SUMMARY OF CHANGES – Consent Part II

For Protocol Amendment to: A Randomized Phase II Study of Gemcitabine, Cisplatin +/- Veliparib in Patients with Pancreas Adenocarcinoma and a Known BRCA/ PALB2 Mutation (Part I) and a Phase II Single Arm Study of Single-Agent Veliparib in Previously Treated Pancreas Adenocarcinoma (Part II)

NCI Protocol #: 8993
Local Protocol #: 12-045

NCI Version Date: 10/23/2023
Protocol Date: 10/23/2023

#	Page(s)	Change
1	Throughout	NCI Version Date has been updated to 10/23/2023
2	Throughout	Formatting and editorial changes were made throughout the protocol document.
3	4	Under the "How long will I be in the study?", revised statement to state "The sponsor will no longer be providing Veliparib, and all treatment with veliparib must end by December 31, 2024."

PATIENT INFORMED CONSENT FOR CLINICAL RESEARCH

A Randomized Phase II Study of Gemcitabine, Cisplatin +/- Veliparib in Patients with Pancreas Adenocarcinoma and a Known BRCA/ PALB2 Mutation (Part I) and a Phase II Single Arm Study of Single-Agent Veliparib in Previously Treated Pancreas Adenocarcinoma (Part II)

(NCI #8993, Version Date: 10/23/2023)

This Consent form applies to Part II only.

You have been asked to participate in a research study. In order to decide whether or not you should agree to be part of this research study, you should know enough about its risks and benefits in order to make a sound judgment. This process is known as informed consent.

This is a clinical trial, a type of research study. Your study doctor will explain the clinical trial to you. Clinical trials include only people who choose to take part. Please take your time to make your decision about taking part. You may discuss your decision with your friends and family. You can also discuss it with your healthcare team. If you have any questions, you can ask your study doctor for more explanation.

This consent form gives you detailed information about the research study. Once you understand the study, its risks, and its benefits, you will be asked to sign the form if you wish to take part. You will be given a copy to keep.

You are being asked to take part in this study because you have pancreas cancer which is either localized and inoperable or metastatic (e.g., cancer which has spread to the liver or lung) and you have a known or suspected BRCA or PALB2 mutation in your DNA. A BRCA or PALB2 mutation may increase your susceptibility to certain cancers, e.g., breast, ovary, pancreas or prostate.
It is possible that you have been given this consent form to consider this trial without firm knowledge of whether or not you have a mutation. To be eligible for this study you will need to have confirmed evidence of a BRCA or PALB2 mutation. Any testing needed to determine the presence or not of a mutation will be determined outside this trial.

Why is this study being done?

The purpose of this study is to evaluate veliparib (ABT-888) in patients with previously treated advanced pancreas cancer. Veliparib is a new medication belonging to a class of drugs called PARP inhibitors. Veliparib is an experimental drug. Veliparib is not FDA-approved and is in clinical trial testing for patients with various cancers. In this trial we are studying the effect of veliparib administered in patients with previously treated pancreas cancer. We want to find out what effects, good and/or bad veliparib has in patients with pancreas cancer with a BRCA or PALB2 mutation.

Cells contain a type of molecule called deoxyribonucleic acid, or DNA for short. DNA carries the genetic information for the development of cells. If DNA becomes damaged, chemicals inside the cell try to repair it. One such chemical is the protein PARP. Veliparib is a drug that stops PARP from repairing DNA. Cancer cells with abnormal BRCA or PALB2 genes, have difficulty fixing this damage, causing cells to die.

A phase II trial is conducted when a dose of a medication (e.g., veliparib) has been determined and the goal is to determine the effect that it has on a specific patient population (e.g., previously treated pancreas cancer patients with a BRCA or PALB2 mutation).

Is there a potential conflict of interest for this study?

The manufacturer of the study drug, veliparib, is Abbott Laboratories. Several of the investigators involved in this research receive extra money from Abbott Laboratories for consulting work that is not part of the study. If you would like to know more about the steps MSK has taken to protect your best interests while you are in this study, please contact the MSK Patient Representative Department at 212-639-7202.

How many people will take part in the study?

About 10-12 people will take part in this study at Memorial Sloan Kettering Cancer Center and up to 33 patients will take part in this study worldwide.

What will happen if I take part in this research study?

