

Appendix O – Recruitment letter

Name
Address

Dear ****:

Thank you for your interest in the study; **Multi-Center, Phase Ib/IIa Safety and Preliminary Efficacy Study of Phenoxodiol (Intravenous Dosage Form) as a Chemo-Sensitizing Agent for Cisplatin and Paclitaxel in Epithelial Ovarian Cancer or Primary Peritoneal Cancer that is Platinum- and/or Taxane-Refractory or Resistant.**

We are currently finalizing the protocol and plan to begin treating patients in April 2004. Due to the large number of people who have contacted our office regarding this study, we will offer study enrollment to those patients who meet the study inclusion criteria in a randomized fashion. Those patients that are not able to be part of the current study will be considered for any future protocols involving Phenoxodiol.

It is vital that each person who is eligible for this current protocol can commit to the time that participation in the study requires. The current protocol involves receiving Phenoxodiol by intravenous injection on two consecutive days every week. Each treatment cycle will last for six weeks and the maximum number of treatment cycles is eight. Therefore, it may be necessary to be available for treatment for two consecutive days a week for up to forty-eight weeks.

It will be necessary for our office to receive pertinent medical information in order to evaluate if you meet the study inclusion criteria. If you meet all of the following criteria, you will be considered for admission to the study:

- a) Patients must have histological evidence of epithelial ovarian, fallopian or primary peritoneal carcinoma and have been previously surgically staged
- b) Patients must have received 4 prior chemotherapy regimens for this malignancy
- c) Patients must have been treated previously with a taxane (paclitaxel or taxotere) and/or platinum (cisplatin or carboplatin) and be considered refractory or resistant to either or both therapies based on the following: must have a treatment-free interval following platinum or paclitaxel of less than 6 months, or have progressed during platinum or paclitaxel-based therapy.
- d) Patients must have either measurable or evaluable disease by the following criteria.
 - o Measurable disease is defined as having at least one lesion that can be accurately measured in at least one dimension (longest dimension to be recorded) allowing a response to be determined by the RECIST criteria. Each lesion must be 20 mm when measured by conventional techniques, including palpation, plain x-ray, CT, and MRI, or 10 mm when measured by spiral CT.
 - o Patients with evaluable disease must have experienced doubling of blood levels of CA125 in the six (6) months leading up to enrollment in the study and have a CA125 level at least two times greater than the institutional upper limit of normal values, within 1 week of study entry.
- e) Patients must be > 18 years of age and must be able to understand the risks and benefits of the study and to be able to give written informed consent to participation
- f) Patients must have a Karnofsky Performance Score of at least 60%
- g) Patients must be off any standard therapy directed at the malignant tumor for at least 4 weeks, and in the case of any investigational anti-cancer drugs, for at least 6 months

- h) Patients should be free of active infection requiring antibiotics
- i) Patients of childbearing potential must have a negative serum pregnancy test prior to study entry and be practicing an effective form of contraception
- j) Patients must have;
 - o Renal function: creatinine levels 1.5 x institutional upper limit normal (ULN) (equivalent to Common Toxicity Criteria (CTC) Grade 1)
 - o Hepatic function: bilirubin levels 1.5 x ULN (CTC Grade 1); SGOT and alkaline phosphatase 2.5 x ULN (CTC Grade 1)
 - o Bone marrow function: platelets Bone marrow function: platelets > 100x10⁹/L , WCC > 3x10⁹/L, Hb > 8g/dL, neutrophils > 1.5 x 10⁹ /L
 - o Neurological function: neuropathy (sensory and motor) less than or equal to CTC Grade 1.
- k) Patients must have signed an approved informed consent.

Please have the following information forwarded to our office:

- ✓ Contact information for yourself and your physician (see attached)
- ✓ Pathology report stating the type of malignancy (from original surgery)
- ✓ Operating room reports from any pertinent surgeries
- ✓ CA-125 levels from the last 6 months
- ✓ Cat Scan or MRI reports for the last 6 months
- ✓ Recent laboratory values that include all of the following: WBC, platelets, hemoglobin, Hematocrit, Liver function tests (AST, ALT and bilirubin), BUN and creatinine.
- ✓ List of the chemotherapy regimens, the number of cycles you have received for each regimen and the dates of treatment
- ✓ A letter from your oncologist stating that you have been treated with a taxane and platin therapy chemotherapy and that your disease was considered resistant to this treatment. This letter should also confirm that you meet the above inclusion criteria and currently have evidence of progressive disease
- ✓ Any radiation therapy records (whole abdomen RT is exclusion criteria)

It is the responsibility of each person who wishes to enroll in the study to ensure that our office receives the above information. Each person will only be evaluated for the above inclusion criterion when this documentation has been received at our office. Please respond if you are interested in being considered for this trial. We may need to contact you for additional information regarding your medical history. Upon review of your medical history, if you do not currently meet the inclusion criteria or are not chosen by the randomization process, you will continue to be a candidate for the current protocol or any future protocols.

We thank you for your interest in this clinical study. Please direct any correspondence and questions to Renee Luongo at the address below:

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Sincerely,

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