Are you participating in any other research studies? _____ Yes _____No

PURPOSE OF RESEARCH

You are invited to participate in a research study of SD-101 and BMS-986178 (both immune system activating drug) to treat your cancer. You were selected as a possible participant in this study because you have been diagnosed with a solid tumor cancer and have sites of disease that can be safely injected with the immune system activating drugs.

We hope to learn about the safety and tolerability of SD-101 and BMS-986178 directly injected into a tumor site, along with BMS-986178 given via a vein to treat your cancer. In addition, this study aims to discover what the outcomes (good or bad) will be when patients are treated with this combination. SD-101 and BMS-986178 are drugs currently being studied separately for the treatment of cancer, and the treatment efficacy of this combination is not yet known. SD-101 and BMS-986178 are not approved by FDA.

If you decide to terminate your participation in this study, you should notify Saad A Khan, MD at 650-498-6000.

This research study is looking for a total of 12 patients with metastatic solid tumor cancers. All patients will be enrolled at Stanford University.

VOLUNTARY PARTICIPATION

Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on you or your medical care. You can decide to participate now, but withdraw your consent later and stop being in the study without any loss of benefits or medical care to which you are entitled.

DURATION OF STUDY INVOLVEMENT

This research study is expected to take approximately 96 weeks, including about two months of active participation, and then a follow-up period (up to 2 years) until definite progression of disease or withdrawal by you or at the Protocol Director's discretion.

PROCEDURES

You will be screened at Stanford Cancer Center to see if you are a suitable candidate and meet all research criteria. You will be given this consent to look over and to share with your family and/or health advocates to review with you.

You will be asked if you have any questions regarding the study calendar below and any of the events within that calendar. You are strongly encouraged to take all the time you need to understand all the contents of this consent form. This is

a 96-week study, with the following experimental treatments given over the first approximately 9 weeks:

- Three injections of intratumoral (I-TUMOR) SD-101 and I-TUMOR BMS-986178 directly into an accessible tumor given at weekly intervals; Accessible tumors will also be assessed to ensure they are in an area that is safe for injections. These injections will be performed by interventional radiology physicians.
- Intravenous infusions of BMS-986178 given every 4 weeks for three total doses

After treatment, there will be follow-up visits every 2 months for the first 6 months, then every 3 months with computed tomography (CT) scans performed at some of those visits. This follow up will be ongoing and you will be considered part of this study unless you experience disease progression, or you decide to withdraw from the study, or the Principal Investigator, Saad A Khan, MD, removes you from the study at his discretion.

If you withdraw from treatment due to progressive disease, you will be seen within four weeks of the determination of progressive disease for a final visit. If you withdraw due to intolerance of treatment you will be followed weekly until all toxicities have stabilized in the opinion of the Investigator, at which point you will undergo the final visit. If you withdraw for any reason other than progressive disease, you will be seen within 4 weeks of withdrawal for a final visit. Withdrawal of consent for study treatment does not imply withdrawal of study consent. The study team may ask for clarification of your withdrawal of consent to determine appropriate next steps in regards to the final study visit and saved sample use for future research.

If you choose to participate, Dr Khan and his research study staff will follow the following schedule of study events.

Before treatment begins:

- Complete physical exam including vital signs, weight, and performance status (your ability to perform basic daily activities)
- Collection of medical history
- Monitoring of medications you are taking
- Routine safety labs: Complete blood count (CBC), comprehensive metabolic panel (CMP), prothrombin time/International Normalized Ratio (PT/INR), C-reactive protein (CRP), thyroid stimulating hormone (TSH), lipase, amylase
- Research blood draws

- Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) testing
- Women of child-bearing potential (WOCBP) only: Urine or serum pregnancy test within 72 hours prior to the first dose of trial treatment. If a urine test cannot be confirmed as negative, then a serum test will need to be negative
- Imaging by CT scan or position emission tomography (PET)/CT scan to assess extent of disease as indicated by study protocol (if not already done within 4 weeks of planned treatment start)

Day 1:

