CIRB Stipulations		
1.	Headers	Updated to reflect the current Protocol Version date submitted in response to an RA from CTEP

Consent Form

Study Title for Study Participants: Testing the Addition of M6620 (VX-970) to Approved Chemotherapy in Recurrent Platinum-Sensitive Ovarian Cancer**, Peritoneal, and Fallopian Tube Cancer** (Expansion Cohort)

Official Study Title for Internet Search on http://www.ClinicalTrials.gov:
9948 / MC1563: Phase 1 Dose escalation and Expansion Cohort Trial of Carboplatin and Gemcitabine with or without M6620 (VX-970) in First or second Recurrence Platinum-Sensitive Epithelial Ovarian, Peritoneal, and Fallopian Tube Cancer

What is the usual approach to my platinum-sensitive ovarian cancer?

You are being asked to take part in this study because you have ovarian, peritoneal or fallopian tube cancer that has recurred.

Women who are not in a study are usually treated with chemotherapy. There are several FDA approved combination chemotherapy treatments that are commonly used, one of which is carboplatin and gemcitabine. These treatments can reduce symptoms and may stop the tumor from growing for several months or more.

Your doctors have recommended the standard of care carboplatin and gemcitabine to treat your cancer. In some cases, physicians recommend the addition of bevacizumab to carboplatin and gemcitabine. This is also an Food and Drug Administration (FDA) approved treatment. Please discuss with your doctor if you would like more information regarding the advantages and disadvantages of receiving bevacizumab with carboplatin and gemcitabine. If you elect to receive bevacizumab with carboplatin and gemcitabine, you cannot participate in the present study.

Occasionally recurrent platinum sensitive ovarian cancer is treated with additional surgery. The feasibility of this option should be discussed with your doctor.

If your tumor shrinks or is no longer visible on imaging after treatment with the carboplatin and gemcitabine, there is the option to get maintenance treatment with a class of oral medications

called poly adenosine diphosphate-ribose polymerase (PARP) inhibitors. This is an option for you whether or not you enroll in this clinical trial. Please discuss with your doctor if you would like more information regarding this option. If you elect to be treated with a PARP inhibitor, that therapy would start after completion of chemotherapy on the present protocol and would not impact your ability to participate in the present study.

What are my other choices if I do not take part in this study?

If you decide not to take part in this study, you have other choices. For example:

- you may choose to take any one of the many usual approaches described above
- you may choose to take part in a different study, if one is available or
- you may choose not to be treated for cancer but you may want to receive comfort care to relieve symptoms

Why is this study being done?

The purpose of this study is to compare any good and bad effects of using M6620 (VX-970) along with the usual chemotherapy. M6620 (VX-970) is not approved by the FDA and is considered investigational or experimental. M6620 (VX-970) has been tested in humans by itself or in combination with other chemotherapy agents for various diagnoses. The addition of M6620 (VX-970) to the usual chemotherapy could shrink your cancer but it could also cause side effects. The usual chemotherapy, carboplatin and gemcitabine, is already approved for use in the first recurrence of your cancer but is usually given when the other initial treatment options are considered too toxic or you have certain medical conditions that prevent you from receiving these treatments. The combination of M6620 (VX-970) with carboplatin and gemcitabine is also considered experimental.

There are two parts to this study. The first part of the study is known as the 'phase 1' part and the second part of the study is known as the 'Expansion Cohort' part. You are being asked to join the Expansion Cohort part of the study. The Expansion Cohort part of the study tests the addition of M6620 (VX-970) to the standard chemotherapy treatment of carboplatin and gemcitabine to determine whether the addition of M6620 (VX-970) is more effective than carboplatin and gemcitabine alone. This will be the first time that the combination of carboplatin, gemcitabine and M6620 (VX-970) is being tried in people. About 31 people total will be taking part in both the phase 1 and Expansion Cohort portions of this study. There will be about 20 people taking part in the Expansion Cohort part of the study.

Another purpose of this study is for researchers to learn if biomarker tests are helpful to determine how much of M6620 (VX-970) is in the blood when given in combination with carboplatin and gemcitabine, to see if M6620 (VX-970) in combination with carboplatin and gemcitabine have an effect on your cancer, and to identify whether patients having certain genetic makeups respond differently to M6620 (VX-970) in combination with carboplatin and gemcitabine or with the usual chemotherapy without M6620 (VX-970). Extra blood will be drawn and tissue from your surgery will be used or fresh tissue will be collected for the biomarker tests.

