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) in combination with low-dose radiation therapy to treat your low-grade Lymphoma.

You were selected as a possible participant in this study because you have been diagnosed with Low Grade B-cell Lymphoma and have at least one site of disease that is accessible for an intratumoral injection.

We hope to learn about the safety and tolerability of SD-101 and BMS-986178 directly injected into a tumor site and low-dose radiation to that tumor site, along with BMS-986178 given via a vein to treat your low-grade lymphoma. 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 for the treatment of cancer, and the efficacy of this combination for treatment is not yet known.

If you decide to terminate your participation in this study, you should notify **Dr. Ronald Levy** at **(650) 725-6452.**

This research study is looking for a total of up to 15 patients with low-grade Lymphoma. 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 with follow up 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 go over 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 treatments given over the first 24 weeks as follows:

- Local low-dose radiation to a single lymph node region site on days 1 and 2 of the study
- Five injections of intratumoral (I-TUMOR) SD-101 and I-TUMOR BMS-986178 directly into an accessible tumor over the first four weeks of the study; Accessible tumors will also be assessed to ensure they are in an area that is low-risk for potential complications from injections. First injection will be given on the second day of treatment
- Intravenous infusions of BMS-986178 given every 4 weeks for six total doses. First infusion will take place on the second day of treatment.

You will be monitored for at least 30 minutes (longer on some days) after the end of all treatments for the day prior to being discharged home. Vital signs will be taken during this time.

After treatment, there will be follow-up visits every 3-6 months with computed tomography (CT) scans performed at some of those visits as well as routine safety labs and physical exam. 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, Dr. Ronald Levy, 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.

If you choose to participate, Dr. Ronald Levy 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), c-reactive protein (CRP), thyroid stimulating hormone (TSH), lipase, amylase
- Lactate dehydrogenase (LDH) and Research blood draws
- Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) testing
- Urine pregnancy test
- Fine needle aspiration (FNA) of designated tumor lesion in the treatment site (Lesion A). Fine needle aspiration biopsies of additional lesions may be performed if accessible to needle biopsy.
- Meeting with a Radiation Oncologist
- Imaging by CT scan or position emission tomography (PET)/CT scan to assess extent of disease as indicated by study protocol
- A surgical biopsy may be performed, to exclude the possibility of a more aggressive type of lymphoma, if medically necessary. In this case, or potentially in the case that you have lymphoma cells in your blood, we may also collect blood cells by a procedure called apheresis.
- For patients who do not undergo a surgical biopsy, core needle tumor biopsies may be performed (under image guidance, by an interventional radiologist).

Day 1:

- First treatment of radiotherapy to the designated tumor lesion (lesion A)

Day 2:

- Vital signs, weight, and performance status; assessment of side effects; monitoring of medications currently being taken
- For women of childbearing potential only: urine or serum pregnancy test
- Second treatment of radiotherapy
- History and physical examination
- Intratumoral injection of SD-101 and BMS-986178 to lesion A (#1) within 12 hours of radiotherapy
- BMS-986178 intravenous infusion (#1)

- 2 hours monitoring after BMS-986178 intravenous infusion

Day 9:

- Vital signs, weight, and performance status; assessment of side effects; monitoring of medications currently being taken
- Collection of 9 Research blood tubes
- Fine needle aspiration of the treated tumor and an untreated tumor. To be performed prior to intratumoral injection #2
- Intratumoral injection of SD101 and BMS-986178 to lesion A (#2)

Day 16:

- Vital signs, weight, and performance status; assessment of side effects; monitoring of medications currently being taken
- Routine safety labs
- Intratumoral injection of SD101 and BMS-986178 to lesion A (#3)

Day 23:

- Vital signs, weight, and performance status; assessment of side effects; monitoring of medications currently being taken
- Collection of 9 research blood tubes
- Intratumoral injection of SD101 and BMS-986178 to lesion A (#4)

Day 30:

- Vital signs, weight, and performance status; assessment of side effects; monitoring of medications currently being taken
- For women of childbearing potential only: urine or serum pregnancy test
- Complete Physical Exam and Interval History
- Research blood draw
- Routine safety labs
- Core needle tumor biopsy under image guidance by an interventional radiologist
- Intratumoral injection of SD101 and BMS-986178 to lesion A (#5)
- BMS-986178 intravenous infusion (#2)
- 2 hours monitoring after BMS-986178 intravenous infusion

Day 37:

- Assessment of side effects; monitoring of medications currently being taken
  Collection of 9 research blood tubes.
- Fine needle aspiration of the treated tumor and an untreated tumor

Day 58:

- Vital signs, weight, and performance status; assessment of side effects; monitoring of medications currently being taken
- For women of childbearing potential only: urine or serum pregnancy test
- Routine safety labs
- BMS-986178 intravenous infusion (#3)
- 30 minutes monitoring after BMS-986178 intravenous infusion

