

INSTITUTE: National Cancer Institute

STUDY NUMBER: 16-C-0128 PRINCIPAL INVESTIGATOR: Christine Alewine, M.D., Ph. D.

STUDY TITLE: A Phase I/II Study of Mesothelin-Targeted Immunotoxin LMB-100 Alone or in Combination with Nab-Paclitaxel in Participants with Previously Treated Metastatic and/or Locally Advanced Pancreatic Ductal Adenocarcinoma and Mesothelin Expressing Solid Tumors

Continuing Review Approved by the IRB on 08/31/20

Amendment Approved by the IRB on 12/13/18 (L)

Date posted to web: 09/04/20

Arm B1 (Continuous Infusion Single Agent Lead-in)

INTRODUCTION

We invite you to take part in a research study at the National Institutes of Health (NIH).

First, we want you to know that:

Taking part in NIH research is entirely voluntary.

You may choose not to take part, or you may withdraw from the study at any time. In either case, you will not lose any benefits to which you are otherwise entitled. However, to receive care at the NIH, you must be taking part in a study or be under evaluation for study participation.

You may receive no benefit from taking part. The research may give us knowledge that may help people in the future.

Second, some people have personal, religious or ethical beliefs that may limit the kinds of medical or research treatments they would want to receive (such as blood transfusions). If you have such beliefs, please discuss them with your NIH doctors or research team before you agree to the study.

Now we will describe this research study. Before you decide to take part, please take as much time as you need to ask any questions and discuss this study with anyone at NIH, or with family, friends or your personal physician or other health professional.

Why is this study being done?

LMB-100 is an investigational agent, meaning that it has not been approved by the US Food and Drug Administration. It is a type of manufactured protein which is similar to protein normally produced by your body. LMB-100 is attracted to the mesothelin protein, which is present on the

MEDICAL RECORD	CONTINUATION SHEET for either: NIH 2514-1, Consent to Participate in A Clinical Research Study NIH 2514-2, Minor Patient's Assent to Participate In A Clinical Research Study
STUDY NUMBER: 16-C-0128	CONTINUATION: page 2 of 15 pages

surface of many different tumors. The mesothelin protein is found in only a very small number of normal tissues. After binding to the mesothelin on tumors, LMB-100 can then attack and kill cancer cells.

Nab-paclitaxel is an FDA approved agent in the treatment of pancreatic cancer. It has not, however been tried in combination with LMB-100.

This study, which is divided into multiple parts will determine a safe dose of LMB-100 on different administration schedules alone or in combination with a fixed dose of nab-paclitaxel in the phase 1 portion.

- In phase 1, Arm A1 – subjects with pancreatic cancer will receive nab-paclitaxel in combination with LMB-100 given every other day for 3 days in each 21-day cycle.
- In phase 1, Arm B1, (single Agent lead-in) – subjects that have tumors that test positive for mesothelin will receive LMB-100 alone for 1, 2, 3 or 4 days continuously or two 24-hour infusions (days 1 and 4) depending on dose level in each 21-day cycle.
- In phase 1, Arm B2, (combination therapy) – subjects with pancreatic cancer will receive nab-paclitaxel in combination with LMB-100 given for 1, 2, 3 or 4 days continuously or two 24-hour infusions (days 1 and 4) depending on dose level in each 21-day cycle.

In the phase 2 portion of the study (Arm A2), we will determine whether the dose established in phase 1, Arm A1 reduces the size of tumors in patients with pancreatic cancer.

You are participating in the phase 1, Arm B1 single agent lead-in portion of the study. Note: If you are a patient with pancreatic cancer, by taking part in this portion of the study, you are foregoing treatment with chemotherapy regimens that have been shown to increase survival in your disease.

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

You are being asked to take part in this study because you have a cancer that expresses mesothelin that has worsened after anti-cancer therapy.

How many people will take part in this study?

Up to 100 participants will be enrolled in the study overall.