You will take veliparib by mouth twice daily on a continuous basis for 28 days (a cycle). Veliparib should be taken with a glass of water and can be taken with or without food. You should take your medication at set times twice a day. The doses should be taken about 12 hours apart. Veliparib is supplied as capsules. You should not open these capsules.

This drug is yours and should not be taken by anyone else. If you forget to take study drug at the scheduled dosing time, you may still take your dose if it is within 2 hours of the scheduled time. If you forget to take study drug more than 2 hours after the scheduled dosing time, you should not take another capsule until your next scheduled dosing time, when you should take the capsules as prescribed.

All treatment and tests will be in the outpatient center except the administration of veliparib which you will take at home.

During the study your cancer will be assessed with scans (CT or MRI) at end of week 8 and approx. 3-6 months thereafter pending health status. If your cancer is stable or shrinking and you are tolerating the treatment well, you will continue on the study.

Before you begin the study …

You will need to have the following exams, tests or procedures to find out if you can be in the study. These exams, tests or procedures are part of regular cancer care and may be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated. This will be up to your study doctor.

- Review of your medical history and medications
- Physical examination including height and weight
- Vital signs (temperature, blood pressure, pulse)
- Routine blood tests
- Tumor marker blood tests (Ca 19-9, CEA)

- Pregnancy blood or urine test (if you are female and of childbearing potential)
- Baseline CT or MRI scan to measure the extent of your cancer
- EKG – an electrical tracing of your heart
- Review of your pathology (biopsy) slides
- Review of genetic test results (BRCA or PALB2 mutation) or genetic testing for these mutations, if not previously performed
- Provide you with a pill diary to record when you take veliparib and note any observations you have about the medication

During the study…

If the exams, tests and procedures show that you can be in the study, and you choose to take part, then you will need the following tests and procedures. They are part of regular cancer care.

- Review of your medical history and medications
- Review your pill diary
- Physical examination and weight check
- Vital signs
- Routine blood tests
- Tumor marker blood tests (e.g., Ca 19-9)
- CT or MRI scan to measure the status of your cancer

On Day 1 of each cycle you will be given a new supply of veliparib. You will also be given a drug diary to record every pill that you take. Your doctor will review the drug diary during each cycle. You will be asked to complete the patient diary to document when you took each dose or to give a reason if you did not take the capsules. You will be expected to bring the diary and unused capsules to the study doctor at the scheduled visits as described below.

If you have side effects, you may have to stop taking the study drug for a while and may need to restart it. The study doctor will provide you with complete instructions if this happens. Any leftover study medication that you do not take and the container (even if it is empty) must be returned at the end of each treatment cycle to your study doctor.

You must store the study drug capsules below 86 degrees Fahrenheit (i.e., room temperature) and protect them from the light.

You will need these tests and procedures that are either being tested in this study or being done to see how the study is affecting your body. These tests are not optional and are part of your participation in the study. The research tests below are designed to allow us to understand who may benefit or not from veliparib.

- Review of original diagnostic (archival) pathology slides (8-10 unstained slides or paraffin block).

When I am finished taking veliparib:

You will undergo the following tests when you finish the study treatment:

- Review of your medical history and medications
- Review of your pill diary
- Physical examination including weight
- Vital signs
- Routine blood tests
- Tumor marker blood tests (Ca 19-9)
- CT or MRI scan to measure the status of your cancer

How long will I be in the study?

You will be asked to take the veliparib for an indefinite time period or until your cancer starts to grow and you are no longer benefiting from the treatment. Treatment will also be stopped if you are having unacceptable side effects. After you are finished taking veliparib the study doctor will ask you to visit the office for follow-up exams (within 28 days of your last dose of drug on study).

We would like to keep track of your medical condition for the rest of your life. We would like to do this by calling you on the telephone once every 3 months to see how you are doing. Keeping in touch with you and checking on your condition every year helps us look at the long-term effects of the study.

The sponsor will no longer be providing Veliparib, and all treatment with veliparib must end by December 31, 2024. If you are still on study, your doctor will discuss treatment options with you.

Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop safely.

It is important to tell the study doctor if you are thinking about stopping so any risks form stopping veliparib can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

The following tables illustrate study procedures and timing.

