MC250402 / 25-003418

Phase 2, Single-arm Trial of BMS-986340 in Combination with Nivolumab, Gemcitabine and Nab-paclitaxel in the First Line Setting of Advanced Pancreatic Adenocarcinoma

NCT07226856

Document Date: 04/09/2026

MAYO CLINIC

Name and Clinic Number

Approval Date: **April 9, 2026**
Not to be used after: **November 20, 2026**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: MC250402 Phase 2, Single-arm Trial of BMS-986340 in Combination with Nivolumab, Gemcitabine and Nab-paclitaxel in the First line Setting of Metastatic Pancreatic Adenocarcinoma

IRB#: 25-003418

Principal Investigator: Tanios S. Bekaii-Saab and Colleagues

Key Study Information

This section provides a brief summary of the study. It is important for you to understand why the research is being done and what it will involve before you decide. **Please take the time to read the entire consent form carefully and talk to a member of the research team before making your decision.** You should not sign this form if you have any questions that have not been answered.	
It's Your Choice	This is a research study. Being in this research study is your choice; you do not have to participate. If you decide to join, you can still stop at any time. You should only participate if you want to do so. You will not lose any services, benefits or rights you would normally have if you choose not to take part.
Research Purpose	The purpose of this research is to find out more about the side effects of **Imzokitug** (BMS-986340) and what doses of **Imzokitug** (BMS-986340) administered in combination with nivolumab, gemcitabine and nab-paclitaxel are safe for patients with metastatic pancreatic cancer. Everyone in this study will receive **Imzokitug** (BMS-986340), which is still experimental and isn't approved by the U.S. Food and Drug Administration (FDA). However, the FDA has allowed the use of this drug in this research study. You have been asked to take part in this research because you have advanced pancreatic cancer.

Approval Date: **April 9, 2026**
Not to be used after: **November 20, 2026**

What's Involved	If you are eligible and choose to take part in this study, you will receive **Imzokitug** (BMS-986340) and Nivolumab by intravenous (IV) infusion on Day 1 of every 28 cycle. You will also receive Gemcitabine and Nab-paclitaxel by IV infusion on Days 1 and 15 of every 28 days. This study will involve but is not limited to physical examinations, imaging of your cancer, routine blood tests, urinalysis and ECG's. The study also requires the following tests and procedures which are done only for research: • Additional blood collected for research at the same time as blood drawn for your regular care • 1-2 biopsies of your cancer if your doctor thinks it is safe Your study participation is expected to last approximately 36 months.
Key Information	There are alternatives to taking part in this research. The research team will discuss the other treatment options with you. The most common risk associated with **Imzokitug** (BMS-986340) include: • Rash • Rash maculo-papular (flat, reddish/brown, raised bumps) • Diarrhea • Fatigue The main risks from this study are due to the drugs being used to treat your cancer. The risks associated with study participation are completely described later in this consent form. Be sure to review them carefully. The study drug, **Imzokitug** (BMS-986340) and Nivolumab will be given to you at no cost; however, you and/or your insurance will need to pay for all other tests and procedures that are part of this research study as they are needed for your clinical care, including copayments and deductibles. Before you take part in this study, you should call your insurer to find out if the cost of these tests and/or procedures will be covered.

	You will have to pay for any costs not covered by your insurance. You and/or your insurance might also have to pay for other drugs or treatments given to help control side effects. It is not known whether this treatment will be better or worse for you than what your doctor would normally choose. By participating in this research study, you may help doctors answer this question.
Learn More	If you are interested in learning more about this study, read the rest of this form carefully. The information in this form will help you decide if you want to participate in this research or not. A member of our research team will talk with you about taking part in this study before you sign this form. If you have questions at any time, please ask us.

Making Your Decision

Taking part in research is your decision. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision. Taking part in this study is completely voluntary and you do not have to participate.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you either a printed or electronic copy of this form to keep. A copy of this form will be put in your medical record.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

MAYO CLINIC

Name and Clinic Number

Approval Date: **April 9, 2026**
Not to be used after: **November 20, 2026**

Contact Information

If you have questions about …	You can contact …
▪ Study tests and procedures ▪ Materials you receive ▪ Research-related appointments ▪ Research-related concern or complaint ▪ Research-related injuries or emergencies ▪ Withdrawing from the research study	**Principal Investigator**: Dr. Tanios S. Bekaii-Saab **(Arizona)** **Phone:** (480) 301-8000 **Institution Name and Address:** Mayo Clinic Hospital in Arizona 5777 E Mayo Blvd Phoenix, AZ 85054 **Co-Principal Investigator:** Dr. Ryan M. Carr **(Rochester)** **Phone:** (507) 284-2511 **Institution Name and Address:** Mayo Clinic 200 First St SW Rochester, MN 55905 **Co-Principal Investigator:** Dr. Umair Majeed **(Florida)** **Phone:** (904) 953-2000 **Institution Name and Address:** Mayo Clinic Florida 4500 San Pablo Rd Jacksonville, FL 32224 **Cancer Center Clinical Trials Referral Office** **(Contact for all Mayo locations)** **Phone:** (507) 293-6386
▪ Rights of a research participant	**Mayo Clinic Institutional Review Board (IRB)** **Toll-Free:** (866) 273-4681
▪ Rights of a research participant ▪ Any research-related concern or complaint ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information ▪ Withdrawing from the research study	**Research Participant Advocate (RPA)** **(The RPA is independent of the Study Team)** **Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchparticipantadvocate@mayo.edu

If you have questions about …	You can contact …
▪ Billing or insurance related to this research study	**Patient Account Services** **Toll-Free:** (844) 217-9591

Other Information:
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.