What is the treatment ?

Treatment in this study will follow a schedule of 21-day long periods and each 21-day period is known as a 'cycle.' M6620 (VX-970) will be given intravenously (IV, through a vein) twice per cycle, on days 2 and 9. Carboplatin will be given once per cycle, on day 1, while gemcitabine is given twice per cycle on days 1 and 8.

Drug	Route	Length of IV infusion	Days given during cycle
Carboplatin	IV	30 minutes	1
Gemcitabine	IV	30 minutes	1 and 8
M6620 (VX-970)	IV	60 minutes	2 and 9

The study medication M6620 (VX-970) has the potential to interact with other medications; you will be given a drug interaction handout and wallet card as a resource for yourself, caregivers and other health care providers.

How long will I be in this study?

During the study, you may continue to receive treatment with M6620 (VX-970), carboplatin and gemcitabine for an indefinite number of cycles; 'indefinite' means that it is not known exactly how long you will be in this study because each person responds to the study treatment differently.

You may continue to receive treatment as long as your doctor feels the treatment is helping you, you are not having unacceptable side effects or you do not withdraw study consent.

After you finish your treatment, your doctor will continue to watch you for side effects and follow your condition for 3 years. If you are removed from the study for unacceptable side effects, your doctor will continue to monitor you until resolution or stabilization of the side effect. You will be contacted every three months to check on your health status.

If your physician notes that your cancer has responded well to the therapy, you may have the option to discontinue the study treatments (carboplatin, gemcitabine and M6620 (VX-970) and start a class of drugs called "PARP inhibitors" that are now FDA approved as maintenance therapy. You may be eligible for PARP inhibitor use prior to reaching the target of the study. If you participate in the trial, you will be asked to remain on the study until attaining your best benefit of the treatment. You may risk having your disease get worse and then no longer be

eligible for use of PARP inhibitor treatment. Your physician will discuss this option with you, so please ask if you have further questions about this option.

What extra tests and procedures will I have if I take part in this study?

Before you begin the study, your doctor will review the results of your exams, tests, and procedures. This helps your doctor decide if it is safe for you to take part in the study. Most of the exams, texts, and procedures you will have are part of the usual approach for your cancer. However, there are some extra procedures that you will need to have if you take part in this study.

You will need to have a blood sample taken for the study. You will have a blood draw for research before Cycle 1 Day 2. About four teaspoons (20 mL) of blood will be drawn. Researchers will obtain genetic material (DNA) from your blood samples. You and your study doctor will not get any results of this testing.

If you choose to take part, you will need additional tests which are not part of the usual approach for your type of cancer. These tests are:

- Blood draws for research tests before Cycle 1 Day 2 Blood draws for research tests on Cycle 1 Day 1 and Cycle 1 Day 2 and tumor tissue biopsy before Cycle 1 and on Cycle 1 Day 2

About four teaspoons (20 mL) of blood will be drawn before Cycle 1 Day 2.

About one teaspoon (6 mL) of blood will be drawn prior to and after the infusion of gemcitabine on Cycle 1 Day 1. About one teaspoon of blood will be drawn prior to M6620 (VX-970) infusion, 30 and 55 minutes after the start of the M6620 (VX-970) infusion and 15, 30 and 60 minutes after the end of the M6620 (VX-970) infusion for a total of about 2 ½ tablespoons (36 mL) of blood on Cycle 1 Day 2.

Three tumor tissue biopsies are required. The first at baseline (pre-study) and then either Cycle 1 day 1 and cycle 2 day 2 OR cycle 1 day 2 and cycle 2 day 1. Biopsy tissue samples, small pieces of cancer tissue removed by surgery, and blood samples are required in order for you to take part in this study because the research on the samples is an important part of the study. The research biopsies are done in a similar way to biopsies done for diagnosis. The tumor samples will be used to study the changes within the tumor after the chemotherapy and/or study drug. Common side effects of a biopsy are a small amount of bleeding at the time of the procedure, pain at the biopsy site, which can be treated with regular pain medications, and bruising. Rarely, an infection can occur. You will sign a separate consent form before the biopsy is taken. This will be a standard surgical consent form from the institution where the biopsy procedure takes place.