- Vital signs, weight, assessment of performance status, assessment of side effects; monitoring of medications currently being taken
- History and physical examination
- WOCBP only: Pregnancy test (for females of childbearing potential)
- Tumor biopsy of one tumor – treatment site (Lesion A) – by Interventional Radiology using CT or ultrasound guidance
- Intratumoral injection (Dose #1) of SD-101 and BMS-986178 to Lesion A. **Note:** The first seven patients on the study receive only SD-101 intratumorally on the first day.
- BMS-986178 intravenous infusion (Dose #1). **Note:** The first 6 to 8 patients on the study will not receive their first intravenous infusion of BMS-986178 until Day 8

Day 8:

- Vital signs, weight, assessment of performance status, assessment of side effects; monitoring of medications currently being taken
- History and physical examination
- Routine safety labs: Complete blood count (CBC), comprehensive metabolic panel (CMP), prothrombin time/International Normalized Ratio (PT/INR), C-reactive protein (CRP), thyroid stimulating hormone (TSH), lipase, amylase
- Research blood draws
- Only for WOCBP choosing complete abstinence: Urine or serum pregnancy test within 72 hours of each dose of study treatment. If a urine test cannot be confirmed as negative, then a serum test will need to be negative

- Biopsies of two tumors – treatment site (Lesion A), and a distant site (Lesion B)– by Interventional Radiology using CT or ultrasound guidance
- Intratumoral injection (Dose #2) of SD-101 and BMS-986178 to Lesion A.
- For the first 6-8 participants in the study: BMS-986178 intravenous infusion (Dose #1). (All other participants will receive the first infusion on Day 1)

Day 15:

- Vital signs, weight, assessment of performance status, assessment of side effects; monitoring of medications currently being taken
- History and physical examination
- Routine safety labs: Complete blood count (CBC), comprehensive metabolic panel (CMP), prothrombin time/International Normalized Ratio (PT/INR), C-reactive protein (CRP), thyroid stimulating hormone (TSH), lipase, amylase
- Research blood draws
- Only for WOCBP choosing complete abstinence: Urine or serum pregnancy within 72 hours of each dose of study treatment. If a urine test cannot be confirmed as negative, then a serum test will need to be negative
- Intratumoral injection (Dose #3) of SD-101 and BMS-986178 to Lesion A

Day 29:

- Vital signs, weight, assessment of performance status, assessment of side effects; monitoring of medications currently being taken
- History and physical examination
- Routine safety labs: Complete blood count (CBC), comprehensive metabolic panel (CMP), C-reactive protein (CRP), thyroid stimulating hormone (TSH), lipase, amylase
- Only for WOCBP choosing complete abstinence: Urine or serum pregnancy test within 72 hours of each dose of study treatment. If a urine test cannot be confirmed as negative, then a serum test will need to be negative
- BMS-986178 intravenous infusion (Dose #2)

Day 57:

- Vital signs, weight, assessment of performance status, assessment of side effects; monitoring of medications currently being taken
- History and physical examination
- Routine safety labs: Complete blood count (CBC), comprehensive metabolic panel (CMP), C-reactive protein (CRP), thyroid stimulating hormone (TSH), lipase, amylase
- Research blood draws
- Only for WOCBP choosing complete abstinence: Urine or serum pregnancy test within 72 hours of each dose of study treatment. If a urine test cannot be confirmed as negative, then a serum test will need to be negative.
- BMS-986178 intravenous infusion
- Determination of response to treatment with CT scans of the chest/ abdomen/pelvis (and neck, if needed)

Days 113, 169, 253, 337, 421, 505, 589, 673 (approximately 4, 6, 9, 12, 15, 18, 21, and 24 months after treatment start):

- Vital signs, weight, assessment of performance status, assessment of side effects; monitoring of medications currently being taken
- History and physical examination
- Routine safety labs: Complete blood count (CBC), comprehensive metabolic panel (CMP), C-reactive protein (CRP), thyroid stimulating hormone (TSH), lipase, amylase
- Determination of response to treatment with CT scans of the chest/ abdomen/pelvis (and neck, if needed)

Final study visit:

- Vital signs, weight, assessment of performance status, assessment of side effects; monitoring of medications currently being taken
- History and physical examination
- Routine safety labs: Complete blood count (CBC), comprehensive metabolic panel (CMP), C-reactive protein (CRP), thyroid stimulating hormone (TSH), lipase, amylase
- If study discontinuation is due to cancer progression: Research blood draws

- If there has not been a recent CT scan, then response to treatment will be assessed with CT scans of the chest/abdomen/pelvis (and neck if needed)

The study schedule is summarized in Table 1.

