



FDA Approves New Drug for Gastrointestinal Stromal Tumors

On February 1, the U.S. Food and Drug Administration (FDA) approved Gleevec™ (imatinib mesylate, Novartis Pharmaceuticals, Basel, Switzerland) for the treatment of patients with metastatic or unresectable malignant gastrointestinal stromal tumors (GIST).

Gleevec was assessed in a single, open-label randomized trial at one center in Finland and three centers in the United States. A total of 147 patients were enrolled, with 73 randomized to receive 400 mg of Gleevec daily and 74 randomized to receive 600 mg daily. At the cutoff date for the study report, an overall objective response was confirmed in

56 patients, for an overall response rate of 38% (95% confidence interval 30%, 46%). These were all partial responses, and no complete responses were observed. The study was not powered to show a statistically significant difference in response rate between the two dose groups.

Most adverse side effects were of mild to moderate severity and included interstitial edema, fluid retention (i.e., ascites, pleural effusion), nausea, vomiting, diarrhea, myalgias, skin rash, bone marrow suppression, bleeding, and elevations in serum glutamic oxaloacetic transaminase, serum glutamic pyruvic transaminase, or bilirubin. Hemorrhagic

events included bleeding into the gastrointestinal tract or tumor sites, which occurred in seven patients (5%) and was not correlated with thrombocytopenia or tumor bulk. Adverse events were similar in patients receiving Gleevec 400 or 600 mg daily, in males and females, and in patients older or younger than age 65. The approved dose for the treatment of patients with GIST is 400 or 600 mg daily.

For full prescribing information, including clinical trial information, safety, dosing, drug interactions, and contraindications, visit www.fda.gov/cder/foi/label/2002/21335s11bl.pdf.

Steps Taken to Ensure Narcotics' Availability for Legitimate Use

Efforts to control the abuse of narcotic pain medications should not prevent their legitimate use by pain sufferers, the head of the Drug Enforcement Administration (DEA) announced at a Washington press conference last fall.

DEA Administrator Asa Hutchinson and

21 healthcare and pain prevention organizations issued a joint statement that called for a balanced policy addressing the availability of prescription pain medications. The DEA monitors and regulates the use of legal controlled substances, and this collaboration marks the first of its kind to support better pain management.

Hutchinson said that patients with a legitimate need for prescription painkillers should not be "discouraged or afraid to use them." Physicians and pharmacists also should not be concerned about providing them when appropriate.

The DEA is taking steps that favor education over more or stricter regulations. Opioid analgesics are the most effective treatment options for some of the 50 million Americans who suffer from chronic pain.

However, as a result of heightened media reports of abuse, some healthcare providers are hesitant to provide the drugs, fearing regulatory scrutiny. The DEA's actions are making progress toward ensuring prescription painkillers are available to people who legitimately need them.

According to Hutchinson, some states have taken the DEA's efforts one step further, developing "monitoring tools" that law enforcement can use to track the drugs' uses. Fourteen states currently have drug-monitoring programs, where physicians and pharmacists notify a central registry each time they prescribe or dispense narcotic pain medications.

To view a copy of the joint statement, visit <http://lastacts.org/briefingoct01/Consensus.pdf>.

Did You Know?

- 41% of caregivers are caring for children under age 18 at the same time they care for an elderly relative or friend.
- The typical caregiver is a 46-year-old employed woman who spends 18 hours per week caring for a mother who lives nearby.
- The population of seniors in America is projected to more than double its current size over the next 30 years.
- If faced with a terminal illness, 96% of Americans would prefer to be cared for and die in their homes.
- 96,000 hospice volunteers work at hospitals throughout the United States.

Additional information can be found at www.lastacts.org.

Health Issues Postponed in U.S. Congress

The war on terrorism has drawn Congress's attention away from several healthcare issues that were top priorities before September 11. A Patients' Bill of Rights was nearing approval, with a Senate and House committee working out legal liability issues, the last major difference between the two bodies. Support of prescription drug coverage for Medicare beneficiaries was expected to add \$300 billion to the

budget to cover that expense. In addition, \$28 billion was being considered for America's uninsured, and the National Institute of Health's budget was proposed to double.

Currently, the talks about the Patients' Bill of Rights have been put off until later in the year, and budget priorities have changed as defense spending now is at the top of the list.