Day 86:

- Vital signs, weight, and performance status; assessment of side effects; monitoring of medications currently being taken
- Complete Physical Exam and Interval History
- For women of childbearing potential only: urine or serum pregnancy test
- Routine safety labs and LDH
- Collection of 9 research blood draw
- Determination of response to treatment with CT scans of the chest/ abdomen/ pelvis (and neck, if needed)
- Optional: If there is no evidence of disease on the CT scan, a bone marrow biopsy may be obtained to document whether a complete response is achieved.
- Optional fine needle aspiration of the treated site (lesion A) for research studies, if lesion A remains after treatment. In addition, if other untreated sites of disease are safely accessible via fine needle aspiration, these may be biopsied.
- BMS-986178 intravenous infusion (#4)
- 30 minutes monitoring after BMS-986178 intravenous infusion

Days 114 and 142:

- Vital signs, weight, and performance status; assessment of side effects; monitoring of medications currently being taken
- Complete Physical Exam and Interval History
- For women of childbearing potential only: urine or serum pregnancy test
- Routine safety labs
- BMS-986178 intravenous infusion (#5 in week 17 and #6 in week 21)
- 30 minutes monitoring after BMS-986178 intravenous infusion

Weeks 24:

- Vital signs, weight, and performance status; assessment of side effects; monitoring of medications currently being taken
- Complete Physical Exam and Interval History
- Routine safety labs and LDH
- Collection of 1 research blood tubes
- Determination of response to treatment with CT scans of the chest/ abdomen/ pelvis (and neck, if needed)
- Optional: If there is no evidence of disease on the CT scan, a bone marrow biopsy may be obtained to document whether a complete response is achieved.

Weeks 36, 60, and 84:

- Vital signs, weight, and performance status; assessment of side effects; monitoring of medications currently being taken
- Complete Physical Exam and Interval History
- Routine safety labs and LDH

Weeks 48 and 72:

- Vital signs, weight, and performance status; assessment of side effects; monitoring of medications currently being taken
- Complete Physical Exam and Interval History
- Routine safety labs and LDH
- Collection of 1 research blood tube
- Determination of response to treatment with CT scans of the chest/ abdomen/ pelvis (and neck, if needed)
- Optional: If there is no evidence of disease on the CT scan, a bone marrow biopsy may be obtained to document whether a complete response is achieved.

Final study visit:

- Vital signs, weight, and performance status; assessment of side effects; monitoring of medications currently being taken
- Complete Physical Exam and Interval History
- Routine safety labs and LDH
- Research blood draw

- *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)
- *If* you are coming off the study due to your cancer growing, a fine needle aspiration may be performed on an accessible tumor site for research studies.
- *If* there is no evidence of disease on the CT scan, a bone marrow biopsy may be obtained to document whether a complete response is achieved.

The study schedule is summarized in Table 1.

Table 1: Study Schedule

Procedures	Screen	Week 1 Day 1 RT	Week 1 Day 2 RT, SD-01	Week 2 SD-101	Week 3 SD-101	Week 4 SD-101	Week 5 SD-101, BMS-986178	Week 6 FNA	Week 9 BMS-986178	Week 13 BMS-986178	Weeks 17, 21 BMS-986178	Weeks 24, 36, 48, 60, 72, 84	Final Study Visit
Written Informed Consent	X												
History and Physical Exam	X						X		X	X	X	X	X
Adverse Event Evaluation			X	X	X	X	X	X	X	X	X	X	X
Review of Medications	X		X	X	X	X	X	X	X	X	X	X	X
Vital Signs	X		X	X	X	X	X		X	X	X	X	X
Urine Pregnancy Test (for appropriate patients)	X						X		X	X	X		
Excisional Tumor Biopsy (some patients)	X												
Core Needle Tumor Biopsy (some patients)	X						X						
Fine needle aspiration	X			X				X		(X)			X
Research Blood Samples	X			X		X		X		X		X	X
Routine Safety Labs	X				X		X		X	X	X	X	X
LDH	X									X		X	X
HIV and Hepatitis testing	X												
Radiation therapy		X	X										
SD-101 Injection			X	X	X	X	X						
I-TUMOR BMS-986178 Injection			X	X	X	X	X						
BMS-986178 Infusion			X				X		X	X	X		
CT Scan	X (if needed)									X		X	X
Bone Marrow Biopsy (only if needed)										X		X	X
Apheresis (some patients)	X												

Participant ID:

STUDY

Dosing of BMS-986178:

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

3.75 mg intratumorally (I-TUMOR) weekly for five doses.

Dosing of SD101:

2 mg intratumorally (I-TUMOR) weekly for five doses.