Why are you being asked to take part in this research study?

You have been asked to take part in this research because you have advanced pancreatic cancer.

The plan is to have about 43 people take part in this study at Mayo Clinic.

Why is this research study being done?

In this study we want to find out more about the side effects of a new drug for advanced pancreatic cancer, **Imzokitug** (BMS-986340) and what doses of **Imzokitug** (BMS-986340) administered in combination with nivolumab, gemcitabine and nab-paclitaxel are safe for people to take. Everyone in this study will receive **Imzokitug** (BMS-986340), which is still experimental and isn't approved by the U.S. Food and Drug Administration (FDA). However, the FDA has allowed the use of this drug in this research study. We don't know all the ways that this drug may affect people. This study isn't likely to help you, but we hope the information from this study will help us develop a better treatment for patients with advanced pancreatic cancer in the future.

Nivolumab, gemcitabine and nab-paclitaxel have all been approved by the FDA; however, the FDA approved frequency of administration of the nab-paclitaxel and gemcitabine is different than the frequency of administration being used in this protocol for nab-paclitaxel and gemcitabine.

Information you should know

Who is Funding the Study?
Bristol Myers Squibb will provide the funding and will pay Mayo Clinic, the Study Sponsor, to cover costs related to running the study.

Information Regarding Conflict of Interest:
Your healthcare provider may be referring you to this research study. If your healthcare provider is also an investigator on this study, there is the chance that his or her responsibilities for the study could influence his or her recommendation for your participation. If you prefer, your healthcare provider will be happy to refer you to another investigator on the research study team for you to decide if you want to participate in the study and to see you for the research study activities while you are in the study.

How long will you be in this research study?

You may be in the study for up to 2 years or until your cancer gets worse, you experience unacceptable side effects, or you or your study doctor decide to stop treatment earlier.

What will happen to you while you are in this research study?

If you decide to take part in this study, you will first be asked to sign this consent form. Then you will go through what is known as the screening phase to help the study doctor decide if you meet all criteria for study participation.

Screening Phase
During this phase, we will do some tests and procedures to see if you are eligible to take part in this research study. The Principal Investigator will review the results of these tests and procedures. If you aren't eligible, the Principal Investigator will tell you why.

At this visit we will:

- Ask you about your medical history
- Give you a physical exam, including height, weight, and "vital signs" (blood pressure, temperature, heart and breathing rates)

- **Blood collection:** The study team will collect blood samples. These blood samples will be used to check your health status, and some will be collected for research. Approximately 50 mL (about 3.4 tablespoons) of blood will be collected for research and safety labs.
- Ask you for a urine sample
- Test your blood or urine for pregnancy if you are of childbearing potential and able to become pregnant
- Give you an electrocardiogram (ECG)
- Give you imaging scans
    - Computed tomography (CT)/magnetic resonance imaging (MRI) of the chest, abdomen, pelvis
    - Brain MRI (for participants with known or suspected brain metastases)
- Archival tumor sample - Archival tumor sample at screening is allowed if obtained in less than 3 months from the first dose and meets tissue requirements
- Mandatory tumor biopsy – if archival tumor sample is not available, a mandatory fresh tumor biopsy is required for all subjects

Some of these exams, tests or procedures are part of regular clinical 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 the Principal Investigator.

Treatment Phase

If you are eligible and choose to take part in this study, you will receive **Imzokitug** (BMS-986340) and Nivolumab by IV infusion on Day 1 of every 28 cycle. You will also receive Gemcitabine and Nab-paclitaxel by IV infusion on Days 1 and 15 of every 28 days.

Blood collection: The study team will collect blood samples. These blood samples will be used to check your health status, and some will be collected for research. During the treatment phase, the total volume of blood taken will depend on the visit. Approximately 50 mL (about 3.4 tablespoons) of blood will be collected for research and safety labs.

Cycle 1 and Subsequent Cycles Day 1 -

At these visits we will:

- Give you a physical exam, including weight, and "vital signs" (blood pressure, temperature, heart and breathing rates)
- Assess adverse events
- Approximately 50 mL (about 3.4 tablespoons) of blood will be collected for research and safety labs.
- Ask you for a urine sample

- Test your blood or urine for pregnancy if you are of childbearing potential and able to become pregnant
- Give you an ECG
- Administer Nivolumab by IV infusion over 30 minutes
- Administer Imzokitug (BMS-986340) by IV infusion over 60 minutes
- Administer Nab-paclitaxel by IV infusion over 30 to 40 minutes
- Administer Gemcitabine by IV infusion over 30 minutes

Cycle 1 Day 15 -
At this visit we will:

- Give you a physical exam, including weight, and "vital signs" (blood pressure, temperature, heart and breathing rates)
- Assess adverse events
- Approximately 50 mL (about 3.4 tablespoons) of blood will be collected for research and safety labs.
- Give you an ECG
- Administer Nab-paclitaxel by IV infusion over 30 to 40 minutes
- Administer Gemcitabine by IV infusion over 30 minutes

Cycle 2 and Subsequent Cycles Day 1 -
At these visits we will:

- Give you a physical exam, including weight, and "vital signs" (blood pressure, temperature, heart and breathing rates)
- Assess adverse events
- Approximately 50 mL (about 3.4 tablespoons) of blood will be collected for research and safety labs.
- Test your blood or urine for pregnancy if you are of childbearing potential and able to become pregnant
- Ask you for a urine sample
- Give you an ECG (Cycles 2 & 3 Day 1 only)
- Administer Nivolumab by IV infusion over 30 minutes
- Administer Imzokitug (BMS-986340) by IV infusion over 60 minutes
- Administer Nab-paclitaxel by IV infusion over 30 to 40 minutes
- Administer Gemcitabine by IV infusion over 30 minutes

Cycle 2 Day 15 and Subsequent Cycles Day 15 -
At these visits we will:

- Give you a physical exam, including weight, and "vital signs" (blood pressure, temperature, heart and breathing rates)

- Assess adverse events
- Approximately 30 mL (about 2 tablespoons) of blood will be collected for safety labs.
- Give you an ECG (Cycle 2 Day 15 only)
- Administer Nab-paclitaxel by IV infusion over 30 to 40 minutes
- Administer Gemcitabine by IV infusion over 30 minutes

Prior to Cycle 3 Day 1

- Mandatory tumor biopsy (if the PI determines it is clinically infeasible or poses unacceptable risk, the procedure will not be performed).