Description of Research Study

Participants will be enrolled in this portion of the study in groups of 3 to 6 at increasing doses or dose durations until a dose is reached where 2 or more participants experience intolerable side effects. If no dose level is reached where 2 or more participants experience intolerable side effects, then the highest tested dose will be selected as the maximum tolerated dose (MTD). If a

PATIENT IDENTIFICATION	CONTINUATION SHEET for either: NIH-2514-1 (07-09) NIH-2514-2 (10-84) P.A.: 09-25-0099 File in Section 4: Protocol Consent
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MEDICAL RECORD	CONTINUATION SHEET for either: NIH 2514-1, Consent to Participate in A Clinical Research Study NIH 2514-2, Minor Patient's Assent to Participate In A Clinical Research Study
STUDY NUMBER: 16-C-0128	CONTINUATION: page 3 of 15 pages

dose is reached where there are 2 or more intolerable side effects, the dose just below it will be selected as the MTD provided that no more than 1 of 6 participants experienced intolerable side effects at that dose.

Depending on your assigned dose level, you will receive LMB-100 through an IV catheter (a tube inserted in a vein, usually in your arm) continuously for 24, 48, 72 or 96 hours on 1, 2, 3 or 4 days of each cycle. Alternatively, you may receive two 24-hour infusions (days 1 and 4) during each cycle. On the first day of each cycle, unless you are among the first 3 participants in this part of the study, you will also receive what is called a loading dose (lasting no more than 3 hours) of LMB-100 before the start of the continuous infusion. You will have to stay in the hospital while you are receiving the infusion. You will receive LMB-100 for up to 2 cycles or until your disease worsens or you have intolerable side effects, whichever happens first. We will continue to follow you after you have finished taking the study drug to keep track of your disease status (progression), your survival status or whether you have taken any additional cancer therapy. The specific procedures you will have are described below.

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

Before you begin the study

Before beginning the study, you will need to undergo tests and/or procedures to help your doctor verify whether you can participate. This is called screening. Most of the exams, tests, and procedures you will have are part of the usual approach for your cancer. However, there are some extra procedures that you will need to have if you take part in this study. If you have already undergone some of these examinations very recently, your doctor may decide not to repeat them. Briefly, these tests, which are performed under a separate consent, include:

- Confirmation of diagnosis (You must provide a sample tumor tissue for formal evaluation by the NCI Laboratory of Pathology. The tissue may be from a previous surgery or biopsy. If none is available, we will ask you to have a biopsy to provide a fresh sample).
- Mesothelin testing. Previously collected tissue from your tumor or any leftover tissue that may be collected for the confirmation of diagnosis will be used to determine whether your tumor cells have mesothelin, unless you have pancreatic cancer or a type of mesothelioma referred to as epithelioid.
- Medical history and physical examination
- Routine blood and urine tests including pregnancy test in women who can have children. Pregnant women will not be allowed on study.
- Scans
- Electrocardiogram (ECG)
- Echocardiogram
- Blood for tumor markers

PATIENT IDENTIFICATION	CONTINUATION SHEET for either: NIH-2514-1 (07-09) NIH-2514-2 (10-84) P.A.: 09-25-0099 File in Section 4: Protocol Consent
------------------------	--

MEDICAL RECORD	CONTINUATION SHEET for either: NIH 2514-1, Consent to Participate in A Clinical Research Study NIH 2514-2, Minor Patient's Assent to Participate In A Clinical Research Study
STUDY NUMBER: 16-C-0128	CONTINUATION: page 4 of 15 pages

During the study

Once it is determined that you are eligible and you have signed this consent, you will receive IV infusions of LMB-100 as described above. Depending on your assigned dose level each LMB-100 infusion will last for 24 hours (1 day), 48 hours (2 days), 72 hours (3 days) or 96 hours (4 days) or 24 hours each on day 1 and day 4 and will be given through a central line (an IV tube placed in a large vein for long term therapy) or through a mediport if you already have one installed. As indicated above, a short loading dose may also be given. You will be monitored for side effects during each LMB-100 infusion. You will be given standard pre-medications that include an antihistamine (such a Benadryl), acetaminophen (Tylenol) and ranitidine to help prevent infusion related side effects. Dexamethasone or an equivalent steroid may be added if you experience a reaction even after using the standard pre-medications.

While you are taking study medication, we will perform a number of tests and examinations for safety and to test the effect of the study therapy:

These include routine blood and urine tests that will be on each day you receive an infusion, scans that will be performed approximately every 6 weeks, and ECGs that will be done while you are receiving LMB-100.

