Clinical Trials in Ovarian Cancer, Part 2

Review Article [1] | December 01, 2002
By Edward L. Trimble, MD, PhD [2], Mason Schoenfeldt [3], Terri L. Cornelison, MD, PhD [4], John Wright, MD, PhD [5], Ann Kolker [6], and Michaele C. Christian, MD [7]

The American Cancer Society has estimated that 23,300 women will develop ovarian cancer in 2002, and 13,900 women will die from the disease.[1] The 5-year survival rate is about 80% for women with stage I disease, 50% for women with stage II disease, 25% for women with stage III disease, and 15% for women with stage IV disease. Among women with advanced-stage disease, optimal debulking surgery, as well as platinum/taxane-based adjuvant therapy prolongs disease-free and median survival.[2,3] Population-based data suggest that guidelines for therapy are not uniformly followed in community practice.[4] In addition, older patients appear to receive less aggressive treatment than younger patients.

Clinical Trials Referral Resource is designed to serve as a ready reference for oncologists to help identify clinical trials that might be suitable for their patients. We hope it will also enhance accrual to clinical trials by informing practicing oncologists of ongoing protocols. Currently in the United States less than 10% of eligible adult patients are entered into clinical trials. The result is a delay in answering important therapeutic and scientific questions and disseminating therapeutic advances to the general oncology community.

It should be emphasized that including a specific trial does not imply that it is more important than another trial. Among the criteria for selection are that the trial is addressing an important question and is not expected to close in the immediate future (less than 1 year), and that initial staging or laboratory tests required for patient eligibility are widely practiced and available. Information on other protocols can be accessed via Physician’s Data Query (PDQ).* We emphasize that this is an attempt to encourage referral of patients to these trials. We are specifically not soliciting additional members for the cooperative groups, nor are we suggesting how practicing oncologists should be treating patients who are not in a study.

This month’s installment of Clinical Trials Referral Resource is devoted to current clinical trials of the Cancer Trials Support Unit, a National Cancer Institute pilot program. For patient entry information, see the individual trials.

Part 2 of this two-part series will discuss diagnosis and treatment trials for recurrent disease. Part 1, published in last month’s issue of ONCOLOGY, discussed prevention, screening, adjuvant treatment, neoadjuvant chemotherapy, and adjuvant chemotherapy trials for ovarian cancer.

Treatment of Persistent or Progressive Ovarian Cancer

Disease that persists or progresses during primary chemotherapy is termed "resistant" or "refractory." In such cases, the response to alternative agents such as gemcitabine (Gemzar), topotecan (Hycamtin), anthracyclines, hexamethylmelamine (Hexalen), and tamoxifen is generally modest and of short duration. These patients should be encouraged to consider early (phase I/II) trials of new investigational agents.
Treatment of Recurrent Ovarian Cancer

It has been hypothesized that women with recurrent ovarian cancer may benefit from surgery to debulk recurrent disease, followed by additional chemotherapy. The Gynecologic Oncology Group (GOG) will soon open a phase III clinical trial evaluating the role of secondary surgery, as well as two different chemotherapy regimens (GOG-0202). Women who have never received a platinum agent or those with disease recurring more than 12 months after platinum-based therapy should be treated with a platinum drug, which has demonstrated the most activity against epithelial ovarian cancer. If the patient has never received platinum or taxanes, ie, in the case of recurrent stage I disease, then use of a platinum/taxane combination is reasonable. We do not know whether combination chemotherapy, sequential chemotherapy, or single-agent platinum therapy is most effective in women with previously treated ovarian cancer. These patients should be encouraged to consider enrolling in the phase I-III trials for which they may be eligible.

Patient Counseling

Women at possible familial risk for ovarian cancer should undergo appropriate pedigree analysis and counseling by either a cancer genetic counselor or a gynecologic/medical oncologist with expertise in ovarian cancer genetics. Women diagnosed with ovarian cancer should be told about available resources for support and information. Particularly helpful are professionally led groups such as the Gynecologic Cancer Foundation and the American Society of Clinical Oncology, patient-led organizations such as the Ovarian Cancer National Alliance (www.ovariancancer.org), the National Coalition of Cancer Survivorship, the newsletter Conversations, SHARE-Self-Help for Women With Breast or Ovarian Cancer (www.sharecancersupport.org), voluntary associations such as Cancer Care (www.cancercare.org), the Wellness Community, Gilda’s Club, and of course, the National Cancer Institute (NCI). Most offer printed materials as well as websites, and several provide teleconferences and online support groups. In addition, a number of hospitals host support groups, usually facilitated by an oncology nurse or social worker. Acute toxicities during treatment often include alopecia and fatigue. Chronic toxicities after treatment may include fatigue, depression, and cognitive deficiencies ("chemobrain"). Clinicians should counsel patients about these potential side effects and make recommendations for appropriate interventions as needed.