If there is remaining blood and tumor tissue, the specimen left over may be stored for biobanking if you agree and this will be discussed in the section on optional studies.

A study calendar that show when and how often the exams, tests and procedures will be done is attached to the end of this consent form

Your privacy is very important and the researchers will make every effort to protect it. Your test results will be identified by a unique code and the list that links the code to your name will be kept separate from your sample and health information. The tests are performed solely for research and the results will not be available to you or your study doctor.

Neither you nor your health care plan/insurance carrier will be billed for the collection of the blood and the tumor tissue samples that will be used for research in this study.

What possible risks can I expect from taking part in this study?

If you choose to take part in this study, there is a risk that:

- You may lose time at work or home and spend more time in the hospital or doctor's office than usual
- You may be asked sensitive or private questions which you normally do not discuss
- The study drug(s)/study approach may not be better, and could possibly be worse, than the usual approach for your cancer.
- There is a risk someone could get access to the personal information in your medical records or other information researchers have kept about you. Someone might be able to trace this information back to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information. In some cases, this information could be used to make it harder for you to get or keep a job. (For non-U.S. participants, please verify the existence of such laws before including the following sentence.) There are laws against misuse of genetic information, but they may not give full protection. The researchers believe the chance these things will happen is very small, but cannot promise that they will not occur.

The M6620 (VX-970) used in this study may affect how different parts of your body work such as your liver, kidneys, heart, and blood. The study doctor will be testing your blood and will let you know if changes occur that may affect your health.

There is also a risk that you could have side effects from the study drug(s)/study approach.

Here are important points about side effects:

- The study doctors do not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, or some may never go away.
- Some side effects may interfere with your ability to have children.
- Some side effects may be serious and may even result in death.

Here are important points about how you and the study doctor can make side effects less of a problem:

- Tell the study doctor if you notice or feel anything different so they can see if you are having a side effect.
- The study doctor may be able to treat some side effects.
- The study doctor may adjust the study drugs to try to reduce side effects.
- The study doctor will provide you with information about other drugs you may need to avoid while receiving the study drug.

The tables below show the most common and the most serious side effects that researchers know about. There might be other side effects that researchers do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

Possible Side Effects of M6620 (VX-970)

POSSIBLE, SOME MAY BE SERIOUS
• Anemia which may require blood transfusion • Diarrhea, nausea, vomiting • Tiredness • Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat • Infection especially when white blood cell count is low which may cause painful and frequent urination • Bruising, bleeding • Pain in tumor • Dizziness, headache • Itching, rash • Flushing

Risk of Increased Sensitivity to Sunlight
There is a possibility that M6620 (VX-970) may make you more sensitive to sunlight. You should limit your exposure to the sun, including indoor tanning. It is recommended to use sunscreen and wear long sleeved clothing, hats, and sunglasses.

Possible Side Effects of Carboplatin

COMMON, SOME MAY BE SERIOUS In 100 people receiving Carboplatin, more than 20 and up to 100 may have:
• Hair loss • Vomiting, nausea • Infection, especially when white blood cell count is low • Anemia which may cause tiredness, or may require blood transfusions • Bruising, bleeding • Belly pain

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Carboplatin, from 4 to 20 may have:
• Diarrhea, Constipation • Numbness and tingling in fingers and toes • Allergic reaction which may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat • Changes in taste • Changes in vision

RARE, AND SERIOUS In 100 people receiving Carboplatin, 3 or fewer may have:
• Damage to organs which may cause hearing and balance problems

Possible Side Effects of Gemcitabine

COMMON, SOME MAY BE SERIOUS In 100 people receiving Gemcitabine, more than 20 and up to 100 may have:
• Flu-like symptoms of muscle pain, fever, headache, chills and fatigue • Nausea, vomiting • Rash • Hair loss • Infection, especially when white blood cell count is low • Bruising, bleeding • Anemia which may require a blood transfusion • Muscle weakness • Blood in urine • Feeling of "pins and needles" in arms and legs • Numbness and tingling of the arms and legs • Tiredness • Difficulty sleeping • Hearing loss • Swelling of arms, legs