In addition to the safety tests, we will also perform tests for research studies to find out how your body handles the LMB-100 (PKs), how your body, including your immune system, reacts to the drug and how certain side effects of the LMB-100 might be caused. We will also conduct genetic studies focused on genes that process drugs, nab-paclitaxel in particular. Most of the sampling for these research tests will be done before your first dose of study drug or on the days you take the study drug just before or during the infusion. A sample will also be drawn about 2 hours after the end of infusion in cycle 1.

An optional biopsy may also be collected after you have received 2 cycles of study therapy. The biopsies to be performed are exclusively for research purposes and will not benefit you. It might help other people in the future. You will be given the opportunity to decide whether you want to have these sample collected at the time of each biopsy. All tissue will be reviewed by the NCI Laboratory of Pathology. Please see page 9, Tumor Biopsies and Effusions for the risks of a biopsy.

When you are finished taking the drugs

Withdrawal Visit

If you received 2 cycles of LMB-100, the following assessments will be performed at the end of cycle 2:

- Medical history and physical examination
- Routine blood and urine tests
- Scans
- Blood tests for tumor markers

PATIENT IDENTIFICATION	CONTINUATION SHEET for either: NIH-2514-1 (07-09) NIH-2514-2 (10-84) P.A.: 09-25-0099 File in Section 4: Protocol Consent
------------------------	--

- ECG

Safety Visit

If you did not complete both cycles of the study drug, or if you have completed 2 cycles but the scans above showed that your disease has gotten worse, you will be asked to return to the NIH approximately 3 – 6 weeks after you have had last dose of study drug for a safety visit.

If you completed cycle 2 and your scans did not reveal worsening disease, you will be asked to return approximately six weeks after your last scan for a restaging scan and safety visit.

The visit will include the following tests:

- Medical history and physical exam
- Routine blood and urine tests including pregnancy test in women who can have children
- ECG
- Scans if your disease has not worsened since the beginning of the study

Long term follow up

If after the safety visit, your disease remains stable or improved, you will continue to be scanned every 6 weeks until your disease gets worse.

About once a year, regardless of whether your disease has gotten worse, we will contact you or your physician by telephone to ask about any other cancer therapies you may have started and about your survival status.

Birth Control

If you are a woman who is breast feeding or pregnant, you may not take part in the study because we don't know how this medicine would affect your baby or your unborn child. If you are a woman who can become pregnant, or are the partner of a woman who can become pregnant, you will need to practice an effective form of birth control before starting study treatment, during study treatment, and for 3 months after you finish study treatment. In addition, male subjects should not donate sperm during the study and for 3 months after the last dose of study therapy. If you think that you or your partner is pregnant, you should tell your study doctor or nurse at once.

Effective forms of birth control include:

- abstinence
- intrauterine device (IUD)
- hormonal [birth control pills, injections, or implants]
- tubal ligation
- vasectomy

MEDICAL RECORD	CONTINUATION SHEET for either: NIH 2514-1, Consent to Participate in A Clinical Research Study NIH 2514-2, Minor Patient's Assent to Participate In A Clinical Research Study
STUDY NUMBER: 16-C-0128	CONTINUATION: page 6 of 15 pages

Risks or Discomforts of Participation

Risks and Possible Undesirable Effects of LMB-100

Because LMB-100 is still being tested for safety, we do not know all of the possible side effects. However, below is a list of the most common and most serious side effects occurring on an earlier and ongoing studies, some occurring at higher doses than will be used in this study.

The most common side effects (some were serious) were:

- Low levels of the blood protein albumin which may lead to swelling, muscle weakness or loss of appetite
- Tiredness
- Swelling of the arms and legs
- Nausea
- Fever
- Decreased appetite
- Shortness of breath
- Pain in muscles
- Reactions during or following the infusion of the drug which may cause fever, chills, rash or low blood pressure

Less common, but serious side effects included:

- Fluid in the organs which may cause low blood pressure, shortness of breath, swelling of ankles
- Abnormal heartbeat
- Pain in joints
- Kidney damage which may cause swelling, may require dialysis

Other possible side effects

Other possible side effects discussed below are based on side effects that occurred when testing a similar agent, SS1P and also in animal studies of LMB-100. It is possible that there may be other unexpected side-effects that occur in addition to those listed below.