Cycle 3 and every other Cycle Day 1 (Cycle 5 Day 1, Cycle 7 Day 1, etc) -

- Give you imaging scans
    - CT/MRI of the chest, abdomen, pelvis
    - Brain MRI (for participants with known or suspected brain metastases)

End of Treatment (EOT) –

- Give you a physical exam, including weight, and "vital signs" (blood pressure, temperature, heart and breathing rates)
- Assess adverse events
- Approximately 50 mL (about 3.4 tablespoons) of blood will be collected for research and safety labs.
- Test your blood or urine for pregnancy if you are of childbearing potential and able to become pregnant
- Ask you for a urine sample
- Give you an ECG
- Give you imaging scans
    - CT/MRI of the chest, abdomen, pelvis
    - Brain MRI (for participants with known or suspected brain metastases)

<u>Safety Follow-up Phase</u>

Safety Follow Up (30, 60 & 100 days after last dose of study drug)

- Give you a physical exam, including weight, and "vital signs" (blood pressure, temperature, heart and breathing rates)
- Assess adverse events
- Approximately 30 mL (about 2 tablespoons) of blood will be collected for safety labs.
- Test your blood or urine for pregnancy if you are of childbearing potential and able to become pregnant
- Ask you for a urine sample
- Give you an ECG

Clinical Follow Up (Every 12 weeks)

- Give you a physical exam, including weight, and "vital signs" (blood pressure, temperature, heart and breathing rates)
- Assess adverse events
- Approximately 30 mL (about 2 tablespoons) of blood will be collected for safety labs.
- Ask you for a urine sample
- Give you imaging scans
    - CT/MRI of the chest, abdomen, pelvis
    - Brain MRI (for participants with known or suspected brain metastases)

After you stop treatment, we will follow your health every 3 months for up to 2 years after you start this study. We may contact you by telephone, email, or through the patient portal.

OPTIONAL Tumor Sample

This research study includes an optional biopsy at disease progression to obtain tumor tissue sample(s). The biopsy will only be obtained if the tumor is easily accessible for the collection of the tissue sample(s) and the procedure is medically safe. The sample(s) will be used to study how the tumor changes over time, including possible genetic changes, which may help physicians and the research team to develop further treatment strategies. You do not have to have this optional biopsy collected to participate in the study.

Please read the following statement and mark your choices:

1. I agree to undergo an optional biopsy at disease progression, if my tumor is easily accessible and medically safe, to obtain tumor tissue sample(s) to be stored and used for future research to study how the tumor changes over time, including possible genetic changes, which may help physicians and research team to develop further treatment strategies:

☐ Yes ☐ No Please initial here: _____Date: _____

Research Results

Tests done only for research purposes are not meant to provide clinical information or care for you. The results are only important for research. Therefore, the results of tests done with your information and samples will not be provided to you. In the rare event that a finding might affect the health of you or your family, we will contact you and you can choose whether to receive or refuse the information. If you decide to follow up and further medical testing or care is needed, the costs will be billed to you or your insurance.

What are your responsibilities?
If you take part in this research, you will be responsible to:

- Come to study visits and follow the instructions you are given by the study doctor or other study staff.
- Immediately report to the study doctor or other study staff any changes in your health or regular medications.
- Tell your study doctor or study staff if you think you are experiencing a harmful effect from the study participation.
- If sexually active, use adequate birth control/contraceptive measures (specified later in this consent) for the duration of your time on the study and inform the study doctor or study staff if you become pregnant.
- Do not participate in other research studies while participating in this study before discussing with your study doctor or study staff.
- Tell the study doctor or study staff if you want to stop being in this research study

What are the possible risks or discomforts from being in this research study?

Possible Risks and Side Effects Related to Imzokitug (BMS-986340)
The most common treatment-related adverse events (TRAEs) (≥ 10%) include:

- Rash
- Rash maculo-papular (flat, reddish/brown, raised bumps)
- Diarrhea
- Fatigue

Treatment-related adverse events (TRAEs) (< 10%) include:

- Immune-mediated enterocolitis (inflammation of intestines)
- Anemia
- Psoriasis (red, itchy, scaly patches)
- Vomiting
- Colitis (inflammation of the colon)
- Pancreatitis (inflammation of the pancreas)
- Asthenia (weakness, lack of energy)
- Amylase increased
- Pancreatogenous diabetes (diabetes from pancreatic disease)
- Type 1 diabetes mellitus
- Pneumonitis (inflammation of the lung tissue)
- Hypertension (high blood pressure)

- Enterocolitis (inflammation of small intestine & colon caused by infection)
- Autoimmune Hemolytic Anemia (AIHA)- rare immune reaction to immune check point inhibitors- may need blood transfusion
- Psychiatric disorders- confusion
- Cancer metastasis to spine in one patient

Many side effects go away shortly after the Imzokitug (BMS-986340) is stopped, but in some cases side effects can be serious, long-lasting, or may never go away. There may be a risk of death. Some side effects may not be known. Side effects may range from mild to life-threatening. Other drugs may be given to make side effects less serious and less uncomfortable. Talk to the researcher and/or your healthcare provider about side effects and ask any other questions.