Table 1: Study Schedule

Procedures	Screening	Day 1 **I-TUMOR Dose #1, IV Dose #1**	Day 8 **I-TUMOR Dose #2**	Day 15 **I-TUMOR Dose #3**	Day 29 **IV Dose #2**	Day 57 **IV Dose #3**	Clinical Follow-Up (Until Disease Progression)	Final Study Visit
Written Informed Consent	X							
History and Physical Exam	X#	X	X	X	X#	X#	X#	X#
Adverse Event Evaluation		X	X	X	X	X	X	X
Review of Medications	X	X	X	X	X	X	X	X
Vital Signs	X#	X	X	X	X#	X#	X#	X#
Urine Pregnancy Test (for appropriate patients)		X#+	X#+	X#+	X#+	X#+		
Biopsy of Tumor(s)		X	X					
Research Blood Samples		X	X	X		X		(X)
Routine Safety Labs	X#		X	X	X#	X#	X#	X#
PT/INR (measures bleeding tendency)	X#		X	X				
HIV and hepatitis testing	X#							
SD-101 Injection		X	X	X				
I-TUMOR BMS-986178 Injection		X*	X	X				
IV BMS-986178 Infusion		X**	X**		X	X		
Imaging Studies (CT)	X#					X#	X#	X#

( ) = Optional * = Not given to first 6-8 patients on study ** = Given either week 1 or week 2 (not both)
+ = for women of childbearing potential (WOCBP) only
# = These procedures are standard of care and may be billed to your insurance.

Dosing of BMS-986178:

3.75 mg intratumorally (I-TUMOR) every week for 3 doses.

40 mg intravenously (IV) every 4 weeks for 3 doses.

Dosing of SD-101:

2 mg intratumorally (I-TUMOR) every week for 3 doses.

Alternate Dosing:

The first 6-8 participants will receive 2 mg of SD-101 into their tumor without any BMS-986178 (I-TUMOR or IV). These patients will receive their first dose of IV BMS-986178 in week 2 instead of week 1. If less than one third of these patients experience a serious side effect, then the study will proceed to enroll more patients and these subsequent patients will receiving both SD-101 and BMS-986178 in week 1 and will also receiving their first intravenous dose of BMS-986178 in week 1.

It is possible that doses will be delayed or omitted if you have significant side effects.

Other procedures:

CT (computed tomography) scans: create pictures of the inside of your body. CT scans use an x-ray machine together with a special dye injected into a vein in your arm before the scan. CT scans will occur at the Screening visit, then every 2 months for the first 6 months, and approximately every 3 months thereafter, for the rest of the study or at a time when your doctor suspects your cancer is getting worse. CT scans are standard of care for cancer.

Specimens Collection: Blood, Urine and Tissue (Lymph Node samples)

- Blood samples (approximately 1 to 5 tablespoons, depending on the week) will be taken from a vein in your arm at each study visit.
- Tumor biopsies involve the insertion of a needle into the tumor to collect a sample. This is done by a specialist, using some anesthesia and under image guidance.
- If you are able to become pregnant, you will be asked to have a urine pregnancy test done before beginning this research study.

HIV/HBV/HCV testing: You will have blood tests for HIV, Hepatitis B and Hepatitis C during screening. Positive results will be reported to the local health agency and may disqualify you from the study. If you test positive for HIV, counseling and resources will be provided.

Requirements for men and women of childbearing potential:

If you are a woman who is able to become pregnant, it is expected that you will use an effective method of birth control to prevent exposing a fetus to a potentially dangerous agent with unknown risk. If you are pregnant or currently breast feeding, you may not participate in this study. You understand that if you are pregnant, if you become pregnant, or if you are breast-feeding during this study, you or your child may be exposed to an unknown risk.