LMB-100 may cause inflammation to membranes causing chest pain, shortness of breath, low blood pressure, and heart failure. In animals, some mild kidney toxicity was seen, characterized by increased enzymes and protein in the urine. This will be checked for with regular blood and urine tests.

As with other drugs similar to LMB-100, there is a chance that the drug could cause the body to produce an unwanted response called 'Anti-drug antibodies' (ADAs). These might not cause

PATIENT IDENTIFICATION	CONTINUATION SHEET for either: NIH-2514-1 (07-09) NIH-2514-2 (10-84) P.A.: 09-25-0099 File in Section 4: Protocol Consent
------------------------	--

MEDICAL RECORD	CONTINUATION SHEET for either: NIH 2514-1, Consent to Participate in A Clinical Research Study NIH 2514-2, Minor Patient's Assent to Participate In A Clinical Research Study
STUDY NUMBER: 16-C-0128	CONTINUATION: page 7 of 15 pages

problems however there is a chance they could lead to a severe anti-drug response in the body. ADA levels will be measured during the study to monitor any changes.

There may also be pain and swelling at the infusion site.

It is important that you contact your doctor as soon as you experience any side effects whether you think the treatment has caused them or not. You must also tell your doctor if you have started any new medication or had a change to your existing medication. This includes medications available without a prescription (over the counter) and alternative medicines. If you have any questions or concerns about any of the information provided above, about the possible side effects of treatment, or the possible consequences of treatment for those side effects, please ask the principal investigator or the research staff for more information.

The most important symptoms you need to report to your doctor immediately are:

- possible infusion or allergic reactions (symptoms that start during or within a few hours of the infusion, e.g. wheezing, tightness in the throat or chest, rash, and facial swelling)
- chest pain
- shortness of breath
- palpitations (fast heart beat)
- bleeding and high fever
- impaired brain function (e.g., dizziness, blurred vision, confusion)

If you experience any severe or dangerous side effect, you should:

1. Seek professional medical help immediately.
2. Call your study doctor.
3. If necessary, go to the nearest emergency room.

Risks from pre-medications

Acetaminophen

Acetaminophen is considered to be safe and effective in the recommended doses. However, when taken incorrectly acetaminophen can cause liver damage. Your risk of liver damage may be increased if you drink more than three alcoholic drinks every day, take more than the recommended dose (overdose), or if you take any additional drugs that also contain acetaminophen at the same time.

PATIENT IDENTIFICATION	CONTINUATION SHEET for either: NIH-2514-1 (07-09) NIH-2514-2 (10-84) P.A.: 09-25-0099 File in Section 4: Protocol Consent
------------------------	--

MEDICAL RECORD	CONTINUATION SHEET for either: NIH 2514-1, Consent to Participate in A Clinical Research Study NIH 2514-2, Minor Patient's Assent to Participate In A Clinical Research Study
STUDY NUMBER: 16-C-0128	CONTINUATION: page 8 of 15 pages

Diphenhydramine

Drowsiness, dizziness, constipation, stomach upset, blurred vision, or dry mouth/nose/throat may occur when taking diphenhydramine. *Ranitidine:*

It can cause constipation, diarrhea, headache, nausea or upset stomach. Rare serious side effects include severe allergic reaction with rash, hives, itching, difficulty breathing; confusion, dark urine, depression, fast or slow heartbeat, unusual bruising or bleeding, yellowing of the eyes or skin (indicating liver damage).

Dexamethasone:

Stomach upset, headache, dizziness, changes in your period, trouble sleeping, increased appetite, or weight gain may occur. Rarely patients using dexamethasone have experienced increased infection, bone/joint pain, thirst, increased urination, irregular heartbeat, eye pain, vision problems, black stools, vomit that looks like coffee grounds, puffy face, swelling of the feet and ankles, pain/redness/swelling of the arms or legs, tiredness, mood changes, unusual hair/skin growth, muscle cramps, weakness, easy bruising/bleeding, slow wound healing, thinning skin and seizures.