By enrolling in this trial, you may experience effects that result in lower doses or strength of your standard of care chemotherapy treatment.

Possible Risks and Side Effects Related to Nivolumab
The most common treatment-related adverse events (TRAEs) (≥ 10%) include:

- Tiredness
- Rash/itching
- Diarrhea
- Nausea
- Decreased appetite
- Joint or muscle pain
- Cough
- Headache
- Lab test changes (e.g., liver or thyroid tests)

Serious Treatment-related adverse events (TRAEs) (< 10%) include:

- Anemia
- Pyrexia (fever)
- Vomiting
- Dry mouth
- Constipation
- Chills
- Dry eye
- High blood pressure
- Low blood pressure
- Dehydration

- Bronchitis
- Sarcoidosis (a chronic inflammatory disease of unknown cause that primarily affects the lungs but can involve other organs)
- Lung infiltration
- Guillain-Barre syndrome (a rare autoimmune disorder in which the body's immune system mistakenly attacks the peripheral nerves (nerves outside the brain and spinal cord))
- Vogt Koyanagi Harada syndrome (a rare autoimmune disorder that affects multiple body systems, including the eyes, ears, skin, and central nervous system)
- Lungs (pneumonitis): new or worse cough, chest pain, shortness of breath.
- Intestines (colitis): diarrhea, black or bloody stools, severe belly pain.
- Liver (hepatitis): yellowing of skin/eyes, dark urine, severe nausea/vomiting, right-side belly pain.
- Hormone glands (endocrine): extreme tiredness, dizziness/fainting, headache, weight change, hair loss, feeling very cold or very hot, mood changes. These may include inflammation or reduced function of the pituitary, thyroid, or adrenal glands, and type 1 diabetes (can cause diabetic ketoacidosis: thirst, frequent urination, confusion, fruity breath).
- Kidneys (nephritis): swelling in legs, less urine, bloody urine.
- Skin: severe rash, blistering/peeling skin, mouth sores, itching; rare severe reactions like Stevens–Johnson syndrome.
- Nerves and muscles: weakness, numbness/tingling, facial droop, severe muscle aches, vision changes, seizures, confusion (can include encephalitis, neuropathy, myasthenia-like symptoms).
- Heart (myocarditis) and blood vessels: chest pain, irregular heartbeat, shortness of breath, swelling, fainting.
- Eyes (uveitis/iritis): eye pain/redness, light sensitivity, vision changes.
- Other organs: inflammation can occur in almost any part of the body (for example, pancreas causing severe belly/back pain; hematologic/immune effects).

Infusion-related reactions
Can occur during or shortly after the infusion: chills, fever, flushing, rash/itching, shortness of breath, low blood pressure, dizziness. The team may slow or stop the infusion and give medicines to treat symptoms. Severe reactions are rare.

Risks in special situations

- Transplants: Nivolumab can cause organ transplant rejection (if you have a prior solid-organ transplant) and can worsen graft-versus-host disease or other complications after allogeneic stem-cell transplant (before or after nivolumab). These can be serious or fatal. Tell the team if you have ever had a transplant.

- Pregnancy and breastfeeding: Can harm an unborn baby (embryo-fetal toxicity). Use effective birth control while on study and for the timeframe specified below in section "Birth Control Requirements" after the last dose; do not breastfeed during treatment and for the recommended period after the last dose. If you become or plan to become pregnant, tell the team immediately.
- Combination therapy: If nivolumab is given with other treatments (e.g., ipilimumab/chemotherapy/targeted drugs), side effects may be more frequent or more severe

Possible Risks and Side Effects Related to Gemcitabine

Very common (may affect more than 1 in 10 people):

- Nausea and vomiting (feeling of being sick to your stomach)
- Low blood cell counts (red blood cells, platelets, and white blood cells): A low red blood cell count (anemia) may cause difficulty breathing and/or fatigue. You may need a blood transfusion. A low platelet count increases your risk of bleeding (such as nosebleeds, bruising, stroke, and/or digestive system bleeding). You may need a platelet transfusion. A low white blood cell count increases your risk of infection (such as pneumonia and/or severe blood infection). Infections may occur anywhere and become life-threatening. Symptoms of infection may include fever, pain, redness, and/or difficulty breathing.
- Difficulty breathing that is usually mild and passes rapidly without treatment
- Skin rash associated with itchy skin
- Hair loss
- Changes in liver function tests (tests that show how your liver is working); these changes are usually mild and nonprogressive.
- Abnormal liver tests (possible liver damage)
- Abnormal liver or bone enzyme level. You may not have any symptoms.
- Blood in the urine
- Excess protein in the urine. This may cause fluid retention.
- Flu-like symptoms, including fever, headache, chills, muscle soreness, fatigue, weakness, lethargy, loss of appetite, cough, runny nose, and sweating
- Swelling of ankles, fingers, feet, face.