For women of childbearing potential: To confirm to the extent medically possible that you are not pregnant, you agree to have a pregnancy test done before beginning this research study and intermittently during treatment. You must agree to avoid sexual intercourse or use birth control methods judged to be effective by the investigator and which will not interfere with the proposed investigation. You must agree to do this until at least 160 days after your last treatment. You must accept the risk that pregnancy could still result despite the responsible use of reliable method of birth control. You agree to notify the investigator as soon as possible of any failure of proper use of your birth control method, or if you become pregnant, either of which may result in your being withdrawn from the study.

If you are a man participating in this study and your partner is able to become pregnant, you and your partner must use adequate contraception while you are participating in the study, for at least 165 days after your last treatment. Your doctor will discuss with you what methods of birth control are considered adequate. You should inform your study doctor if your partner becomes pregnant. Men must agree to not donate sperm during the study and for at least 165 days after the last treatment.

Tissue Samples for Research: The investigators would like to include your tissues in research on cancer and they want to save the samples for future research. There are several things you should know before allowing your tissues to be studied.

You have the right to refuse to allow your tissues to be studied now or saved for future study. If you withdraw your permission, the investigators might retain the samples as part of your routine clinical care, but not for additional research.

In order to protect your identity, your study doctor will assign you a unique code, such as a series of numbers and/or letters. Your tissue will be stored under this code. Your study doctor will keep a confidential list linking your name or medical record number to your code number and only authorized persons will have access to this list.

You will be told the results of tests that are part of your clinical care, but you will not be told the results of the research tests, including any future research tests. Any of your samples which are used in research may result in new products, tests

or discoveries. In some instances, these may have potential commercial value and may be developed and owned by the Investigators, Stanford University, TriSalus Life Sciences, Bristol-Myers Squibb Company and/or others. Donors of samples do not retain any property rights to the materials. Therefore, you would not share in any financial benefits from these products, tests or discoveries. Please mark one of the following statements with your initial.

_____ I consent to my samples being saved for future research

_____ I do not consent to my samples being saved for future research

Tissue Samples for Genetic Testing:

As part of the analysis on your samples, the investigators may do genetic testing. Genetic research is research that studies genes, including gene characteristics and gene versions that are transmitted by parents to children. Genetic research may include looking at information, such as personal appearance and biochemistry, gene sequences, genetic landmarks, individual and family medical histories, reactions to medications and responses to treatment. Genetic research raises certain questions about informing you of any results. Possible risks of knowing results include: anxiety; other psychological distress; and the possibility of insurance and job discrimination. A possible risk of not knowing includes being unaware of the need for treatment. These risks can change depending on the results of the research and whether there is a treatment or cure for a particular disease.

Sometimes patients have been required to furnish information from genetic testing for health insurance, life insurance, and/or a job. A Federal law, the Genetic Information Nondiscrimination Act of 2008 (GINA), generally makes it illegal for health insurance companies, group health plans, and employers with 15 or more employees to discriminate against you based on your genetic information.

The results of the study of your samples from this project will be used for research purposes only, and you will not be told the results of the tests unless it impacts your clinical care.

Investigators in this study may try to re-contact you in the future. If you are re-contacted and want to know what the investigators have learned about your tissue samples, you should understand the following:

- The information may be too limited to give you particular details or consequences;
- You may be determined to carry a gene for a particular disease that can be treated;

- You may be determined to carry a gene for a particular disease for which there is no current treatment;
- You carry a gene for a disease and might consider informing relatives that they, too, might carry the gene.

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- Keep your study appointments. If it is necessary to miss an appointment, please contact the Protocol Director or research study staff to reschedule as soon as you know you will miss the appointment.
- Tell the Protocol Director or research study staff about any side effects, doctor visits, or hospitalizations that you may have.
- Tell the Protocol Director or research staff if you believe you might be pregnant or might have gotten your partner pregnant.
- Keep your diaries as instructed.
- Complete your questionnaires as instructed.
- Ask questions as you think of them.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.

