” “estimates,” “believe,” “may,” “will,” or similar expressions, or by express or implied discussions regarding potential new indications for Gleevec or potential future sales of Gleevec, or regarding the long-term impact of a patient's use of Gleevec. Such forward-looking statements 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 approved for any additional indications in any market. Nor can there be any guarantee that Gleevec will achieve any particular level of sales. Neither can there be any guarantee regarding the long-term impact of a patient's use of Gleevec. In particular, management's expectations regarding commercialization of Gleevec could be affected by, among other things, unexpected clinical trial results, including additional analysis of Gleevec clinical data or new clinical data; unexpected regulatory actions or delays or government regulation generally; competition in general; government, industry, and general public pricing pressures; the company's ability to obtain or maintain patent or other proprietary intellectual property protection; and other risks and factors referred to in the Company'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 this information as of this date and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

About Novartis

Novartis AG (NYSE: NVS) is a world leader in offering medicines to protect health, cure disease and improve well-being. Our goal is to discover, develop and successfully market innovative products to treat patients, ease suffering and enhance the quality of life. We are strengthening our medicine-based portfolio, which is focused on strategic growth platforms in innovation-driven pharmaceuticals, high-quality and low-cost generics, human vaccines and leading self-medication OTC brands. Novartis is the only company with leadership positions in these areas. In 2006, the Group’s businesses achieved net sales of USD 37.0 billion and net income of USD 7.2 billion. Approximately USD 5.4 billion was invested in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 100,000 associates and operate in over 140 countries around the world. For more information, please visit http://www.novartis.com.

# # #

Novartis Media Relations

Media only:
Geoffrey Cook
Novartis Oncology
P: +1 862 778 5587
F: +1 773 781 2074

Dana Kahn Cooper
P: +1 732 817 1800
F: +1 732 817 1834

Véronique Boissonnas
Ruder Finn
P: +1 212 593 6396
F: +1 646 792 4415

Investors only:
Jill Pozarek
Novartis Corporation
P: +1 212 830 2445