Risks from Study Procedures

The following study procedures and treatments may have risks and cause discomfort while you participate on this study:

Blood draws

There is the risk of slight pain, bruising or infection when your blood is drawn. Drawing blood may cause some people to faint.

ECGs

The glue used to keep the electrodes in place during the ECG may irritate your skin and caused redness.

Central Line Insertion

- Contamination of the catheter which would result in a serious blood stream infection, requiring admission to the hospital and giving you antibiotics through the vein.
- Collapsed lung particularly if the central line is placed in the vein under your collarbone. Collapsed lung is treated with a chest tube when necessary.
- During the insertion of some types of central lines, the heart may be irritated by the process while the line travels through the blood vessels near the heart, causing an alteration in the heart's rhythm. This typically gets better once the line is in place but may require medication for some rare individuals.
- Air embolism, a condition where air enters the blood stream and begins to travel through the body. This condition, which is very serious, is also very rare and largely preventable.

PATIENT IDENTIFICATION	CONTINUATION SHEET for either: NIH-2514-1 (07-09) NIH-2514-2 (10-84) P.A.: 09-25-0099 File in Section 4: Protocol Consent
------------------------	--

MEDICAL RECORD	CONTINUATION SHEET for either: NIH 2514-1, Consent to Participate in A Clinical Research Study NIH 2514-2, Minor Patient's Assent to Participate In A Clinical Research Study
STUDY NUMBER: 16-C-0128	CONTINUATION: page 9 of 15 pages

Tumor Biopsies and Effusions

Tumor biopsies and tumor effusions: local anesthesia of the skin will be given prior to any tumor biopsy or effusion collection, in order to prevent painful sensations. However, you may still experience pain or discomfort at the biopsy site. Irritation, redness, swelling and/or bleeding may also occur. There is a risk of abnormal healing, fever, infection or of an allergic reaction to the anesthetic agent used to anesthetize the skin at the biopsy site. Once the sample has been obtained, a stitch may be used to close the wound and assist in healing.

In some cases, we may use CT scans to help guide us during your tumor biopsy. This introduces the added risk of research radiation. This research study may involve exposure to radiation from up to 1 CT guided research biopsy. This radiation exposure is not required for your medical care and is for research purposes only. The amount of radiation you will receive in this study is 0.77 rem which is below the guideline of 5 rem per year allowed for research subjects by the NIH Radiation Safety Committee. The average person in the United States receives a radiation exposure of 0.3 rem per year from natural sources, such as the sun, outer space, and the earth's air and soil. If you would like more information about radiation, please ask the investigator for a copy of the pamphlet, An Introduction to Radiation for NIH Research Subjects.

While there is no direct evidence that the amount of exposure received from participating in this study is harmful, there is indirect evidence it may not be completely safe. There may be a very slight increase in the risk of cancer.

Please tell your doctor if you have had any radiation exposure in the past year, either from other research studies or from medical tests or care, so we can make sure that you will not receive too much radiation. Radiation exposure includes x-rays taken in radiology departments, cardiac catheterization, and fluoroscopy as well as nuclear medicine scans in which radioactive materials were injected into your body.

Potential Benefits of Participation

Are there benefits to taking part in this study?

The aim of this study is to find a safe dose as well as to see if this experimental treatment will cause your tumors to shrink. We do not know if you will receive personal, medical benefit from taking part in this study. These potential benefits could include shrinking of your tumor or lessening of your symptoms, such as pain, that are caused by the cancer. Because there is not much information about the drug's effect on your cancer, we do not know if you will benefit from taking part in this study, although the knowledge gained from this study may help others in the future who have cancer.

PATIENT IDENTIFICATION	CONTINUATION SHEET for either: NIH-2514-1 (07-09) NIH-2514-2 (10-84) P.A.: 09-25-0099 File in Section 4: Protocol Consent
------------------------	--

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

Instead of being in this study, you have these options:

- Getting treatment or care for your cancer without being in a study, including standard options
- Taking part in another study
- 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. Instead, it tries to improve how you feel. Comfort care tries to keep you as active and comfortable as possible.

Please talk to your doctor about these and other options.

