

## Postoperative adjuvant therapy for gastrointestinal stromal tumor

by David Ota, MD, FACS, Durham, NC; and Heidi Nelson, MD, FACS, Rochester, MN

Gastrointestinal stromal tumor (GIST) is a relatively uncommon tumor that affects approximately 5,000 people annually in the U.S. GIST develops in the stomach or intestinal tract and can metastasize to the abdomen or liver. Until the development of Gleevec™ (imatinib), there has been no therapy other than surgery for GIST. Surgical resection includes either a gastrectomy or intestinal resection, depending on tumor location. Recurrence is related to tumor size (greater than 3 cm in diameter) and tumor rupture at the time of surgical resection.

There is considerable interest in Gleevec, an antineoplastic drug that blocks a specific growth factor in GIST. There is relatively low toxicity associated with this targeted agent. Gleevec has been approved for the treatment of metastatic GIST, but it is not known if Gleevec is effective in a postoperative adjuvant setting in patients who have had a completely resected GIST. ACOSOG Z9001 is a trial designed to answer this question.

Z9001 is a phase III, double-blind, randomized trial in which patients who have had their GIST completely resected receive either Gleevec or placebo for one year. Primary endpoint is disease-free survival, and if

a patient relapses with disease, unblinding occurs and the patient is treated appropriately. There are no drug costs to the patients during protocol treatment. More than 620 patients have been enrolled in this trial, which has a target accrual of 803 patients. ACOSOG is interested in completing patient accrual by 2007.

ACOSOG needs your assistance to enroll patients in this trial. Eligible patients include those who have had an R0 or R1 resection of a GIST greater than 3 cm in diameter. There are more than 460 hospitals with approval from the Institutional Review Board (IRB) for this trial. A list of sites and investigators with IRB approval can be found at [\[trials.gov\]\(http://trials.gov\). Run a search query for Z9001. Eligibility criteria are listed on this Web page. If you have an eligible patient and do not have IRB approval at your hospital, please consider referring your patient to a nearby IRB-approved site listed on the Clinical Trials Web page.](http://www.clinical</a></p></div><div data-bbox=)

Z9001 is an important trial for a rare but treatable malignancy. We strongly encourage you to consider this trial for your patients.

**Disclosure:** Dr. Ota has served on the Novartis Femara Surgical Advisory Board and is principal investigator of a Novartis grant for Z9001.

*Dr. Ota and Dr. Nelson are ACOSOG Group Co-Chairs.*

### Trauma meetings calendar

The following continuing medical education courses in trauma are cosponsored by the American College of Surgeons Committee on Trauma and Regional Committees:

- **Advances in Trauma**, December 8–9, Kansas City, MO.
- **Trauma and Critical**

**Care—2007**, March 26–28, 2007, Las Vegas, NV.

Complete course information can be viewed online (as it becomes available) through the American College of Surgeons Web site at <http://www.facs.org/trauma/cme/traumtgs.html>, or contact the Trauma Office at 312/202-5342.