Recurrent Disease: Diagnosis

**Title:** Pilot Diagnostic Study of Proteomic Evaluation in Patients With Stage III or IV Primary Peritoneal, Fallopian Tube, or Ovarian Epithelial Cancer, or Stage IIIC Ovarian Clear Cell Cystadenocarcinoma in First Clinical Remission to Develop a Protein Profile Associated With Relapse (active)

**Protocol Number:** NCI-00-C-0018

**Participating Institutions:** Center for Cancer Research (NCI)

**Contact:** Mahrukh Hussain, (301) 435-0591

Recurrent Disease: Treatment

**Phase III**

**Title:** A Randomized Study of Tamoxifen Versus Thalidomide in Patients With Biochemical-Recurrence-Only Epithelial Ovarian Cancer, Cancer of the Fallopian Tube, and Primary Peritoneal Carcinoma After First-Line Chemotherapy (approved)

**Protocol Number:** GOG-0198

**Participating Institutions:** Gynecologic Oncology Group

**Contact:** Jean A. Hurteau, (317) 274-8157

**Title:** A Bifactorial, Randomized, Controlled Clinical Trial of Sequence Dependent Chemotherapy and Secondary Cytoreductive Surgery in Platinum-Sensitive Recurrent Ovarian and Primary Peritoneal Cancer (in review)

**Protocol Number:** GOG-0202

**Participating Institutions:** Gynecologic Oncology Group

**Contact:** Robert L. Coleman, (214) 648-3026

**Title:** A Phase III Randomized Study of Pegylated Liposomal Doxorubicin plus Carboplatin Versus
Carboplatin in Platinum-Sensitive Patients With Recurrent Epithelial Ovarian or Peritoneal Carcinoma After Failure of Initial Platinum-Based Chemotherapy (active)

**Protocol Number:** S0200
**Participating Institutions:** Southwest Oncology Group
**Contact:** David S. Alberts, (520) 318-7018

**Phase II**

**Title:** Phase II Trial of Fenretinide (NSC 374551) in Recurrent Ovarian Cancer and Primary Peritoneal Carcinoma (active)

**Protocol Number:** 19
**Participating Institutions:** University of Southern California, Los Angeles
**Contact:** Agustin A. Garcia, (323) 865-0470

**Title:** Phase II Study of Intraperitoneal Recombinant Human Interleukin-12 (rhIL-12) (NSC 672423) in Patients With Peritoneal Carcinomatosis (Residual Disease < 1 cm) Associated With Ovarian Epithelial Cancer (active)

**Protocol Number:** 2251
**Participating Institutions:** M. D. Anderson Cancer Center
**Contact:** Renato Lenzi, (713) 792-2828

**Title:** Phase II Study of Intraperitoneal Recombinant Human Interleukin-12 (rhIL-12) (NSC 672423) in Patients With Peritoneal Carcinomatosis (Residual Disease < 1 cm) Associated With Ovarian Epithelial Cancer (active)

**Protocol Number:** 3632
**Participating Institutions:** Moffitt Cancer Center
**Contact:** Kapil N. Bhalla, (813) 979-3980

**Title:** Phase II Pilot Study of Clinical Activity and Proteomic Pathway Profiling of the EGFR Inhibitor ZD1839 (Iressa [R]; Getifinib) in Patients With Epithelial Ovarian Cancer or Cervical Cancer (approved)

**Protocol Number:** 5561
**Participating Institutions:** National Cancer Institute Medicine Branch
**Contact:** Mahrukh Hussain, (301) 435-0591

**Title:** Phase II Clinical Trial With Proteomic Profiling of Imatinib Mesylate (Gleevec; STI571), a PDGFR and C-Kit Inhibitor, in Patients With Refractory or Relapsed Epithelial Ovarian Cancer, Fallopian Tube, and Primary Peritoneal Cancer (active)

**Protocol Number:** 5672
**Participating Institutions:** National Cancer Institute Medicine Branch
**Contact:** Mahrukh Hussain, (301) 435-0591

**Title:** Phase II Study of Docetaxel in Women With Platinum Resistant, Refractory Ovarian Epithelial or Primary Peritoneal Serous Cancer (active)

**Protocol Number:** BIH-99-1286, NCI-V99-1565
**Participating Institutions:** Beth Israel Deaconess Medical Center
**Contact:** Stephen A. Cannistra, (617) 667-1909