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving Gemcitabine, from 4 to 20 may have:
• Swelling and redness of the area of radiation • Blisters on the skin • Diarrhea, constipation • Sores in mouth which may cause difficulty swallowing • Liver damage which may cause yellowing of eyes and skin, swelling • Allergic reaction wchih may cause rash, low blood pressure, wheezing, shortness of breath, swelling of the face or throat • Scarring of the lungs • Shortness of breath • Fluid in the organs which may cause low blood pressure, shortness of breath, swelling of ankles • Brain damage, Reversible Posterior Leukoencephalopathy Syndrome, which may cause headache, seizure, blindness

RARE, AND SERIOUS In 100 people receiving Gemcitabine, 3 or fewer may have:
• Severe blood infection • Anemia, kidney problems which may require dialysis • Blood clot • Blockage of the airway which may cause cough

Let your study doctor know of any questions you have about possible side effects. You can ask the study doctor questions about side effects at any time.

Reproductive risks for females of child bearing potential: You should not get pregnant or breastfeed a baby while in this study. The M6620 (VX-970), carboplatin and gemcitabine used in this study could be very damaging to an unborn baby. Check with the study doctor about what types of birth control, or pregnancy prevention, to use while in this study. Use of birth control or pregnancy prevention should continue for 6 months after end of treatment. If you become pregnant during study treatment, please notify your doctor immediately.

Common side effects of a biopsy are a small amount of bleeding at the time of the procedure, pain at the biopsy site, which can be treated with regular pain medications, and bruising. Rarely, an infection can occur. You will sign a separate consent form before the biopsy is taken. This will be a standard consent form from the institution where the biopsy procedure takes place.

What possible benefits can I expect from taking part in this study?

This study is unlikely to help you. Researchers hope that the addition of the study drug M6620 (VX-970) to the standard chemotherapy treatment will work better to kill cancer cells compared to the standard chemotherapy alone. This study may help researchers learn things that may help other people in the future.

Can I stop taking part in this study?

Yes. You can decide to stop at any time. If you decide to stop for any reason, it is important to let the study doctor know as soon as possible so you can stop safely. If you stop, you can decide whether or not to let the study doctor continue to provide your medical information to the organization running the study.

The study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

The study doctor may take you out of the study:

- If your health changes and the study is no longer in your best interest
- If new information becomes available
- If you do not follow the study rules
- If the study is stopped by the sponsor, IRB or FDA.

What are my rights in this study?

Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

For questions about your rights while in this study, call the _____*(insert name of center)* Institutional Review Board at _____ *(insert telephone number). (Note to Local Investigator: Contact information for patient representatives or other individuals at a local institution who are not on the IRB or research team but take calls regarding clinical trial questions can also be listed here.)*

What are the costs of taking part in this study?

The M6620 (VX-970) will be supplied at no charge by NCI while you take part in this study. The cost of getting the M6620 (VX-970) ready and giving it to you is also provided at no charge. It is possible that the M6620 (VX-970) may not continue to be supplied while you are on the study. Although not likely, if this occurs, your study doctor will talk to you about your options.

You will not need to pay for the research tests and procedures performed in this study. These research tests and procedures include:

- Blood draws for research tests
- Collection of a tumor tissue sample by biopsy procedure
- Research tests performed on the blood and tumor tissue samples

You and/or your health plan/insurance company will need to pay for all of the other costs of caring for your cancer while in this study, including the cost of tests, procedures, or medicines to manage any side effects, unless you are told that certain tests are supplied at no charge. The cost of getting the carboplatin and gemcitabine ready and giving it to you is not paid by the study sponsor so you or your insurance company may have to pay for this. Before you decide to be in the study, you should check with your health plan or insurance company to find out exactly what they will pay for.

You will not be paid for taking part in this study.

What happens if I am injured or hurt because I took part in this study?

If you are injured or hurt as a result of taking part in this study and need medical treatment, please tell your study doctor. The study sponsors will not offer to pay for medical treatment for injury. Your insurance company may not be willing to pay for study-related injury. If you have no insurance, you would be responsible for any costs.

If you feel this injury was a result of medical error, you keep all your legal rights to receive payment for this even though you are in a study.

Who will see my medical information?

