

Title:

Cancer Therapies Right On Target

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Summary:

With today's new advancements in prevention, detection and treatment, a diagnosis of cancer no longer necessarily means facing a terminal disease.

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Article Body:

Cancer has always been synonymous with loss and fear. With today's new advancements in prevention, detection and treatment, a diagnosis of cancer no longer necessarily means facing a terminal disease. Rather, as new advances provide more treatment options, cancer increasingly takes on the shape of a chronic condition.

Recently, the National Cancer Institute (NCI) announced that leading cancer organizations report that Americans' risk of dying from cancer continues to decline, indicating that progress in prevention, early detection, and newer treatments appear to be helping in the fight against this disease.

The next revolution in cancer therapy will likely find its roots in the ongoing Cancer Genome Atlas (TCGA), a pilot project initiated by the National Cancer Institute (NCI) and the National Human Genome Research Institute (NHGRI). Scientists have begun to discover that numerous genes play a role in cancer, but they have only uncovered a small portion of these genes. The Cancer Genome Atlas is aimed at helping to accelerate the understanding of the genetic make-up of cancer. Researchers hope that a better understanding of how cancer develops and spreads, will lead to new tests to detect cancer in its early, most treatable stages; new therapies to target cancer; and, ultimately, new strategies to prevent cancer.

Understanding of the genetic basis for cancer has already allowed researchers to develop the first drugs that target faulty genes, which are making a difference in the lives of patients. Just ask Bob Ferber. In July of 1999, the Los Angeles attorney was diagnosed with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML), a malignant cancer of the bone marrow and blood.

Ferber tried many futile attempts at treatment before entering a clinical trial for a drug now called Gleevec (imatinib mesylate) tablets to help fight his disease. Gleevec, approved by the FDA in 2001, is one of the first "targeted therapies" and works by turning off the specific cause of Ph+ CML, something The Cancer Genome Atlas hopes to make possible for many more cancers. Within months, Ferber's white blood cell counts were within normal range and his disease was in remission.

"My CML diagnosis was a real scare. But, I'm grateful now. I'm grateful for every new day I have."

Sadly, not everyone's story is as positive as Ferber's. Hopefully, with the continued advancement of cancer awareness and research, preventative treatment and The Cancer Genome Atlas, cancer patients will one day be able to breathe a sigh of relief and agree with Ferber when he says, "Every time I challenge this cancer, emotionally or physically-and survive-that's a victory for me."

Researchers have developed the first cancer-fighting drugs that target faulty genes.

Note to Editors: About Gleevec Tablets: Gleevec (imatinib mesylate) tablets are indicated for the treatment of newly diagnosed adult patients with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase. Follow-up is limited. Gleevec tablets are also indicated for the treatment of patients with Ph+ CML in blast crisis, in accelerated phase or in chronic phase after failure of interferon-alpha (IFN-a) therapy.

Important Safety Information1: Severe (NCI Grades 3/4) neutropenia (3%#8722;48%), anemia (<1%#8722;42%), thrombocytopenia (<1%#8722;33%), hemorrhage (1%#8722;19%), fluid retention (<1%#8722;8%) (eg, pleural effusion, pulmonary edema, and ascites) and superficial edema (1%#8722;6%), musculoskeletal pain (1%#8722;9%), and hepatotoxicity (3%#8722;8%) were reported among Gleevec® recipients. 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 perforation. Bullous dermatologic reactions (eg, erythema multiforme and Stevens-Johnson syndrome) have also been reported. In some cases, the reaction recurred upon rechallenge. Several foreign postmarketing cases note a resolution or improvement of bullous reaction following dose reduction with or without supportive care. 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 3% to 5% of patients. Patients with severe hepatic impairment should be treated at a starting dose of 300mg/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 Tablets should increase by at least 50% and clinical response should be carefully monitored in patients receiving Gleevec Tablets 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 enclosed full prescribing information for other potential drug interactions. For daily dosing of 800mg and above, dosing should be accomplished using the 400mg tablets 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. Because of the potential for serious adverse reactions in nursing infants, women should be advised to avoid breast-feeding while taking Gleevec Tablets.

Common Side Effects of Gleevec Tablets<sup>1</sup>: The majority of the approximately 1700 adult patients who received Gleevec in clinical studies experienced adverse events at some time, but most were mild to moderate in severity. The most frequently reported adverse events were superficial edema (58%#8722;81%), nausea (47%#8722;74%), diarrhea (39%#8722;70%), muscle cramps (28%#8722;62%), vomiting (21%#8722;58%), rash (36%#8722;53%), fatigue (30%#8722;53%), musculoskeletal pain (30%#8722;49%), and abdominal pain (30%#8722;40%).\* Supportive care may help management of most mild-to-moderate adverse events so that prescribed dose can be maintained whenever possible. Gleevec tablets should be taken with food and a large glass of water to minimize gastrointestinal (GI) irritation. Gleevec tablets should not be taken with grapefruit juice.

1 Gleevec® (imatinib mesylate) tablets prescribing information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; 2005.

\* Numbers indicate the range of percentages in 4 studies among adult patients with Ph+ CML in blast crisis, accelerated phase, and chronic phase.