Alternate Dosing:

The first 6 participants will receive 2 mg of SD-101, 3.75 mg of I-TUMOR BMS-986178 and 40 mg of IV BMS-986178. If less than a third of these first 6 participants experience a serious side effect, then three more patients will be treated at these doses. If less than a third of the first 9 participants experience a serious side effect, then patients will continue to be treated at these doses for the rest of the study. Otherwise, if enough patients experience serious side effects, then the dose of IV BMS-986178 will be reduced to 20 mg every 4 weeks. It is also possible that the dose of IV BMS-986178 will be reduced for an individual patient under specific circumstances.

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, and approximately every 3-6 months after your first study treatment, for the rest of the study or at time if your doctor suspects your Lymphoma is getting worse. CT scans are standard of care for lymphoma.

Bone marrow aspiration and biopsy: First, an area of the hip is numbed, and then a needle is inserted into the hipbone to collect the sample. This procedure is done to determine if your lymphoma has spread to the bone marrow. This may be required if your CT scan shows no evidence of residual lymphoma to determine whether there is still lymphoma within the bone marrow.

Localized Low-dose Radiation Therapy: is a procedure that uses high-energy radiation like x-rays to kill cancer cells. Low dose radiation (locally to the area of one site of one lesion; "2 Gray (Gy)** x 2") is being given to help SD-101 to increase your immune system to fight your lymphoma. You will receive 2 treatments of low dose radiation at Day 1 and Day 2. In addition, the injection of SD-101 will be given on Day 2 within 12 hours of radiotherapy. As this injection

will be in a different location in the Cancer Center from where you receive your radiotherapy at Stanford, we hope at best to have your wait be less than 2 hours.

**2 Gray (Gy) has the equivalent radiation dose of approximately 10000 x-rays. This radiation is localized only to the treatment area.

Apheresis (only for patients with pre-treatment biopsy): This procedure is similar to donating blood but allows certain parts of your blood to be collected while the red blood cells are returned to you. A needle is placed in each arm and you will spend 3-5 hours resting in a chair while the blood is collected from one arm and returned to the other arm. (Patients usually watch a movie or two during the procedure).

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

- Blood samples (about 1 to 6 tablespoons) will be taken from a vein in your arm at each study visit.
- Fine needle aspirates (FNA) involves the insertion of a needle into the tumor to collect a sample. We will do this from the tumor that we treat and, if possible from a tumor that we do not treat at screening and weeks 2, 6, 13 and at the end of the study if there is residual tumor.
- Core needle biopsies involve the insertion of a core 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 You will have blood tests for HIV, Hepatitis B and Hepatitis C during screening. Positive results will be reported to the local health agency. If you test positive for HIV, counseling and resources will be provided.

Tissue Samples for Research: The investigators would like to include your tissues in research on lymphoma 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, Dynavax Technologies Corporation, 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
Initial

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

Women of Childbearing Potential *(see risks below)*
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.

To confirm to the extent medically possible that you are not pregnant, you agree to have a urine pregnancy test done before beginning this research study and intermittently during treatment. You must agree to avoid sexual intercourse or use a birth control method judged to be effective by the investigator and which will not interfere with the proposed investigation, until at least five months 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 seven months 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 and after the study.

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Follow the instructions of the Protocol Director and study staff.
- Ask questions at your visits and/or by contacting the study staff/research coordinator
- 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 gotten your partner pregnant.
- Ask questions as you think of them.
- Tell the Protocol Director or research staff if you change your mind about staying in the study.
- COVID-19 precautions: If you are coming in-person to research visits, you are required to be fully vaccinated—2 doses (1 for Johnson and Johnson), 2 weeks out and to provide proof of your vaccination (e.g., CDC COVID-19 Vaccination Card, e-Health record, etc.) to the researcher prior to study participation. Alternately, you can provide a negative COVID test within 72 hours of your visit.

WITHDRAWAL FROM STUDY

Participation in the study is entirely your choice. 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 study staff at (650) 725-8589. You may also want to speak directly with the **Dr. Ronald Levy at 650- 725-6452**

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. All study-related supplies, including unused study drug, must be returned to the study personnel.

The Protocol Director may also withdraw you from the study 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.

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, **Dr. Ronald Levy** 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.

SD-101:
As of July 12th, 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 March 8th, 2019, 20 patients had been treated with BMS-986178 alone and 145 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 1-2 patients) receiving BMS-986178 (alone or in combination with other experimental treatments).

- Infusion-related reactions
- Rash
- Decreased appetite
- Pneumonitis (lung inflammation)
- Fatigue
- Lab abnormalities without symptoms
- Diarrhea
- Weakness
- Duodenitis (small intestine inflammation)
- Itchiness
- Psoriatic arthropathy (Autoimmune joint inflammation)
- Low adrenal gland function
- Facial paralysis

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 have a significant allergic to the drug, the drug may be discontinued permanently for your safety. If the doctors feel the reaction was not significant enough to require discontinuation, they will discuss this with you and obtain your explicit consent again prior to re-starting treatment. **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 1-6 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.

