ACOSOG news: Clinical trials update

New trials highlight surgical innovations

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The American College of Surgeons Oncology Group (ACOSOG) is excited to offer several new trials with advancements in surgical innovations, including cryoablation for primary breast cancer, local excision plus neoadjuvant therapy for early rectal cancer.

Three times a year, we will summarize new concepts, new trials, and ongoing trial activity, both through ACOSOG and the Cancer Trials Support Unit (CTSU).

Future efforts will be directed toward creating dialogue between the American Col-

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**Figure 1—Z1052**

**Figure 2—Z4032**

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*Patients may be offered Z4031 if available at institution
*For patients with CT and/or PET suggesting N2 / N3 involvement
lege of Surgeons members and ACOSOG on surgical innovations of clinical trial interest.

Further information on other opportunities to participate in clinical trials is also available on the Web sites provided. We encourage you to join the effort of creating tomorrow’s practice through today’s clinical trials.

**New trial concepts**
- Z1052—Cryoablation for Primary Breast Cancer. (See Figure 1, previous page.) A Phase II Trial Evaluating the Efficacy of Pre- and Post-Treatment Imaging to Determine Residual Diseases in Patients with Invasive Breast Carcinoma Undergoing Cryoablation Therapy. Primary investigator (PI): Rache Simmons, MD.

**New trials**
- Z4032—Brachytherapy and Sublobar Resection in Non-Small Cell Lung Cancer. (See Figure 2, previous page.) A Randomized Phase III Study of Sublobar Resection versus Sublobar Resection Plus Brachytherapy in High Risk Patients with Non-Small Cell Lung Cancer (NSCLC), 3 cm or Smaller. PI: Heran Fernando, MD. Web posting: July 15, 2005
- Z6041—Local Excision Neoadjuvant Chemoradiation for Early Rectal Cancer. A Phase II Trial of Neoadjuvant Chemoradiation and Local Excision for uT2uN0 Rectal Cancer. (See Figure 3, this page.)

**Figure 3—Z6041**

![Diagram](image1)

**Figure 4—Z1031**

![Diagram](image2)
ACOSOG-led and ACOSOG-endorsed (CTSU*) protocols open to accrual

<table>
<thead>
<tr>
<th>Area</th>
<th>Protocol Number</th>
<th>Description</th>
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<tbody>
<tr>
<td>Breast</td>
<td>NSABP B-35*</td>
<td>A clinical trial comparing anastrozole with tamoxifen in postmenopausal patients with ductal carcinoma in situ (DCIS) undergoing lumpectomy with radiation therapy.</td>
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<tr>
<td></td>
<td>NSABP B-39*</td>
<td>A randomized phase III study of conventional whole breast irradiation (WBI) versus partial breast irradiation (PBI) for women with stage 0, I, or II breast cancer.</td>
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<tr>
<td>Head and Neck</td>
<td>Z0360</td>
<td>A trial of lymphatic mapping and sentinel node lymphadenectomy for patients with T1 or T2 clinically N0 oral cavity squamous cell carcinoma.</td>
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<tr>
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<td>RTOG 0234*</td>
<td>A phase II randomized trial of surgery followed by chemoradiotherapy plus C225 (cetuximab) for advanced squamous cell carcinoma of the head and neck.</td>
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<tr>
<td>GI</td>
<td>Z5031</td>
<td>A phase II study of interferon-based adjuvant chemoradiation in patients with resected pancreatic adenocarcinoma.</td>
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<tr>
<td>Sarcoma</td>
<td>Z9001</td>
<td>A phase III randomized double-blind study of adjuvant ST1571 versus placebo in patients following the resection of primary gastrointestinal stomal tumor (GIST)</td>
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<tr>
<td></td>
<td>Z9031</td>
<td>A phase III randomized study of preoperative radiation plus surgery versus surgery alone for patients with retroperitoneal sarcomas (RPS).</td>
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<tr>
<td>SWOG S0344/</td>
<td>SWOG S0220*</td>
<td>A phase II surgical trial of intralesional resection of low-grade intracompartmental chondrosarcoma of bone.</td>
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<tr>
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<td>Z9041*</td>
<td>A phase II trial of induction chemoradiotherapy with cisplatin/etoposide followed by surgical resection, followed by docetaxel for non-small cell lung cancer involving the superior sulcus (Pancost tumors).</td>
</tr>
</tbody>
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PI: Julio Garcia-Aquilar, MD.  
Web posting: August 15, 2005
- Z1031—Neoadjuvant Ani- mates Inhibitors in Breast Cancer. (See Figure 4, page 42.) A Randomized Phase III Trial Comparing 16 Weeks of Neoadjuvant Exemestane (25 mg daily), Letrozole (2.5 mg daily) or Anastrozole (1 mg daily) in Postmenopausal Women with Clinical Stage II or III Estrogen Receptor Positive Breast Cancer.

PI: Matthew Ellis, MD.  
Web posting: September 15, 2005

**Clinical trials Web sites**  
Visit the following Web sites for more information on clinical trials:
- National Cancer Institute, 800/4-CANCER, [http://www.nci.nih.govclinicaltrials](http://www.nci.nih.govclinicaltrials)  
- ClinicalTrials.gov (provides updated information on federally and privately supported clinical research), [http://www.clinicaltrials.gov](http://www.clinicaltrials.gov)  
- Coalition of National Cancer Cooperative Groups, 877/520-4457, [http://www.cancertrialshelp.org](http://www.cancertrialshelp.org)  
- Association of Cancer Online Resources, [http://www.acor.org](http://www.acor.org)