Research Subject's Rights**What are the costs of taking part in this study?**

If you choose to take part in the study, the following will apply, in keeping with the NIH policy:

- You will receive study treatment at no charge to you. This may include surgery, medicines, laboratory testing, x-rays or scans done at the Clinical Center, National Institutes of Health (NIH), or arranged for you by the research team to be done outside the Clinical Center, NIH if the study related treatment is not available at the NIH.
- There are limited funds available to cover the cost of some tests and procedures performed outside the Clinical Center, NIH. You may have to pay for these costs if they are not covered by your insurance company.
- Medicines that are not part of the study treatment will not be provided or paid for by the Clinical Center, NIH.
- Once you have completed taking part in the study, medical care will no longer be provided by the Clinical Center, NIH.

Will your medical information be kept private?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The National Cancer Institute (NCI) and other government agencies, like the Food and Drug Administration (FDA), which are involved in keeping research safe for people.
- NIH Intramural Institutional Review Board

MEDICAL RECORD	CONTINUATION SHEET for either: NIH 2514-1, Consent to Participate in A Clinical Research Study NIH 2514-2, Minor Patient's Assent to Participate In A Clinical Research Study
STUDY NUMBER: 16-C-0128	CONTINUATION: page 11 of 15 pages

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.

Certificate of Confidentiality

To help us protect your privacy, we have obtained a Certificate of Confidentiality. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

You should also know that there are several circumstances in which the Certificate does not provide coverage. These include when information:

- will be used for auditing or program evaluation internally by the NIH; or
- must be disclosed to meet the legal requirements of the federal Food and Drug Administration (FDA).
- is necessary for your medical treatment and you have consented to this disclosure;
- is for other research.

In addition, identifiable, sensitive information protected by this Certificate cannot be admissible as evidence or used for any purpose in any action, suit, or proceeding without your consent.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

The Certificate of Confidentiality will not protect against the required reporting by hospital staff of information on suspected child abuse, reportable communicable diseases, and/or possible threat of harm to self or others.

Stopping Therapy

Your doctor may decide to stop your therapy for the following reasons:

- if he/she believes that it is in your best interest
- if your disease comes back during treatment
- if you become pregnant
- if you have side effects from the treatment that your doctor thinks are too severe
- if new information shows that another treatment would be better for you

In this case, you will be informed of the reason therapy is being stopped.

PATIENT IDENTIFICATION	CONTINUATION SHEET for either: NIH-2514-1 (07-09) NIH-2514-2 (10-84) P.A.: 09-25-0099 File in Section 4: Protocol Consent
------------------------	--

MEDICAL RECORD	CONTINUATION SHEET for either: NIH 2514-1, Consent to Participate in A Clinical Research Study NIH 2514-2, Minor Patient's Assent to Participate In A Clinical Research Study
STUDY NUMBER: 16-C-0128	CONTINUATION: page 12 of 15 pages

You can stop taking part in the study at any time. However, if you decide to stop taking part in the study, we would like you to talk to the study doctor and your regular doctor first.

If you decide at any time to withdraw your consent to participate in the trial, we will not collect any additional medical information about you. However, according to FDA guidelines, information collected on you up to that point may still be provided to collaborators or designated representatives. If you withdraw your consent and leave the trial, any samples of yours that have been obtained for the study and stored at the NCI can be destroyed upon request. However, any samples and data generated from the samples that have already been distributed to other researchers or placed in the research databases **cannot** be recalled and destroyed.

Conflict of Interest

The National Institutes of Health (NIH) reviews NIH staff researchers at least yearly for conflicts of interest. This process is detailed in a Protocol Review Guide. You may ask your research team for a copy of the Protocol Review Guide or for more information. Members of the research team who do not work for NIH are expected to follow these guidelines but they do not need to report their personal finances to the NIH.

Members of the research team working on this study may have up to \$15,000 of stock in the companies that make products used in this study. This is allowed under federal rules and is not a conflict of interest.

The National Institutes of Health and the research team for this study have developed a drug being used in this study. This means it is possible that the results of this study could lead to payments to NIH scientists and to the NIH. By law, government scientists are required to receive such payments for their inventions. You will not receive any money from the development of LMB-100 in combination with nab-paclitaxel.