Common (may affect up to 1 in 10 people):

- Fever with dangerously low white blood cell count
- Inflammation of the mucous membranes of the mouth and throat
- Poor appetite
- Headache
- Difficulty sleeping or feeling overly tired
- Sleepiness

- Cough
- Runny nose
- Constipation
- Diarrhea
- Sores or ulcers in the mouth and esophagus, which may be painful and cause difficulty swallowing.
- Abnormal liver tests (possible yellowing of the skin and/ or eyes)
- Itching
- Sweating
- Muscle pain
- Back pain
- Fever
- Feeling weak and having no energy
- Chills
- Infection

Uncommon (may affect up to 1 in 100 people):

- A serious condition that occurs in response to an infection that causes widespread inflammation, resulting in poor blood supply to vital organs (Sepsis). Symptoms may include a fast heart rate, fever, confusion and rapid breathing. Sepsis can rapidly lead to a life threatening clinical deterioration.
- Stroke: A stroke happens when blood flow to a part of the brain is suddenly stopped or when a blood vessel in the brain bursts. This can cause parts of the brain to stop working properly, leading to symptoms like sudden weakness or numbness on one side of the body, trouble speaking or understanding, and difficulty seeing or walking. It's a serious condition that needs immediate medical attention
- Irregular heart rate
- The heart is not able to pump blood properly, which can cause weakness and tiredness, fluid retention, and fluid build-up in the lungs, which can cause shortness of breath.
- Inflammation of the lungs, which can cause shortness of breath and difficulty breathing. If severe, this can be life threatening.
- Mild and transient breathing distress caused by narrowing of the airways
- Irritation or destruction of skin or other body tissues.
- This is a condition associated with decrease in red cells, platelets and kidney function. This may cause high blood pressure or swelling of the face, hands, feet, or the entire body. This can progress to acute kidney failure which can be life threatening.
- Kidney failure, which is when both of your kidneys fail, and your body holds fluid which can be serious or life threatening. Your blood pressure rises, and harmful wastes build up in your body. You may experience fatigue, nausea, and loss of appetite. When this happens, you need treatment to replace the work of your failed kidneys such as dialysis.

- Serious liver damage, including liver failure.
- Abnormal blood clotting in small blood vessels (possible stroke and/or other organ damage)
- Decrease in blood flow to the brain that can lead to a stroke.

Rare (may affect up to 1 in 1,000 people):

- High blood platelet count (possible increased clotting)
- Life-threatening allergic reaction (such as difficulty breathing, low blood pressure, and/or organ failure)
- Decreased blood flow to part of the heart causing damage to the heart muscle. This may be serious or life threatening.
- Blood vessel inflammation (possible bleeding and/or bruising)
- Decay of body tissue
- Abnormal liver function test (increased gamma-glutamyl transpeptidase[GGT])
- Low blood pressure, which may cause dizziness, lightheadedness or fainting.
- Leakage of fluids from blood vessels into surrounding tissue (possible difficulty breathing)
- Severe life-threatening damage to the lungs which can lead to fluid in the lungs and difficulty breathing which may require assistance with breathing.
- Decreased blood flow to part of the bowel (possibly causing death of tissue)
- Skin peeling
- Blisters
- Skin sores
- Very severe blistering skin condition which may lead to the loss of a large portion of your skin. This is a rare life threatening condition that is usually caused by drug reaction.
- Severe skin and digestive tract reaction that may include rash and sloughing or breakdown of tissue. This may manifest as various blisters, hives, and other lesions in various locations on the body including palms and soles, face and other extremities. This is serious and may be life threatening.
- An allergic reaction at the site, usually mild in nature, where an injection (shot) was given, which may cause some redness and swelling
- A skin rash like severe sunburn which can occur on skin that has previously been exposed to radiotherapy.
- Scarring of the air sacs of the lung associated with radiation therapy.
- Bain damage (possible headache, confusion, seizures, and/or vision loss)

Possible Risks and Side Effects Related to Nab-Paclitaxel

Very common (may affect more than 1 in 10 people):

- Infection, including urinary tract and upper respiratory tract infections.

- The study treatment may cause low blood cell counts (red blood cells, platelets, and white blood cells): A low red blood cell count (anemia) may cause difficulty breathing and/or fatigue. You may need a blood transfusion.
  A low platelet count increases your risk of bleeding (such as nosebleeds, bruising, stroke, and/or digestive system bleeding). You may need a platelet transfusion. A low white blood cell count increases your risk of infection (such as pneumonia and/or severe blood infection). Infections may occur anywhere and become life-threatening. Symptoms of infection may include fever, pain, redness, and/or difficulty breathing.
- Minor hypersensitivity reaction, including sudden reddening of the face and/or neck and rash.
- Nerve damage (possible numbness, pain, and/or loss of motor function)
- Low blood pressure, which may cause dizziness, lightheadedness or fainting.
- Diarrhea
- Hair loss
- Joint pain
- Mouth blisters/sores
- Muscle pain
- Feeling sick to your stomach or nausea
- Vomiting

Common (may affect up to 1 in 10 people):

- Slow heart rate which can cause dizziness, fainting and tiredness.
- Transient and mild nail and skin changes.
- An allergic reaction at the site where an injection (shot) was given, which may cause some localized redness, pain, hardening and swelling. It can also lead to vein leakage which can result in localized infection of the skin, scarring or death of the skin around injection site.
- Abnormal liver test (possible liver damage)

Uncommon (may affect up to 1 in 100 people):

- Severe life-threatening infection (possible low blood pressure, kidney failure, and/or heart failure)
- Significant allergic reactions requiring therapy (example abnormal blood pressure, swelling, difficulty breathing, hives, chills, back pain, chest pain, increased heart rate, abdominal pain, arm/leg pain, abnormal sweating)
- Decreased blood flow to part of the heart causing damage to the heart muscle. This may be serious or life threatening.
- Irregular heartbeat
- Fainting

- Heart muscle becomes damaged, and the heart doesn't pump properly which can lead to heart failure.
- Blood clots
- High blood pressure
- Blood clots in a vein (possible pain, swelling, and/or redness).
- Abnormal liver tests (possible yellowing of the skin/eyes)

Rare (may affect up to 1 in 1,000 people):