**Title:** Phase II Study of Antineoplastons A10 and AS2-1 in Patients With Stage III or IV Ovarian Cancer (active)

**Protocol Number:** BRI-OV-2
**Participating Institutions:** Burzynski Research Institute
**Contact:** Stanislaw R. Burzynski, (713) 335-5697

**Title:** Phase II Study of Docetaxel and Carboplatin in Patients With Suboptimally Debulked Stage III or Stage IV Ovarian Carcinoma, Fallopian Tube Carcinoma, Papillary Serous Cancer of the Uterus, or Primary Peritoneal Carcinoma (active)

**Protocol Number:** CPMC-IRB-8437, NCI-V98-1467
**Participating Institutions:** Herbert Irving Comprehensive Cancer Center
**Contact:** Amy D. Tiersten (212) 305-0170

**Title:** A Phase II Evaluation of Gemcitabine and Cisplatin in Recurrent, Platinum Resistant and Refractory Ovarian and Peritoneal Carcinoma (active)

**Protocol Number:** GOG-0126L
**Participating Institutions:** Gynecologic Oncology Group
**Contact:** Cheryl A. Brewer, (309) 655-2955

**Title:** A Phase II Evaluation of Epothilone-B BMS 247550 (IND #59699 NSC #710428) in the
Treatment of Recurrent or Persistent Platinum and Paclitaxel Refractory Ovarian or Primary Peritoneal Cancer (active)

**Protocol Number:** GOG-0126M  
**Participating Institutions:** Gynecologic Oncology Group  
**Contact:** David R. Spriggs, (212) 639-2203

**Title:** A Phase II Evaluation of Weekly Paclitaxel in the Treatment of Recurrent or Persistent Platinum and Paclitaxel-Resistant Ovarian or Primary Peritoneal Cancer (temporarily closed to accrual)

**Protocol Number:** GOG-0126N  
**Participating Institutions:** Gynecologic Oncology Group  
**Contact:** Maurie Markman, (216) 445-6888

**Title:** Phase II Evaluation of Capecitabine in Recurrent Platinum-Sensitive Ovarian or Primary Peritoneal Cancer (temporarily closed to accrual)

**Protocol Number:** GOG-0146L  
**Participating Institutions:** Gynecologic Oncology Group  
**Contact:** Agustin A. Garcia, (323) 865-0470

**Title:** A Phase II Evaluation of Tirapazamine (NSC #130181, IND #46525) in Combination With Cisplatin in Recurrent Platinum Sensitive Ovarian or Primary Peritoneal Cancer (temporarily closed to accrual)

**Protocol Number:** GOG-0146M  
**Participating Institutions:** Gynecologic Oncology Group  
**Contact:** Allan Covens, (416) 480-4026

**Title:** A Phase II Evaluation of PS-341 (NSC #681239) in the Treatment of Recurrent Platinum-Sensitive Ovarian or Primary Peritoneal Cancer (active)

**Protocol Number:** GOG-0146N  
**Participating Institutions:** Gynecologic Oncology Group  
**Contact:** Carol Aghajanian, (212) 639-2252

**Title:** A Phase II Trial of ZD1839 (IRESSA) (NSC #715055, IND #61187) in the Treatment of Persistent or Recurrent Epithelial Ovarian or Primary Peritoneal Carcinoma (temporarily closed to accrual)

**Protocol Number:** GOG-0170C  
**Participating Institutions:** Gynecologic Oncology Group  
**Contact:** Russell J. Schilder, (215) 728-3545

**Title:** A Phase II Evaluation of Bevacizumab (Anti-VEGF Humanized Monoclonal Antibody) in the Treatment of Persistent or Recurrent Epithelial Ovarian or Primary Peritoneal Carcinoma (active)

**Protocol Number—GOG-0170D**

**Participating Institutions:** Gynecologic Oncology Group  
**Contact:** Robert A. Burger, (714) 456-6570

**Title:** A Phase II Evaluation of Gleevec (Imatinib Mesylate) (IND #61135, NSC #716051) in the Treatment of Persistent or Recurrent Epithelial Ovarian or Primary Peritoneal Carcinoma (active)

**Protocol Number:** GOG-0170E  
**Participating Institutions:** Gynecologic Oncology Group  
**Contact:** Russell J. Schilder, (215) 728-3545

**Title:** A Phase II Evaluation of 9-Nitro-Camptothecin in the Third-Line Treatment of Recurrent Ovarian or Primary Peritoneal Cancer (approved)

**Protocol Number:** GOG-0186B  
**Participating Institutions:** Gynecologic Oncology Group  
**Contact:** Edward C. Grendys, (813) 972-8478