Use of Specimens and Data for Future Research

To advance science, it is helpful for researchers to share information they get from studying human samples. They do this by putting it into one or more scientific databases, where it is stored along with information from other studies. A researcher who wants to study the information must apply to the database and be approved. Researchers use specimens and data stored in scientific databases to advance science and learn about health and disease.

We plan to keep some of your specimens and data that we collect and use them for future research and share them with other researchers. We will not contact you to ask about each of these future uses. These specimens and data will be stripped of identifiers such as name, address or account number, so that it may be used for future research on any topic and shared broadly for research purposes. Your specimens and data will be used for research purposes only and will not benefit you. It is also possible that the stored specimens and data may never be used. Results of research done on your specimens and data will not be available to you or your doctor. It might help people who have cancer and other diseases in the future.

PATIENT IDENTIFICATION	CONTINUATION SHEET for either: NIH-2514-1 (07-09) NIH-2514-2 (10-84) P.A.: 09-25-0099 File in Section 4: Protocol Consent
------------------------	--

MEDICAL RECORD

CONTINUATION SHEET for either:

NIH 2514-1, Consent to Participate in A Clinical Research Study

NIH 2514-2, Minor Patient's Assent to Participate In A Clinical Research Study

STUDY NUMBER: 16-C-0128

CONTINUATION: page 13 of 15 pages

If do not want your stored specimens and data used for future research, please contact us in writing and let us know that you do not want us to use your specimens and/or data. Then any specimens that have not already been used or shared will be destroyed and your data will not be used for future research. However, it may not be possible to withdraw or delete materials or data once they have been shared with other researchers.

PATIENT IDENTIFICATION

CONTINUATION SHEET for either:

NIH-2514-1 (07-09)

NIH-2514-2 (10-84)

P.A.: 09-25-0099

File in Section 4: Protocol Consent

OTHER PERTINENT INFORMATION

1. Confidentiality. When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

The Federal Privacy Act protects the confidentiality of your NIH medical records. However, you should know that the Act allows release of some information from your medical record without your permission, for example, if it is required by the Food and Drug Administration (FDA), members of Congress, law enforcement officials, or authorized hospital accreditation organizations.

2. Policy Regarding Research-Related Injuries. The Clinical Center will provide short-term medical care for any injury resulting from your participation in research here. In general, no long-term medical care or financial compensation for research-related injuries will be provided by the National Institutes of Health, the Clinical Center, or the Federal Government. However, you have the right to pursue legal remedy if you believe that your injury justifies such action.

3. Payments. The amount of payment to research volunteers is guided by the National Institutes of Health policies. In general, patients are not paid for taking part in research studies at the National Institutes of Health. Reimbursement of travel and subsistence will be offered consistent with NIH guidelines.

4. Problems or Questions. If you have any problems or questions about this study, or about your rights as a research participant, or about any research-related injury, contact the Principal Investigator, Christine Alewine, M.D., Ph.D., Building 37, Room 5116, Telephone: 240-760-6146. You may also call the Clinical Center Patient Representative at 301-496-2626. If you have any questions about the use of your specimens or data for future research studies, you may also contact the Office of the Clinical Director, Telephone: 240-760-6070.

5. Consent Document. Please keep a copy of this document in case you want to read it again.

COMPLETE APPROPRIATE ITEM(S) BELOW:

A. Adult Patient's Consent

I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby consent to take part in this study.

Signature of Adult Patient/ Date
Legal Representative

Print Name

B. Parent's Permission for Minor Patient.

I have read the explanation about this study and have been given the opportunity to discuss it and to ask questions. I hereby give permission for my child to take part in this study.

(Attach NIH 2514-2, Minor's Assent, if applicable.)

Signature of Parent(s)/ Guardian Date

Print Name

C. Child's Verbal Assent (If Applicable)

The information in the above consent was described to my child and my child agrees to participate in the study.

Signature of Parent(s)/Guardian Date Print Name

**THIS CONSENT DOCUMENT HAS BEEN APPROVED FOR USE
FROM AUGUST 31, 2020 THROUGH AUGUST 30, 2021.**

Signature of Investigator Date Signature of Witness Date

Print Name

Print Name