Fine Needle Aspirate (FNA): Lymph node aspirate may cause pain, bruising and/or bleeding at site of biopsy, infection, inflammation and swelling; care will be taken 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.

Localized radiation therapy (RT): Radiation therapy is painless. Side effects from radiation are usually limited to the area of the patient's body that is under treatment. The main side effects are fatigue and skin irritation, like a mild to moderate sun burn. The fatigue can last for weeks after treatment ends. The irritated skin will heal, but may not be as elastic as it was before. With the low dose of radiation used in this study we do not expect any of these side effects.

Bone marrow aspiration and biopsy: This biopsy may cause pain and bruising at the site of puncture, inflammation, pain, and infection; care will be taken to avoid these complications. Other side effects may include bleeding at the biopsy

site. If you have bleeding problems, pressure will be put on the biopsy site to stop the bleeding.

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 birth control methods judged to be effective by the investigator and which will not interfere with the proposed investigation. 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 if you do not use your birth control method, or if you become pregnant, either of which may result in your being withdrawn from the study. By agreeing to participate in this study, you are also allowing the study staff to ask follow-up questions and request medical records about your pregnancy and its outcome (for example, type of birth, number of babies and health of baby[ies]).

POTENTIAL BENEFITS

This research study is being conducted to understand the safety, and potential good effects of SD-101 in combination with BMS-986178 and Radiation therapy for low-grade B-cell lymphoma. Knowledge gained from this study may also help to develop this therapy for other people with Lymphoma or even people with other cancers.

The investigational drugs SD-101 and BMS-986178 may stimulate your immune system to fight your lymphoma. 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 lymphoma. If you choose not to participate in this study, there may be other treatments available to you. You may discuss alternative treatments and their risks and benefits with your study doctor.

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 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.

CONFIDENTIALITY

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.

Your information will be kept in a secure location at Stanford University Medical Center, accessible only to research authorized personnel. The patient identity will be kept as confidential as possible as required by law. Except as required by law, the patient will not be identified by name, social security number, address, telephone number, or any other direct personal identifier. Study patients will be assigned an ID code that will consist of a three-digit number. Information about the code will be kept in a secure location and access limited to research study personnel. The results of this research study may be presented at scientific or

medical meetings or published in scientific journals. However, the patient identity will not be disclosed. Your personal data which may be included in the investigator's database shall be treated in compliance with all applicable laws and regulations.

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.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by The National Cancer Institute which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document such as the inclusion of research data in the medical record.

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 dose levels of intratumoral injections (into your tumor site) of SD-101 in combination with BMS-986178 given intravenously and local low-dose radiation to treat your low-grade, B-cell lymphoma. In addition, this study has been designed to discover what the outcomes (good or bad) will be in patients treated with this combination.

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 (e.g., 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:

Dr. Ronald Levy
269 Campus Drive
CCSR 1105
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 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 **Ronald Levy, 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 lab staff, study coordinators, research nurses, data managers, pharmacists, and the radiology department.

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
- National Institutes of Health (NIH)
- The U.S. Food and Drug Administration (FDA)
- Dynavax Technologies Corporation
- Bristol-Myers Squibb Company

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 December 31, 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 (e.g., if included in your official medical record).

_____ _____
Signature of Adult Participant Date

_____
Printed name of Adult Participant

FINANCIAL CONSIDERATIONS

Payment
You will not be paid to participate in this research study.

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.

Supporters
Dynavax Technologies Corporation and Bristol-Myers Squibb Company are providing the 2 drugs for this study. Dynavax Technologies Corporation will be providing the **SD-101** and Bristol-Myers Squibb Company will provide the **BMS-986178** and financial support for the clinical trial. Upon this trial's completion, neither Bristol-Myers Squibb Company nor Dynavax Technologies Corporation will continue to supply study drug to subjects/investigators. Your doctor is responsible to ensure that you receive appropriate standard of care or other appropriate treatment to treat your condition.

The **National Institutes of Health** is providing financial support for some of the research portions of this study and some financial support for the facility and staff where part or all of the study is taking place.

The Leukemia & Lymphoma Foundation also provides financial support for some of the research portions of the study.

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**, Dr. Ronald Levy.** You may contact him now or later at **650-725-6452**.

Injury Notification: If you feel you have been hurt by being a part of this study, please contact the Protocol Director, **Dr. Ronald Levy** at **650-725-6452.**

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 Contact: If you need to change your appointment, please contact **the research coordinator at 650-498-6000**

Alternate Contact: If you cannot reach the Protocol Director, please contact **the research coordinator 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 were given a copy of this signed and dated consent form.

_____ _____
Signature of Adult Participant Date

_____
Printed name of Adult Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed 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

_____
Printed 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.