WITHDRAWAL FROM STUDY

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your ability to receive medical care for your disease and you will not lose any benefits to which you would otherwise be entitled.

If you decide to withdraw from this study, you should notify the program director, Saad A Khan, MD at 650-498-6000.

The Protocol Director may also withdraw you from the study and the study treatments stopped without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- Pregnancy
- You need treatment not allowed in the study.
- The study is cancelled.

- Other administrative reasons.
- Unanticipated circumstances.

If you choose to withdraw, or are withdrawn from the study, you will be asked to return to the study clinic for at least one final visit assessment as part of the study's ongoing safety evaluations. Withdrawal of consent for study treatment does not imply withdrawal of study consent. The study team may ask for clarification of your withdrawal of consent to determine appropriate next steps in regards to the final study visit and saved sample use for future research.

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Protocol Director if you have any questions.

Drugs may have side effects. The drug used in this study may cause some or all of the side effects listed below. There may also be side effects that we cannot predict at this time. Described below are the experiences with these drugs in humans thus far.

SD-101:

As of 12 July 2019, SD-101 has been tested in 358 subjects, including healthy volunteers, patients with chronic hepatitis C, and patients with cancer (lymphoma, melanoma, and head and neck cancer). In most of these patients, the SD-101 was given with other experimental or approved therapies. In all these studies, the SD-101 was injected either under the skin or into a tumor (intratumoral).

Side effects that have been reported in people who have received SD-101 injections include the following:

- Fatigue
- Fever, Chills
- Malaise
- Headache
- Redness, pain, itching or swelling at injection site
- Nausea and/or vomiting
- Diarrhea or constipation
- Muscle aches
- Joint pains, neck pain, back pain
- Rash, itching
- Other flu-like symptoms
- Anemia, low neutrophils, low platelets
- Decreased appetite, dehydration
- Abdominal discomfort

- Cough, nasal congestion
- Mouth pain, throat pain
- Night sweats
- Bruising
- Dizziness
- Shortness of breath
- Ankle/leg swelling
- Infections
- Changes in laboratory values without clinical signs or symptoms

Other side effects, which were uncommon (occurred in one patient each), included hyperthyroidism (overactive thyroid gland), pneumonitis (lung inflammation), pituitary dysfunction, atrial fibrillation (abnormal heart rhythm), septic shock, and hypothyroidism (low thyroid function). These all occurred in patients also receiving another treatment at the same time.

There also may be changes in other blood characteristics and components. You will be monitored for any of these changes.

BMS-986178:

As of 20 March 2018, 20 patients had been treated with BMS-986178 alone and 138 patients had been treated with BMS-986178 in combination with other treatments. The side effects listed below have been reported by the patients who have received BMS-986178 in these clinical trials and which were possibly related to the treatment.

Common side effects with mild severity seen in patients receiving BMS-986178 (alone or in combination with other experimental treatments).

- Fever, chills
- Fatigue
- Infusion-related reactions
- Lab abnormalities without symptoms
- Anemia
- Diarrhea
- Itchiness
- Nausea

Side effects that occurred with moderate to high severity or were otherwise termed serious in a few patients (typically 1 to 2 patients) receiving BMS-986178 (alone or in combination with other experimental treatments).

- Infusion-related reactions

- Pneumonitis (lung inflammation)
- Fatigue
- Lab abnormalities without symptoms
- Diarrhea
- Weakness
- Duodenitis (small intestine inflammation)
- Itchiness
- Psoriatic arthropathy (Autoimmune joint inflammation)
- Low adrenal gland function

As with any drug, you may experience an allergic reaction or may have other reactions that are not expected or have not been seen before. Symptoms of an allergic reaction include a rash, hives, itching, and/or difficulty breathing, closing of the throat, swelling of the lips, tongue or face, and rarely, death. You will be monitored carefully at the study site for signs of an allergic reaction after all study injections. Trained medical personnel and emergency equipment are available at the study site to treat you in the event of an allergic reaction. **If you think you are having a severe allergic reaction after you leave the study center, call 9-1-1 and seek medical attention immediately.**

Combination of SD-101 and BMS-986178: The combination of SD-101 and BMS-986178 has not previously been tested in patients. Because each drug alone has been shown to be safe in patients, we think that the combination is likely to be safe as well, but we will be monitoring closely for any new side effects that may arise.