**Title:** A Phase II Evaluation of CT-2103 (IND #61013) in the Third-Line Treatment of Recurrent or Persistent Epithelial Ovarian or Primary Peritoneal Cancer (active)

**Protocol Number:** GOG-0186C  
**Participating Institutions:** Gynecologic Oncology Group  
**Contact:** Paul J. Sabbatini, (212) 639-6423

**Title:** Phase II Randomized Study of Toremifene in Patients With Chemotherapy-Resistant Papillary Carcinoma of the Ovary (active)

**Protocol Number:** GWCC-7096, NCI-V99-1540  
**Participating Institutions:** George Washington University Hospital  
**Contact:** James D. Ahlgren, (202) 994-3556

**Title:** Phase II Study of High-Dose Cyclophosphamide, Carboplatin, and Mitoxantrone Followed by Autologous Bone Marrow Transplantation in Patients With Refractory or Relapsed Ovarian Epithelial Cancer (approved)
Cancer (active)

**Protocol Number:** LUMC-3007, NCI-V91-0058  
**Participating Institutions:** Loyola University Medical Center  
**Contact:** Patrick J. Stiff, (708) 327-3148  
**Title:** Phase II Study of Thalidomide in Patients With Platinum-Refractory or Resistant Ovarian Epithelial Carcinoma (active)  

**Protocol Number:** MSKCC-01006, NCI-G01-1943  
**Participating Institutions:** Memorial Sloan-Kettering Cancer Center  
**Contact:** David R. Spriggs, (212) 639-2203  
**Title:** Phase II Pilot Study of Consolidation Therapy With Intraperitoneal Floxuridine and Cisplatin and/or Carboplatin in Patients With Stage III Ovarian Epithelial or Gastrointestinal Cancer (active)  

**Protocol Number:** NCI-G00-1717, NYU-9645  
**Participating Institutions:** NYU School of Medicine’s Kaplan Comprehensive Cancer Center  
**Contact:** Franco M. Muggia, (212) 263-6485  
**Title:** Phase II Study of Cisplatin and Prolonged Topotecan Followed by Paclitaxel and Carboplatin in Patients With Advanced Ovarian Epithelial Carcinoma (active)  

**Protocol Number:** NCI-G00-1720, NYU-9913  
**Participating Institutions:** NYU School of Medicine’s Kaplan Comprehensive Cancer Center  
**Contact:** Howard S. Hochster, (212) 263-6485  
**Title:** Phase II Study of Whole Body Hyperthermia Combined With Doxorubicin HCl Liposome and Fluorouracil in Patients With Metastatic Breast, Ovarian, Endometrial, or Cervical Cancer (active)  

**Protocol Number:** NCI-V97-1356, UTHSC-MS-96205  
**Participating Institutions:** University of Texas Health Science Center-Houston  
**Contact:** Joan M.C. Bull, (713) 500-6821  
**Title:** A Phase II Study of OSI-774 (NSC 718781) Given in Combination With Carboplatin in Patients With Recurrent Epithelial Ovarian Cancer (active)  

**Protocol Number:** NCIC-149  
**Participating Institutions:** National Cancer Institute of Canada  
**Contact:** Holger W. Hirte, (905) 387-9495, ext. 64601  
**Title:** A Phase II Trial of STI571 for the Treatment of Platinum and Taxane Refractory Stage III and IV Epithelial Ovarian Cancer and Primary Peritoneal Cancer (active)  

**Protocol Number:** S0211  
**Participating Institutions:** Southwest Oncology Group  
**Contact:** David S. Alberts, (520) 318-7018  
**Title:** A Phase II Study of Cyclophosphamide, Paclitaxel, Cisplatin With G-CSF for Patients With Newly Diagnosed Advanced Stage Ovarian Cancer (active)  

**Protocol Number:** T94-0162  
**Participating Institutions:** National Cancer Institute Pharmacology Branch  
**Contact:** Mehrukh Hussain, (301) 435-0591  
**Title:** A Phase II Trial of Orally Administered CAI for Patients With Persistent or Refractory Epithelial Ovarian Cancer, Fallopian Tube Cancer, or Primary Peritoneal Cancer (active)  

**Protocol Number:** T97-0112  
**Participating Institutions:** City of Hope Medical Center  
**Contact:** Robert J. Morgan, (626) 359-8111  
**Title:** A Phase II Trial of Bryostatin in Combination With Cisplatin in Patients With Recurrent or Persistent Epithelial Ovarian Cancer (active)  