- The study treatment may cause an increased risk of infection, such as pneumonia (a infection of the lungs). A low number of white blood cells may increase the risk of infection. It may become life-threatening. Symptoms of infection may include fever, pain, redness, and/or difficulty breathing.
- Abdominal wall inflammation.
- Nerve damage (affecting movement, possible numbness, pain, and/or loss of motor function)
- Paralysis of the intestines
- Secondary blood cancers or disorders
- Serious hypersensitivity reaction that may cause shortness of breath, chest pain, fast or slow heartbeats, chills or exhaustion
- Decreased appetite
- Confusion, severe headache, blurred vision, hearing loss, ringing in the ears, or dizziness
- Low blood pressure (possible dizziness/fainting)
- Condition of the brain that severely alters thinking and may affect consciousness that can be serious or life threatening.
- Loss of muscle coordination including awkward, unsteady walking
- Headache
- Damage to an eye nerve causing disturbances in vision. On receiving higher doses, a temporary visual disturbance that looks like flickering or shimmering lights, often in zigzag patterns, which can appear before a migraine headache.
- Hearing loss
- Ringing in the ears.
- Dizziness
- Irregular heartbeat that is rapid.
- The heart is not able to pump blood properly, which can cause weakness and tiredness, fluid retention, and fluid build-up in the lungs, which can cause shortness of breath.
- When you are unable to maintain enough blood pressure to keep enough blood delivered to your organs. This might be life threatening condition that may require hospitalization.

- Difficulty breathing with low levels of oxygen in the blood, which could be serious and life threatening and require you to have a tube inserted into your windpipe that is hooked up to a machine to help you breathe.
- Blood clots in the lung (possible failure to breathe)
- Lung damage (possible difficulty breathing)
- Shortness of breath.
- Collection of fluid around the lungs in the chest cavity, which can cause shortness of breath and may require treatment.
- Cough
- Blockage and/or hole in the intestines (possibly leaking contents into the abdomen)
- Decreased blood flow to part of the bowel (possibly causing death of tissue)
- Inflammation of the pancreas (possible abdominal pain)
- Blood clot in the belly's blood vessels.
- Severe colon infection causing diarrhea.
- Infection of the colon due to low white blood cell counts.
- Buildup of fluid in the abdomen, which causes bloating and discomfort. This could require that the fluid be removed by a procedure called paracentesis
- Inflammation of the food pipe
- Constipation
- Liver damage and/or failure
- Decreased brain function due to liver damage.
- Itchy skin
- Rash
- Skin redness.
- Severe skin and digestive tract reaction that may include rash and sloughing or breakdown of tissue. This may manifest as various blisters, hives, and other lesions in various locations on the body including palms and soles, face and other extremities. This is serious and may be life threatening.
- Very severe blistering skin condition which may lead to the loss of a large portion of your skin. This is a rare life threatening condition that is usually caused by drug reaction.
- Shedding and scaling of the skin (possible fatal loss of bodily fluids)
- Hives
- Nail lifting off the nail bed
- Fever
- Dehydration
- Feeling weak and having no energy
- Swelling
- Abnormal kidney test (possible kidney damage)
- A seizure

Not known (frequency cannot be estimated from the available data):

- Breakdown of the blood clotting system causing possible severe bleeding, organ dysfunction, and/or organ failure.
- Breakdown products of the cancer cells entering the blood stream (possible weakness, low blood pressure, muscle cramps, kidney damage, and/or other organ damage)
- Vision changes including fluid build-up in the central part of the central part of the eye, flashing lights or floaters
- Irritation or inflammation of a vein
- Severe hardened skin (possible difficult movement)
- Hand-foot syndrome (palms of hands/soles of feet having pain, swelling, and blistering)
- Flare-up or worsening of existing autoimmune disease

When to seek urgent care
Call the study team immediately or 911 if severe for: shortness of breath; chest pain; severe abdominal pain; black/bloody stools; yellowing skin/eyes; confusion or severe headache; vision changes; severe muscle weakness; very high blood sugar symptoms (extreme thirst, frequent urination, nausea, confusion, fruity-smelling breath); or any rapidly worsening symptoms.

Blood Draw Risks
The risks of drawing blood include pain, bruising, lightheadedness, and/or fainting, or rarely, infection at the site of the needle stick.

ECG Risks
This test uses small sticky pads that are placed on your chest and limbs to measure the electrical activity of your heart. There may be mild discomfort from the sticky pads and a possibility of the skin being irritated by the adhesive on the sticky pads. Chest hair may need to be shaved prior to the placement of the sticky pads.

Biopsy Risks
A CT guided biopsy is a medical procedure that involves taking a small sample of tissue so it can be examined under a microscope. How the CT guided biopsy is carried out will depend on where the tissue sample is being taken from. There are a number of different types of CT guided biopsies, these include: scraping cells from the surface layer of tissue, using a needle or endoscope to obtain a sample, or even surgery. The risks of undergoing CT guided biopsy include pain, bruising, bleeding, infection, and possibly death. In addition, sometimes a CT guided biopsy procedure may accidentally cause malignant cells to break away from a tumor, resulting in its spreading to other areas of your body. There may also be accidental injury to a nearby organ during the procedure; for instance, biopsies near the lung may nick your lung and cause part of your lung to collapse.

You may receive anesthesia during your CT guided biopsy. There are very rare, but serious side effects associated with anesthesia which includes, changes in blood pressure or heart rate or rhythm, temporary mental confusion, infections, stroke, heart attack and death.

Radiation Risks
You will be exposed to radiation from the CT guided biopsies. The amount of radiation has a low risk of harmful effects. A negative pregnancy test is required within **48 hours prior to imaging** for research procedures that involve abdominal/pelvic imaging or radioactive materials.