Your privacy is very important to us. The study doctors will make every effort to protect it. The study doctors have a privacy permit to help protect your records if there is a court case. However, some of your medical information may be given out if required by law. If this should happen, the study doctors will do their best to make sure that any information that goes out to others will not identify who you are.

Your privacy is very important to us and the researchers will make every effort to protect it. Your information may be given out if required by law. For example, certain states require doctors to report to health boards if they find a disease like tuberculosis. However, the researchers will do their best to make sure that any information that is released will not identify you. Some of your health information, and/or information about your specimen, from this study will be kept in a central database for research. Your name or contact information will not be put in the database.

There are organizations that may inspect your records . These organizations are required to make sure your information is kept private, unless required by law to provide information. Some of these organizations are:

- Vertex Pharmaceuticals or any drug company supporting the study.
- The Institutional Review Board, IRB, is a group of people who review the research with the goal of protecting the people who take part in the study.
- The Food and Drug Administration in the U.S. and similar ones if other countries are involved in the study.
- The National Cancer Institute will obtain information from this clinical trial under data collection authority Title 42 U.S.C. 285.

Where can I get more information?

You may visit the NCI Web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

A description of this clinical trial will be available on http://www.ClinicalTrials.gov,, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Who can answer my questions about this study?

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact the study doctor_____ *(insert name of study doctor[s] to be contacted))* at _____ *(insert telephone number).*

ADDITIONAL STUDIES SECTION:

This section is about optional studies you can choose to take part in

This part of the consent form is about optional studies that you can choose to take part in. You will not get health benefits from any of these studies. The researchers leading this optional study hope the results will help other people with cancer in the future.

The results will not be added to your medical records and you or your study doctor will not know the results.

You will not be billed for these optional studies. You can still take part in the main study even if you say "no" to any or all of these studies. If you sign up for but cannot complete any of the studies for any reason, you can still take part in the main study.

Circle your choice of "yes" or "no" for each of the following studies.

Optional Sample Collections for Laboratory Studies and/or Biobanking for Possible Future Studies

Researchers are trying to learn more about cancer, diabetes and other health problems. Much of this research is done using samples from your tissue or blood. Through these studies, researchers hope to find new ways to prevent, detect, treat or cure health problems.

Some of these studies may be about genes. Genes carry information about features that are found in you and in people who are related to you. Researchers are interested in the way that genes affect how your body responds to treatment.

If you choose to take part, left over blood and archived or left over tumor tissue samples will be stored. The researchers ask your permission to store and use your samples and related health information (for example, your response to cancer treatment, results of the study tests and medicines you are given) for medical research. The left over tumor tissue would be from the tumor tissue collected by biopsy before Cycle 1, on Cycle 1 Day 2 and on Cycle 2 Day 2. The research that may be done is unknown at this time. Storing samples for future studies is called "biobanking". The Biobank is being run by Mayo Clinic and supported by the National Cancer Institute.

WHAT IS INVOLVED?

If you agree to take part, here is what will happen next:

1) Any left over blood sample and/or the tumor tissue sample that was collected at the time of your biopsy will be sent to the Biobank.
2) Your sample and some related health information may be stored in the Biobank, along with samples and information from other people who take part. The samples will be kept until they are used up. Information from your medical record will be updated from time to time.
3) Qualified researchers can submit a request to use the materials stored in the Biobanks. A science committee at the clinical trials organization, and/or the National Cancer Institute, will review each request. There will also be an ethics review to ensure that

the request is necessary and proper. Researchers will not be given your name or any other information that could directly identify you.

4) Neither you nor your study doctor will be notified when research will be conducted or given reports or other information about any research that is done using your samples.
5) Some of your genetic and health information may be placed in central databases that may be public, along with information from many other people. Information that could directly identify you will not be included.

WHAT ARE THE POSSIBLE RISKS?

1) There is a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you.
2) There is a risk that someone could trace the information in a central database back to you. Even without your name or other identifiers, your genetic information is unique to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information.
3) In some cases, this information could be used to make it harder for you to get or keep a job or insurance. There are laws against the misuse of genetic information, but they may not give full protection. There can also be a risk in knowing genetic information. New health information about inherited traits that might affect you or your blood relatives could be found during a study. The researchers believe the chance these things will happen is very small, but cannot promise that they will not occur.