**Protocol Number:** T99-0039  
**Participating Institutions:** National Cancer Institute Medicine Branch  
**Contact:** Mehrukh Hussain, (301) 435-0591  
**Title:** Phase I/II Study of Topotecan as a Component of Multicourse High Dose Chemotherapy With Peripheral Blood Stem Cell Support in Patients With Recurrent or Persistent Ovarian Epithelial, Fallopian Tube, or Primary Peritoneal Cancer (active)  

**Protocol Number:** CPMC-IRB-7866, NCI-G97-1327  
**Participating Institutions:** Herbert Irving Comprehensive Cancer Center  
**Contact:** Amy D. Tiersten (212) 305-0170  
**Title:** Vaccine Therapy With Tumor Specific P53 Peptide in Adult Patients With Low Burden

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**Phase I/II**

**Title:** Phase I/II Study of Topotecan as a Component of Multicourse High Dose Chemotherapy With Peripheral Blood Stem Cell Support in Patients With Recurrent or Persistent Ovarian Epithelial, Fallopian Tube, or Primary Peritoneal Cancer (active)

**Protocol Number:** CPMC-IRB-7866, NCI-G97-1327  
**Participating Institutions:** Herbert Irving Comprehensive Cancer Center  
**Contact:** Amy D. Tiersten (212) 305-0170  
**Title:** Vaccine Therapy With Tumor Specific P53 Peptide in Adult Patients With Low Burden
Adenocarcinoma of the Ovary (active)

**Protocol Number:** T99-0074  
**Participating Institutions:** National Cancer Institute Medicine Branch  
**Contact:** Samir N. Khleif, khleifs@navmed.nci.nih.gov

**Phase I**

**Title:** A Phase I Dose-Finding Study of Oxaliplatin Combined With Continuous-Infusion Topotecan Hydrochloride as Chemotherapy for Patients With Previously Treated Ovarian Cancer (active)

**Protocol Number:** 690  
**Participating Institutions:** New York University Medical Center  
**Contact:** Howard S. Hochster, (212) 263-6485

**Title:** Phase I Trial of PS-341 (NSC 681239, IND #58443) and Carboplatin in Recurrent or Progressive Epithelial Ovarian Cancer or Primary Peritoneal Cancer (active)

**Protocol Number:** 5326  
**Participating Institutions:** Memorial Sloan-Kettering Cancer Center  
**Contact:** Carol Aghajanian, (212) 639-2252

**Title:** Phase I Trial of PS-341 (NSC 681239, IND #58443) and Carboplatin in Recurrent or Progressive Epithelial Ovarian Cancer or Primary Peritoneal Cancer (active)

**Protocol Number:** 5326  
**Participating Institutions:** Memorial Sloan-Kettering Cancer Center  
**Contact:** Carol Aghajanian, (212) 639-2252

**Title:** A Phase I Study of Yttrium Y 90 Monoclonal Antibody MN-14 in Patients With Chemotherapy-Resistant or Refractory Advanced Ovarian Epithelial Cancer (active)

**Protocol Number:** CMMI-C-039D-01, NCI-V02-1703  
**Participating Institutions:** Memorial Sloan-Kettering Cancer Center  
**Contact:** Jack D. Burton, (973) 844-7024

**Title:** Phase I Study of Paclitaxel Combined With Topotecan and Cisplatin and G-CSF in Patients With Newly Diagnosed Advanced Ovarian Epithelial Malignancies (active)

**Protocol Number:** GOG-9602  
**Participating Institutions:** Gynecologic Oncology Group  
**Contact:** Deborah K. Armstrong, (410) 614-2743

**Title:** A Phase I Study of Paclitaxel, Carboplatin, and Increasing Doses of Doxil in Untreated Ovarian, Peritoneal, and Tubal Carcinoma (active)

**Protocol Number:** GOG-9703  
**Participating Institutions:** Gynecologic Oncology Group  
**Contact:** Peter G. Rose, (216) 778-5885

**Title:** A Phase I Trial of Combination Carboplatin and Liposomal Doxorubicin (Doxil) in Recurrent Ovarian, Fallopian Tube or Primary Peritoneal Cancer (approved)

**Protocol Number:** GOG-9909  
**Participating Institutions:** Gynecologic Oncology Group  
**Contact:** Michael Rodriguez, (574) 237-1328

**Title:** Treatment of Patients With Advanced Epithelial Ovarian Cancer Using Peripheral Blood Lymphocytes Transduced With a Gene Encoding a Chimeric T Cell Receptor Reactive With Folate Binding Protein (active)

**Protocol Number:** T95-0040  
**Participating Institutions:** National Cancer Institute Surgery Branch  
**Contact:** Patrick Hwu, (301) 402-1156

**References:**


