

**GOG 0212: A Randomized Phase III Trial Of Maintenance Chemotherapy Comparing 12, Monthly Cycles Of Single Agent Paclitaxel Or Xyotax™ (CT-2103) (IND# 70177), Versus No Treatment Until Documented Relapse In Women With Advanced Ovarian, Primary Peritoneal, or Fallopian Tube Cancer Who Achieve A Complete Clinical Response To Primary Platinum/Taxane Chemotherapy.**

***FAST FACTS***

**ELIGIBILITY CRITERIA**

1. Patients with a histologic diagnosis of primary peritoneal carcinoma, or Stage III or IV epithelial ovarian or fallopian tube carcinoma, with either optimal (< 1 cm residual disease) or suboptimal residual disease following initial surgery. All patients must have had appropriate surgery for ovarian or peritoneal carcinoma with appropriate tissue available for histologic evaluation to confirm diagnosis and stage.
2. Patients with the following histologic epithelial cell types are eligible: Serous adenocarcinoma, endometrioid adenocarcinoma, mucinous adenocarcinoma, undifferentiated carcinoma, clear cell adenocarcinoma, mixed epithelial carcinoma, transitional cell carcinoma, malignant Brenner's Tumor, or adenocarcinoma N.O.S.
3. Patients must have completed treatment within the past 12 weeks with at least 5 cycles and not more than 8 cycles of a platinum (IV or IP) and paclitaxel or docetaxel-based combination chemotherapy and have no symptoms suggestive of persistent cancer, normal CT scan of the abdomen/pelvis and normal CA-125 following this therapy.
4. Patients treated with neo-adjuvant platinum-taxane chemotherapy for a presumptive diagnosis of stage III or IV primary peritoneal carcinoma or epithelial ovarian carcinoma (by paracentesis, percutaneous biopsy or open biopsy) are eligible provided that they have undergone interval abdominal surgery after at least one but no more than six cycles of standard chemotherapy as defined in section 3.13. Such surgery must meet the same criteria as for those undergoing up front surgery, including tissue diagnosis for confirmation of primary tumor site and Stage III or IV disease. Also, patients must have received at least two cycles after interval abdominal surgery.
5. Patients must a GOG Performance Status of 0, 1, or 2.
6. Patients must have the following lab values:
  - ANC  $\geq$  1,500/ul, equivalent to CTCAE v3.0 Grade 1
  - Platelets  $\geq$  100,000/ul
  - Creatinine  $\leq$  1.5 x ULN, CTCAE v3.0 Grade1
  - Bilirubin  $\leq$  1.5 x ULN, CTCAE v3.0 Grade 1
  - SGOT and alkaline phosphatase  $\leq$  2.5 x ULN, CTCAE v3.0 Grade 1
  - Neuropathy (sensory and motor)  $\leq$  CTC Grade 1

**INELIGIBILITY CRITERIA**

1. Patients with a current diagnosis of epithelial ovarian or fallopian tube tumor of LMP (borderline carcinomas are not eligible. Patients with a prior diagnosis of low malignant potential tumor that was surgically resected and who subsequently develop invasive adenocarcinoma are eligible, **provided that they have not received prior chemotherapy for their ovarian LMP tumor.**
2. Germ cell tumors, sex cord-stromal tumors, carcinomas, mixed mullerian tumors or carcinosarcomas, metastatic carcinomas from other sites to the ovary and low malignant tumors including so called micropapillary serous carcinomas are not eligible.
3. Patients who have received prior radiotherapy to any portion of the abdominal cavity or pelvis are excluded. Prior radiation for localized cancer of the breast, head and neck, or skin is permitted, provided that it was completed more than 3 years prior to registration, and the patient remains free of recurrent or metastatic disease.
4. Patients who have received prior chemotherapy, investigational therapies, and/or biological therapies (i.e. Bevacizumab or Erlotinib) for any other abdominal or pelvic tumor (except as noted above) are excluded. Patients may have received prior adjuvant chemotherapy for localized breast cancer, provided that it was completed more than 3 years prior to registration, and that the patient remains free of recurrent or metastatic disease.

5. Patients with synchronous primary endometrial cancer, or a past history of primary endometrial cancer, are excluded, **unless all of the following conditions are met:**
  - Stage not greater than I-B
  - Less than 3 mm invasion without vascular or lymphatic invasion
  - No poorly differentiated subtypes, including papillary serous, clear cell, or other FIGO Grade 3 lesions.
7. With the exception of non-melanoma skin cancer and other specific malignancies as noted above, patients with other invasive malignancies who had (or have) any evidence of other cancer present within the last 5 years or whose previous cancer treatment contraindicates this protocol therapy are excluded.
8. Patients with acute hepatitis, or known chronic hepatitis.
9. Patients with an active infection that requires antibiotics.
10. Patients with ongoing gastrointestinal bleeding requiring blood product support.
11. Patients with unstable angina or those who have had a myocardial infarction within the past six months. Patients with evidence of abnormal cardiac conduction (e.g. bundle branch block, heart block) are eligible if their disease has been stable for the past six months.
12. Patients are excluded who have had prior therapy with Xyotax (CT-2103).
13. Patients with active bleeding or an unexplained PT of PTT > institutional upper limit normal.

#### PRE-STUDY PARAMETERS

1. History and physical; Ht/Wt
2. CBC/Diff/Platelets; Serum Creatinine; Bilirubin; SGOT; Alkaline Phosphatase; CA-125
3. Chest X-Ray; CT scan of abdomen/pelvis; EKG
4. Coagulation Profile (PT, PTT, INR)

#### TREATMENT PLAN

Drug-specific plan: Eligible patients will be randomized equally to one of the following treatment arms:

##### ARM 1

AGENT	DOSE	ROUTE	RETREATMENT INTERVAL	NOTES
Xyotax™ (CT-2103)	135 mg/m <sup>2</sup>	IV	Q 28 days x 12	Administered over 10-20 minutes

##### ARM 2

AGENT	DOSE	ROUTE	RETREATMENT INTERVAL	NOTES
Paclitaxel	135 mg/m <sup>2</sup>	IV	Q 28 days x 12	Administered over 3 hours

- Paclitaxel will be administered as a 3 hour infusion. It is recommended that a preparative regimen be employed to reduce the risk associated with hypersensitivity reactions. This regimen should include dexamethasone (either IV or PO), anti-histamine H1 (such as diphenhydramine) and anti-histamine H2 (such as cimetidine, ranitidine, or famotidine).

##### ARM 3

#### No anti-cancer treatment until evidence of disease progression.

Submit monthly D2R and T forms to include required CA-125 value and pertinent history/physical information. For Regimen III the cycle number should equal the number of months since registration (i.e. Third months surveillance equals cycle 3).