Washout Period: SD-101 would be expected to be cleared from your body within days to a few weeks after the treatment is stopped. BMS-986178 is an antibody (a type of protein) and would be expected to remain in your body for weeks to a few months even after the treatment is stopped.

Blood Sample Collection: We will collect 1 to 5 tablespoons of blood for testing at several study visits over the course of the trial. Blood collection may cause pain and bruising at the site of vein puncture, inflammation of the vein, and infection; care will be taken to avoid these complications. Collection can also cause redness, temporary pain and sometimes bruising. Fainting or infection may also occur, however these side effects from blood collections are rare.

Tumor Biopsies: Tumor biopsies utilize a needle and may cause pain, bruising and/or bleeding at the site of biopsy, infection, inflammation and swelling; care will be taken to in site selection and procedure execution (including image guidance) to avoid these complications.

Standard radiological test (CT): For a CT scan, a dye is injected into your vein before the scan. Most patients feel a sensation of warmth, a funny metallic taste in their throat, nausea and a feeling of warmth. Some patients develop hives and itching, but this rarely needs to be treated with antihistamines. 1 in 500 patients may develop a severe reaction, which may have to be treated with medications. These reactions may involve tightness in the throat, facial swelling, difficulty breathing, drop in blood pressure, or even a seizure. Medical personnel who perform the scans are trained to treat you if any bad reaction occurs.

Pregnancy Risks: There is no information about the risks of SD-101 or BMS-986178 on pregnancy or to the developing baby; therefore it is important that during the study, you do not get pregnant. If you are pregnant or currently breast-feeding, you may not participate in this study. In addition to pregnancy tests you will be asked to take before beginning the study and during the study, you must agree to avoid sexual intercourse or use an acceptable birth control method during the study. See "Requirements for men and for women of childbearing potential" in the "Procedures" section above.

POTENTIAL BENEFITS

This research study is being conducted to understand the safety, and potential good effects of SD-101 in combination with BMS-986178 for solid tumor cancers. Knowledge gained from this study may also help to develop this therapy for people with other cancers.

The investigational drugs SD-101 and BMS-986178 may stimulate your immune system to fight your cancer. However, there is no assurance that this will happen. There is a chance that your health could get worse or stay the same while you are participating in the study.

We cannot and do not guarantee or promise that you will receive any benefits from this study.

ALTERNATIVES

You do not have to participate in this study to receive treatment for your cancer. If you choose not to participate in this study, there may be other treatments available to you. You should discuss alternative treatments and their potential risks

and benefits with your study doctor and/or other doctors taking care of you. These alternative treatments may include chemotherapy or other drugs, radiation, or other palliative treatments.

PARTICIPANT'S RIGHTS

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. If you decide not to participate, tell the Protocol Director.

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

ClinicalTrials.gov

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by US 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.

The record for this study is at https://clinicaltrials.gov/ct2/show/NCT03831295.

CONFIDENTIALITY

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed except as authorized by you or as required by law**.** However, there is always some risk that even de-identified information might be re-identified.

Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

The purpose of this research study is to obtain data or information on the safety and effectiveness of SD-101 in combination with BMS-986178 and local radiation therapy; the results will be provided to the sponsor, the Food and Drug Administration and other federal and regulatory agencies as required.

Authorization To Use Your Health Information For Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?

We hope to learn about the safety and tolerability of SD-101 and BMS-986178 directly injected into a tumor site, along with BMS-986178 given via a vein to treat your cancer. In addition, this study aims to discover what the outcomes (good or bad) will be when patients are treated with this combination. Study results will be reported in scientific meetings and publications without any patient-identifying information. Information from the trial may also be shared with the FDA and other regulatory agencies as required.

Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study, including receiving any research-related treatment. Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (eg, necessary to

maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to:

Saad A Khan, MD
875 Blake Wilbur Dr. M/C 5151
Stanford, CA 94305

What Personal Information Will Be Obtained, Used or Disclosed?