Cycle 1

Day	Evaluations
Before You Start Therapy	• Get routine blood tests • EKG • CT or MRI scan • Tumor marker blood tests (Ca 19-9) • Confirm BRCA or PALB2 mutation, or arrange for testing if not already performed • Assessment • Medical history, physical examination, vital signs

Day 1	• Assessment • Provision of pill diary • Start veliparib
Day 14	• Assessment • Routine bloods
Day 29	• Next cycle starts (each cycle is 4 weeks long) • New dosing cycle of veliparib • New pill diary • Routine bloods

Future cycles

Day	**Evaluations**
Days 29	• Veliparib by mouth twice daily for 28 days continuously. • New pill diary provided.
Day 14 (mid point of cycle)	• Assessment
4th week	• Routine labs
End of week 8 and approx. every 3-6 months thereafter	• CT or MRI scan to assess the status of your cancer
8th week	• Routine bloods • Tumor marker blood tests (Ca 19-9)
End of study	• Assessment • CT or MRI scan to assess your cancer • Routine blood tests • Tumor marker blood tests (Ca 19-9)

The study doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest; if you do not follow the study rules; or if the study is stopped.

What side effects or risks can I expect from being in the study?

If you choose to take part in this study, there is a risk that the ABT-888 (veliparib) may not be as good as the usual approach for your cancer or condition at shrinking or stabilizing your cancer.

You also may have the following discomforts:

- Spend more time in the hospital or doctor's office.
- Be asked sensitive or private questions about things you normally do not discuss.
- May not be able to take part in future studies.

The ABT-888 (veliparib) 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 test 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 things to know 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, and some may never go away.
- Some side effects may make it hard for you to have children.
- Some side effects may be mild. Other side effects may be very serious and even result in death.

You can ask your study doctor questions about side effects at any time. Here are important ways to make side effects less of a problem:

- If you notice or feel anything different, tell your study doctor. He or she can check to see if it is a side effect.
- Your study doctor will work with you to treat your side effects.
- Your study doctor may adjust the study drugs to try to reduce side effects.

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

Veliparib

COMMON, SOME MAY BE SERIOUS In 100 people receiving ABT-888 (veliparib), more than 20 and up to 100 may have:
• Nausea • Tiredness • Bruising, bleeding

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving ABT-888 (veliparib), from 4 to 20 may have:

- Anemia which may require blood transfusion
- Infection, especially when white blood cell count is low
- Belly pain
- Constipation, diarrhea, vomiting
- Weight loss, loss of appetite
- Dehydration
- Dizziness, Headache
- Changes in taste
- Rash

RARE, AND SERIOUS
In 100 people receiving ABT-888 (veliparib), 3 or fewer may have:

- Cancer of bone marrow caused by chemotherapy
- Damage to the bone marrow (irreversible) which may cause infection, bleeding, may require transfusions
- A new cancer resulting from treatment of earlier cancer
- Seizure
- Blood clot which may cause swelling, pain, shortness of breath

Reproductive risks

You should not become pregnant or father a baby while on this study because the drugs in this study can affect an unborn baby. Women should not breastfeed a baby while on this study. It is important you understand that you need to use birth control while on this study. Two forms of contraception are recommended, e.g., birth control pills and spermicide or condom. Check with your study doctor about what kind of birth control methods to use and how long to use them. Some methods might not be approved for use in this study.

Some of the drugs used in the study may make you unable to have children in the future. If you are a woman of child-bearing potential a pregnancy test will be required before receiving treatment as part of the study.

For more information about risks and side effects, ask your study doctor.

Are there benefits to taking part in the study?

Taking part in this study may or may not make your health better. We do know that the information from this study will help doctors learn more about veliparib as a treatment for cancer. This information could help future cancer patients.

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

Your other choices may include:

- Getting treatment or care for your cancer without being in a study

- Standard therapy such as gemcitabine +/- cisplatin, FOLFOX (5-fluorouracil, oxaliplatin) or FOLFIRINOX (5-fluoruracil, irinotecan, oxaliplatin)
- Taking part in another study
- Getting no treatment
- Getting comfort care, also called palliative care. This type of care helps reduce pain, tiredness, appetite problems and other problems caused by the cancer. It does not treat the cancer directly, but instead tries to improve how you feel. Comfort care tries to keep you as active and comfortable as possible.

Talk to your doctor about your choices before you decide if you will take part in this study.

Will my medical information be kept private?

Every effort will be made to keep your study records private. It is the responsibility of the research staff at Memorial Hospital to make sure that your records are managed to protect your privacy. If information from this study is used in any reports or publications, your name and anything else that could identify you will not be used. Trained staff at Memorial Hospital may review your records if necessary. Access to your medical information will be limited to those listed in the Research Authorization Form, which is a part of the informed consent process.

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.

What are the costs of taking part in this study?

You and/or your health plan/ insurance company will need to pay for some or all of the costs of treating your cancer in this study. Some health plans will not pay these costs for people taking part in studies. Taking part in this study may or may not cost your insurance company more than the cost of getting regular cancer treatment.

The National Cancer Institute (NCI) is supplying veliparib at no cost to you. However, you or your health plan may need to pay for costs of the supplies and personnel who prepare the drug for you.

Even though it probably won't happen, it is possible that the NCI may not be able to provide veliparib for some reason. If this were to occur, other possible options are:

- You might be able to get veliparib from the manufacturer or your pharmacy but you or your insurance company may have to pay for it.
- If there is no veliparib available at all, no one will be able to get more and the study would close.

If a problem with getting veliparib occurs, your study doctor will talk to you about these options.

You/ Your health plan **WILL BE** billed for:

- Physician's fees
- Routine blood tests
- All CT or MRI scans

- Pregnancy test (where needed)
- EKG tests
- Any hospitalizations occurring on study
- Genetic testing to determine if you have a BRCA or PALB2 mutation

You/ Your health plan **WILL NOT BE** billed for:

- Veliparib

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

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

You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. The study will not pay for medical treatment.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

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

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to your study doctor about any questions or concerns you have about this study. Contact your study doctor: Dr. Eileen M. O'Reilly at telephone number: (646) 888-4182.

Any hospital that does research on people has an institutional review board (IRB). This board reviews all new studies to make sure that the patient's rights and welfare are protected. The IRB at MSK has reviewed this study.

For questions about your rights while you are participating in this study, call the MSK Institutional Review Board (IRB) at 212-639-7592. If you have concerns, complaints, or input on research, or if you would like more information about the informed consent process, please contact the MSK Patient Representative Department at 212-639-7202.

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).

RESEARCH AUTHORIZATION

A Randomized Phase II Study of Gemcitabine, Cisplatin +/- Veliparib in Patients with Pancreas Adenocarcinoma and a Known BRCA/ PALB2 Mutation (Part I) and a Phase II Single Arm Study of Single-Agent Veliparib in Previously Treated Pancreas Adenocarcinoma (Part II)
(NCI #8993, Version Date: 10/23/2023)

Research Participant Name: _____

Research Participant MRN :_____

We understand that information about you and your health is personal. We are committed to protecting the privacy of your information. Because of this commitment, we must obtain approval from you before we can use your protected health information for research purposes. This form provides that authorization. This form also helps us make sure that you are informed of how this information will be used or disclosed in the future. Please read the information below carefully before signing this form.

USE AND DISCLOSURE COVERED BY THIS AUTHORIZATION

A representative of Memorial Sloan Kettering Cancer Center must answer these questions completely before providing this authorization form to you*. PLEASE DO NOT SIGN A BLANK FORM.* ***You or your personal representative should read the descriptions below before signing this form.***

Who will have access to and/or use your health information?

The following individuals and/or organization(s) may have access to use, disclose or receive some information about you. They may only share the information to the individuals/parties indicated on this list. This information must be shared with you, the research subject and/or your personal representative, as required by law.

- ☑ Every research site for this study, including Memorial Sloan Kettering Cancer Center (MSK) and the research support staff (for example, research study assistant) and medical staff at each location
- ☑ Every health care personnel who provides services to you in connection with this study
- ☑ Any laboratories, other individuals/organizations that analyze your health information in connection with this study as defined by protocol
- ☑ The following research sponsors: MSK
- ☑ The National Cancer Institute and/or the National Institute of Health
- ☑ The United States Food and Drug Administration and other regulatory agencies responsible for oversight.
- ☑ The members and staff of the hospital's Institutional Review Board and Privacy Board
- ☑ Principal Investigator and Co-Principal Investigator(s): Eileen M. O'Reilly and David P. Kelsen
- ☑ Members of the Research Team including the participating investigators, research assistants,

clinical nurses, fellows/residents, and clerical support staff.

☑Members and staff of the hospital's Clinical Research Administration, Computing Resource Group that manages research databases, and the research management and support staff in the clinical departments

☑ Members of the Hospital's Data Safety Monitoring Board/Committee and Quality Assurance Committee

☑ Others (as described below):

- Abbott Laboratories, the supplier of veliparib
- Member of research teams at participating sites
- University of Pittsburgh

What information will be used or disclosed?

The boxes checked below should provide you with enough detail so that you can understand what information may be used or disclosed.

☒ Your entire research record

☒ Any part of your medical records held by the hospital

☒ HIV-related information. This includes any information indicating that you have had an HIV-related test, or have HIV infection, HIV-related illness or AIDS, or any information which could indicate that you have been potentially exposed to HIV. (New York State requires us to obtain special consent)

☒ The following information:

- Archival tumor biopsies, Pill diaries

SPECIFIC UNDERSTANDINGS

By signing this form, you give permission for the sharing of your protected health information noted above. The purpose for the use and disclosure of your information, is to conduct the research study explained to you during the informed consent process. This form also ensures that the information relating to the research is available to everyone who may need it. Your protected health information may also be used for your research treatment, to collect payment for your treatment while on the study (when applicable), and to run the business operations of the hospital.

Once we have shared your information with the individuals and organizations listed on this form, they may be able to share your information again, if they are not subject to laws that protect your privacy.

It is your right to refuse to sign this authorization form. If you do not sign this form, you will not be able to participate in the research study. You will not receive the research treatment that was described to you. Your health care outside the study will not be affected. The payment for your health care or your health care benefits will not be affected.

If you sign this authorization form, you will have the right to withdraw it at any time. To withdraw the authorization will prohibit further use or disclosure of your health information. If the hospital has already used your health information approved by your authorization or needs the information to fulfill an obligation or analyze the data, the use or disclosure can not be stopped. This authorization form will not expire unless you withdraw it. If you want to withdraw this authorization, please write to Dr. Eileen M. O'Reilly, Department of Medicine at the hospital.

You have a right to see and copy your health information described in this authorization form in accordance with the hospital's policies. You also have a right to receive a copy of this form after you have signed it.

Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that the individuals/organizations are prohibited from sharing any HIV-related information without your approval unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (800) 523-2437 or (212) 480-2493 or the New York City Commission of Human Rights at (212) 306-7450 or (212) 306-7500. These agencies are responsible for protecting your rights.

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Statement of professional obtaining consent

I have fully explained this clinical research study to the participant or his/her Legally Authorized Representative (**LAR**). In my judgment and the participant's or that of his/her Legally Authorized Representative, there was sufficient access to information, including risks and benefits to make an informed decision. The consent discussion will be documented in the participant's EMR.

Consenting Professional Must Personally Sign & Date		
Assent (Minor between the ages of 7 and less than 18): If the participant is a minor, I have obtained his/her assent to participate in the study to the best of their ability to understand. ☐ **YES** ☐ **NO** ☐ **N/A (Adult or Child <7)**		
Consenting Professional's Signature		**Date:**
Consenting Professional's Name (Print)		

Participant's (or Legally Authorized Representative's (LAR)) statement

I have read this form with the description of the clinical research study. I have also talked it over with the consenting professional to my satisfaction. By signing below, I am agreeing to the following: (1) to voluntarily be a participant in this clinical research study (2) authorizing for the use and disclosure of my/their protected health information (data about myself) and (3) that I received a signed copy of this consent form.

Participant/LAR Must Personally Sign & Date		
Participant/LAR Signature		**Date:**
Participant/LAR Name (Print)		
LAR Relationship to Participant		

Witness Signature (If Required)

☐ **Non-English Speaking Participant Witness and/or Interpreter:** I declare that I am fluent in both English and participant's (or LAR) language and confirm that the consent discussion was appropriately translated for the participant (or LAR).

☐ **Other:** I confirm that the consent discussion was appropriate for the participant's (or LAR's) understanding of the study.

Name of Witness: _____

Signature of Witness: _____ Date: _____
(If witness is used for consent discussion, their name must be documented in the EMR.)

The Participant/Legally Authorized Representative Must Be Provided With A Signed Copy Of This Form