HOW WILL INFORMATION ABOUT ME BE KEPT PRIVATE?

Your privacy is very important to the researchers and they will make every effort to protect it. Here are just a few of the steps they will take:

1) When your samples are sent to the researchers, no information identifying you (such as your name) will be sent. Samples will be identified by a unique code only.
2) The list that links the unique code to your name will be kept separate from your sample and health information. Any Biobank and Mayo Clinic staff with access to the list must sign an agreement to keep your identity confidential.
3) Researchers to whom Mayo Clinic sends your sample and information will not know who you are. They must also sign an agreement that they will not try to find out who you are.
4) Information that identifies you will not be given to anyone, unless required by law.
5) If research results are published, your name and other personal information will not be used.

WHAT ARE THE POSSIBLE BENEFITS?

You will not benefit from taking part.

ARE THERE ANY COSTS OR PAYMENTS?

There are no costs to you or your insurance for these optional tests. You will not be paid for taking part. If any of the research leads to new tests, drugs, or other commercial products, you will not share in any profits.

WHAT IF I CHANGE MY MIND?

If you decide you no longer want your samples to be used, you can call the study doctor, _____ *(insert name of study doctor for main trial)* at _____ *(insert telephone number of study doctor for main trial)*

WHAT IF I HAVE MORE QUESTIONS?

If you have questions about the use of your samples for research, contact the study doctor _____ *(insert name of study team for main trial)* at _____ *(insert telephone number of study doctor team for main trial)*

Please circle your answer to show whether or not you would like to take part in each option

SAMPLES FOR FUTURE RESEARCH STUDIES:

.

My blood samples and related information may be kept in a Biobank for use in future health research.

YES NO

My tumor tissue samples and related information may be kept in a Biobank for use in future health research.

YES NO

I agree that my study doctor, or their representative, may contact me or my physician to see if I wish to participate in other research in the future.

YES NO

This is the end of the section about optional studies.

My Signature Agreeing to Take Part in the Main Study

I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed copy of this form. I agree to take part in the main study and any additional studies where I circled 'yes'.

Participant's signature_____

Date of signature_____

Signature of person(s) conducting the informed consent discussion_____

Date of signature_____

Study Calendar

Visit	Patient Activities
Pre-Study	**Within 21 days of registration** • Informed consent • Physical exam and medical history interview • *For females who may become pregnant only*: Serum pregnancy test **Within 7 days of registration** • Physical exam • Routine blood tests for hematology, chemistry, CA-125 • MRI or CT scan of the abdomen/pelvis **After registration, but prior to starting study treatment** • Tumor biopsy **At any time after consent up to Cycle 1 Day 2:** • Blood draw for research
Cycle 1	**Day 1** • Medical history interview • Routine blood tests for hematology, chemistry, CA-125 • Carboplatin and gemcitabine given by IV infusion over about 1 hour • Blood draw for pk prior to start of gemcitabine infusion and 25 minutes after start of gemcitabine infusion **Day 2** • M6620 (VX-970) given by IV infusion over about 1 hour • Blood draw for pk prior to start of M6620 (VX-970) infusion; 30 and 55 minutes after start of M6620 (VX-970) infusion and 15, 30 and 60 minutes after the end of the M6620 (VX-970) infusion. • Tumor biopsy **Day 8** • Routine blood test for hematology • Gemcitabine given by IV infusion over about 30 minutes **Day 9** • M6620 (VX-970) given by IV infusion over about 1 hour

Cycle 2 Day 2	Tumor biopsy randomized to either 18-24 hours after gemcitabine infusion or 4-6 hours after M6620 (VX-970) infusion
All Subsequent Cycles	**Day 1** • Physical exam and medical history interview • Routine blood tests for hematology, chemistry, CA-125 • Carboplatin and gemcitabine given by IV infusion over about 1 hour **Day 2** • M6620 (VX-970) given by IV infusion over about 1 hour **Day 8** • Routine blood test for hematology • Gemcitabine given by IV infusion over about 30 minutes **Day 9** • M6620 (VX-970) given by IV infusion over about 1 hour
At the End of Even Numbered Cycles for 1 year; Then Every 3 Months until the End of the Study	MRI or CT scan of the abdomen/pelvis
Off Treatment	Routine blood tests for hematology, chemistry, CA-125