Your health information related to this study may be used and disclosed in connection with this research study will include but not be limited to, information on the past treatment of your disease and any future tests, examinations, and treatment that you receive as part of this study. This may include blood and urine tests, physical examinations, measurements of your tumor, results of analysis of your tumor samples, study drugs and supportive drugs that are administered and side effects. This health information may include identifiers such as name, date of birth, geographical location, medical record number, and participant number.

Who May Use or Disclose the Information?

The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director, Saad A Khan, MD
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff, which may include laboratory staff, study coordinators, research nurses, data managers, pharmacists, other physicians, and interventional radiology staff

Who May Receive or Use the Information?

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- The Food and Drug Administration
- Bristol-Myers Squibb Company
- TriSalus Life Sciences

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?

Your authorization for the use and/or disclosure of your health information will end on 31 December 2050 or when the research project ends, whichever is earlier.

Will access to my medical record be limited during the study?

To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it was used to make a medical or billing decision about you (eg, if included in your official medical record).

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

FINANCIAL CONSIDERATIONS

Payment/Reimbursement

You will not be paid to participate in this research study. You may be eligible for travel reimbursements. Please ask a member of the study team for more details.

Payments may only be made to US citizens, legal resident aliens, and those who have a work eligible visa. You may need to provide your social security number to receive payment.

Costs

If you participate in this study, the study will pay for those services, supplies, procedures, and care associated with the study that are not a part of your routine medical care. However, there may be additional costs to you. These include basic expenses like transportation and the personal time it will take to come to the study visits. You and/or your health insurance must pay for services, supplies, procedures, and care that are required during this study for routine medical care. **You will also be responsible for any co-payments and/or deductibles as required by your insurance.** Participation in this study is not a substitute for health insurance.

Study Drugs

TriSalus Life Sciences and Bristol-Myers Squibb Company are providing the 2 drugs for this study. TriSalus Life Sciences will be providing the **SD-101** and Bristol-Myers Squibb Company will provide the **BMS-986178** as well as financial support for the clinical trial. Upon this trial's completion, neither Bristol-Myers Squibb Company nor TriSalus Life Sciences will continue to supply study drug to subjects/investigators.

COMPENSATION for Research-Related Injury

All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. **You will be responsible for any associated co-payments or deductibles as required by your insurance.**

If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

You do not waive any liability rights for personal injury by signing this form.

CONTACT INFORMATION

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Saad A Khan, MD. You may contact him now or later at 650-498-6000.

Injury Notification: If you feel you have been hurt by being a part of this study, please contact the Protocol Director, Saad A Khan, MD at 650-498-6000.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at 650-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

Appointment or Alternate Contact: If you need to change your appointment, or if you cannot reach the Study Doctor, please contact the Stanford Cancer Center at 650-498-6000.

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and
- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

May we contact you about future studies that may be of interest to you?

____ Yes ____ No

Signing your name means you agree to be in this study and that you will receive a copy of this signed and dated consent form.

_____ _____

Signature of Adult Participant Date

_____

Print Name of Adult Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Print Name of Person Obtaining Consent

The following witness line is to be signed only if the consent is provided as a summary form and accompanied by a short form foreign language consent.

_____ _____
Signature of Witness Date

_____
Print Name of Witness

(e.g., staff, translator/interpreter, family member)

- *Translated short form must be signed and dated by both the participant (or their LAR) AND the witness.*
- *The English consent form (referred to as the "Summary Form" in the regulations):*
  - *Must be signed by the witness AND the Person Obtaining Consent (POC).*
  - *The non-English speaking participant/LAR does not sign the English consent.*
  - *The non-English speaking participant/LAR should not sign the HIPAA participant line*
  - *If the participant or the LAR is non-English speaking, the Person Obtaining Consent (POC) must ensure that 1) the LAR's Description of Authority is completed and 2) that any questions or options presented by the consent form are documented and initialed by the POC on the Summary Form, per the participant's wishes, as they are understood during the consent process.*