Standard of Care Risks
Your doctor will discuss the risks of CT/Positron emission tomography (PET) and MRI as these tests and procedures are part of your standard clinical care.

Birth Control Requirements
The effect of Imzokitug (BMS-986340) on a fetus (developing baby still in the womb), or on a breastfeeding infant, is unknown and may be harmful. Because of these risks, you cannot take part in this study if you are pregnant or breastfeeding.

If you are a person of childbearing potential, you must have a negative pregnancy test in order to participate in this study unless you cannot become pregnant.

If you are sexually active and able to become pregnant, you must agree to use one of the birth control methods listed below:

- Hormonal methods, such as birth control pills, patches, injections, vaginal ring, or implants
- Barrier methods (such as a condom or diaphragm) used with a spermicide (a foam, cream, or gel that kills sperm)
- Intrauterine device (IUD)
- Abstinence (no sex)

You must use birth control for the entire study and for at least 180 days after your last dose of study drug.

If you miss a period, or think you might be pregnant during the study, you must tell the Principal Investigator immediately. The Principal Investigator may ask for your permission to collect information about the outcome of your pregnancy and your newborn.

If you are sexually active, and able to father a child, you must agree to use one of the birth control methods listed below:

- Barrier methods (such as a condom or diaphragm) used with a spermicide (a foam, cream, or gel that kills sperm)

- Hormonal methods used by your partner, such as birth control pills, patches, injections, vaginal ring, or implants
- Intrauterine device (IUD) used by your partner
- Abstinence (no sex)

You must use birth control for the entire study and for at least 180 days after your last dose of study drug.

If your partner thinks they might have become pregnant while you are in the study or for 180 days afterwards, you must tell the Principal Investigator immediately. The Principal Investigator may ask for your partner's permission to collect information about the outcome of their pregnancy and their newborn. You won't have to stop taking the study drug or stop taking part in the study if your partner becomes pregnant.

Genetic Testing Risks
This study involves testing your DNA, which is the genetic information you inherited from your parents (also known as genetic testing). This testing may include whole genome sequencing (mapping your entire genetic code). You will not be notified of the genetic test results, and they will not be put into your medical record.

Confidentiality Risks
As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk.

Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the Principal Investigator if you decide to stop and you will be advised whether any additional tests may need to be done for your safety.

In addition, the Principal Investigator, or Mayo Clinic may stop you from taking part in this study at any time:

- If it is in your best interest,
- If you don't follow the study procedures,
- If the study is stopped.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.

We will tell you about any new information that may affect your willingness to stay in the research study.

What if you are injured from your participation in this research study?

Where to get help:
If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries?
Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. You will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments, and coinsurance. The study will not offer free medical care or payment for any bad side effects from taking part in this study.

What are the possible benefits from being in this research study?

This study is only being done to gather information. You may choose not to take part in this study. You don't have to be in this study to receive treatment for your condition.

What alternative do you have if you choose not to participate in this research study?

You do not have to be in this study to receive treatment for your cancer.

Your other choices may include:

- Getting treatment or care for your cancer without being in a study
- 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 with the Principal Investigator or your doctor about the benefits and risks of these alternative(s).

What tests or procedures will you need to pay for if you take part in this research study?

You won't need to pay for tests and procedures which are done just for this research study.

These tests and procedures are:

- Blood for research only purposes
- Tissue for research only purposes
- CT/Ultrasound guided tumor biopsy
- Investigational study drugs Imzokitug (BMS-986340) and Nivolumab
- Administration of study drugs Imzokitug (BMS-986340) and Nivolumab

However, You and/or your insurance will need to pay for all other tests and procedures that are part of this research study as they are needed for your clinical care, including copayments and deductibles.

These tests and procedures are:

- Physical exams
- Blood for chemistries, complete blood counts (routine blood tests)
- Blood for SARS-CoV-2 viral tests at Screening
- Pregnancy test (for women of childbearing potential)
- Blood for Follicle Stimulation Hormone (FSH) (for women age <55) at Screening
- Electrocardiogram (ECG)
- Urinalysis
- CT/MRI scans as a part of your standard care

- PET/CT scans as part of your standard care
- Brain MRI scans as a part of your standard care
- Standard of care chemotherapy drugs Gemcitabine and Nab-paclitaxel
- Administration of standard of care chemotherapy drugs Gemcitabine and Nab-paclitaxel

The drugs, Imzokitug (BMS-986340) and Nivolumab, will be given to you at no cost.

You and/or your insurance may also have to pay for other drugs or treatment given to control side effects. You will also be responsible for any co-payments and deductibles.
Before you take part in this study, you should call your insurer to find out if the cost of these tests and/or procedures will be covered. You will have to pay for any costs not covered by your insurance.

If you have billing or insurance questions call Patient Account Services at the telephone number provided in the Contact Information section of this form.

Will you be paid for taking part in this research study?

You will not be paid for participating in this study.

There is a very small chance that some commercial value may result from the use of your sample. This could include new products like a drug or a test to diagnose a disease. If that happens, you will not be offered a share in any profits.

Will your information or samples be used for future research?

Unless you give your permission below, your information or samples collected for this study will not be used or shared for future research, even if the identifiable information such as your name, Mayo Clinic number or date of birth is removed.

We would like to keep your information and samples for future research. You can still take part in this current study even if you don't want your information or samples used for future research.

Researchers at Mayo Clinic who aren't involved with this study may ask to use your information and/or samples for future research. Researchers at other academic or medical institutions or companies may also ask for a part of your information and/or samples for future studies.

Approval Date: **April 9, 2026**
Not to be used after: **November 20, 2026**

Unless you indicate otherwise, the future research may be on any topic. No direct benefits to you are expected from the future research. Your information and/or samples will only be shared consistent with your consent, and with all applicable laws and regulations.

If you approve release of your information and/or samples by checking 'yes' below, Mayo Clinic may send the information and/or samples to researchers who request them, but Mayo Clinic will not send your name, address, phone number, social security number, or any other identifying information with the information and/or samples.

Your information and/or samples may be sent with a code, and only the researchers for this study at Mayo Clinic would be able to link the code to you.

Some future studies may examine your DNA, the genetic information you inherited from your parents (genetic testing). This testing may include whole genome sequencing (mapping your entire genetic code). You will not be notified of the genetic test results, and they will not be put into your medical record.

Even though information traditionally used to identify you will not be shared, people may develop ways in the future to allow someone to link your genetic information back to you. For this reason, confidentiality cannot be guaranteed. It is also possible that reidentified information could be used in discriminatory ways, and there could be additional unknown risks.

There is a chance that some commercial value may result from the future use of your sample or information. This could include new products like a drug or a test to diagnose a disease. If that happens, you will not be offered a share in any profits.

Please read the following statements and mark your choices:

1. I permit my information and samples to be stored and used in future research of cancer at Mayo Clinic.

☐ Yes ☐ No Please initial here: _____Date: _____

2. I permit Mayo Clinic to give my sample(s) to researchers at other institutions:

☐ Yes ☐ No Please initial here: _____Date: _____

3. I permit Mayo Clinic to give my sample(s) for future research to learn, prevent, or treat other health problems:

☐ Yes ☐ No Please initial here: _____Date: _____

Approval Date: **April 9, 2026**
Not to be used after: **November 20, 2026**

You may withdraw your consent for future use of your information and/or samples at any time, by writing to the Principal Investigator at the address provided in the "Contact Information" section of this consent form.

Samples that have already been used for research may not be able to be returned.

How will your privacy and the confidentiality of your records be protected?

General Protections
Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study.

The personal health information that may identify you may include your medical history, physical examinations, blood and/or tissue samples, scans, and any other data collected or reviewed during the course of this research study. This includes copies of your medical records from other health care providers who have treated you before and after you take part in this research study. This information will be used for the study and will become part of your medical records. To protect the data and confidentiality of your data, a code will be used as an identifier. The code will be a registration number assigned specifically to you by the Mayo Clinic Cancer Center Registration Office or Study Sponsor, if applicable. Your correlating Mayo Clinic number and name for reference will be maintained in a secure database accessible by Mayo Clinic assigned research staff. In addition, your research documents/materials will be stored in locked cabinets in a secure, badge access location.

Authorization to Use and Disclose Protected Health Information (HIPAA)
During this research, information about your health will be collected. Under Federal law called the Privacy Rule (also referred to as Health Insurance Portability and Accountability Act [HIPAA]), health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission (or "authorization") to Mayo Clinic.

Your health information may be collected from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

Approval Date: **April 9, 2026**
Not to be used after: **November 20, 2026**

Your health information will be used and/or given to others to:

- Do the research.
- Report the results.
- See if the research was conducted following the approved study plan, and applicable rules and regulations.

Your health information may be used and shared with:

- Mayo Clinic research staff involved in this study.
- Other Mayo Clinic staff involved in your clinical care.
- Other healthcare providers involved in your clinical care.
- Researchers involved in this study at other institutions.
- The sponsor(s) of this study and the people or groups hired by the sponsor(s) to help perform this research.
- Bristol-Myers Squibb
- The Mayo Clinic Institutional Review Board that oversees the research.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.
- A group that oversees the data (study information) and safety of this research.

How your information may be shared with others:

While taking part in this study, you will be assigned a code that is unique to you but does not include information that directly identifies you. This code will be used if your study information is sent outside of Mayo Clinic. The groups or individuals who receive your coded information will use it only for the purposes described in this consent form.

If the results of this study are made public (for example, through scientific meetings, reports or media), information that identifies you will not be used.

In addition, individuals involved in study oversight and <u>not</u> employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you. However, the individuals will not be allowed to record, print, or copy (using paper, digital, photographic or other methods), or remove your identifying information from Mayo Clinic.

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private, and it may no longer be protected by the Privacy Rule.

Genetic Information Nondiscrimination Act (GINA)

A Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information.

This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law.
Be aware that this Federal law doesn't protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Your Rights and Permissions

Participation in this study is completely voluntary. You have the right not to participate at all. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to sign this form, but if you do not, you cannot take part in this research study.

Deciding not to participate or choosing to leave the study will not result in any penalty. Saying 'no' will not harm your relationship with your own doctors or with Mayo Clinic.

If you cancel your permission for Mayo Clinic to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

MAYO CLINIC

Name and Clinic Number

Approval Date: **April 9, 2026**
Not to be used after: **November 20, 2026**

You can cancel your permission for Mayo Clinic to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
Plummer Building PL 3-02
200 First St. SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Participant Advocate at: researchparticipantadvocate@mayo.edu.

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission for Mayo Clinic to use and share your health information lasts until the end of this study, unless you cancel it. The study does not end until all data has been collected, checked (or audited), analyzed, and reported. Because research is an ongoing process, we cannot give you an exact date when the study will end. Sometimes this can be years after your study visits and/or activities have ended.

There is no expiration or end date related to the Sponsor's use of your health information received from Mayo Clinic as part of this study.

MAYO CLINIC

Name and Clinic Number

Approval Date: **April 9, 2026**
Not to be used after: **November 20, 2026**

Enrollment and Permission Signatures

Your signature documents your permission to take part in this research.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature