Cover Page for Clinical Trials Document posting

Official Title: S1400B, “A PHASE II STUDY OF GDC-0032 (TASELISIB) FOR PREVIOUSLY TREATED PI3K POSITIVE PATIENTS WITH STAGE IV SQUAMOUS CELL LUNG CANCER (LUNG-MAP SUB-STUDY)”

NCT Number: 02785913

Version Date: 9/1/2017

Description:

S1400 [NCT 02154490] is the parent study to **S1400B** [NCT 02785913].

The **S1400** Lung-MAP study is considered one study under one IND consisting of:

- S1400 Version Control Protocol
- S1400 Main Screening Protocol Component
- Multiple Sub-Studies (or sub-protocols) Components

Each component is contained in its own separate document.

S1400B is one of these components. Each “component” consists of the protocol document and its associated informed consent document(s). Since each screening and sub-study component operates independently from the other components contained in Lung-MAP, each has its own version date and NCT number. This is due to the complexity of the study and how it must be entered into different computer programs.

Informed Consent Model for S1400B

*NOTES FOR LOCAL INSTITUTION INFORMED CONSENT AUTHORS:

This model informed consent form has been reviewed by the DCTD/NCI and is the official consent document for this study. Local IRB changes to this document are allowed. (Institutions should attempt to use sections of this document that are in bold type in their entirety.) Editorial changes to these sections may be made as long as they do not change information or intent. If the institutional IRB insists on making additions, deletions, or more substantive modifications to the risks or alternatives sections, they may be justified in writing by the investigator and approved by the IRB. Under these circumstances, the revised language, justification and a copy of the IRB minutes must be forwarded to the SWOG Operations Office for approval before a patient may be registered to this study.

Please particularly note that the questions related to banking of specimens for future study are in bolded type and may not be changed in any way without prior approval from the SWOG Operations Office.

Readability Statistics:	
Flesch Reading Ease	59.1 (targeted above 55)
Flesch-Kincaid Grade Level	9.2 (targeted below 8.5)

- Instructions and examples for informed consent authors are in *[italics]*.
- A blank line, _____, indicates that the local investigator should provide the appropriate information before the document is reviewed with the prospective research participant.
- The term "study doctor" has been used throughout the model because the local investigator for a cancer treatment trial is a physician. If this model is used for a trial in which the local investigator is not a physician, another appropriate term should be used instead of "study doctor".
- The dates of protocol updates in the header and in the text of the consent is for reference to this model only and should not be included in the informed consent form given to the prospective research participant.
- The local informed consent must state which parties may inspect the research records. This includes the NCI, the drug manufacturer for investigational studies, any companies or grantors that are providing study support (these will be listed in the protocol's model informed consent form) and SWOG.

  "SWOG" must be listed as one of the parties that may inspect the research records in all protocol consent forms for which patient registration is being credited to SWOG. This includes consent forms for studies where all patients are registered directly through the SWOG Data Operations Office, all intergroup studies for which the registration is being credited to SWOG (whether the registration is through the SWOG Data Operations

Office or directly through the other group), as well as consent forms for studies where patients are registered via CTSU and the registration is credited to SWOG.

- When changes to the protocol require revision of the informed consent document, the IRB should have a system that identifies the revised consent document, in order to preclude continued use of the older version and to identify file copies. An appropriate method to identify the current version of the consent is for the IRB to stamp the final copy of the consent document with the approval date. The stamped consent document is then photocopied for use. Other systems of identifying the current version of the consent such as adding a version or approval date are allowed as long as it is possible to determine during an audit that the patient signed the most current version of the consent form.

*NOTES FOR LOCAL INVESTIGATORS:

- The goal of the informed consent process is to provide people with sufficient information for making informed choices. The informed consent form provides a summary of the clinical study and the individual's rights as a research participant. It serves as a starting point for the necessary exchange of information between the investigator and potential research participant. This model for the informed consent form is only one part of the larger process of informed consent. For more information about informed consent, review the "Recommendations for the Development of Informed Consent Documents for Cancer Clinical Trials" prepared by the Comprehensive Working Group on Informed Consent in Cancer Clinical Trials for the National Cancer Institute. The Web site address for this document is http://cancer.gov/clinicaltrials/understanding/simplification-of-informed-consent-docs/
- A blank line, _____, indicates that the local investigator should provide the appropriate information before the document is reviewed with the prospective research participant.
- Suggestion for Local Investigators: An NCI pamphlet explaining clinical trials is available for your patients. The pamphlet is titled: "Taking Part in Cancer Treatment Research Studies". This pamphlet may be ordered on the NCI Web site at *https://cissecure.nci.nih.gov/ncipubs* or call 1-800-4- CANCER (1-800-422-6237) to request a free copy.
- Optional feature for Local Investigators: Reference and attach drug sheets, pharmaceutical information for the public, or other material on risks. Check with your local IRB regarding review of additional materials.

*These notes for authors and investigators are instructional and should not be included in the informed consent form given to the prospective research participant.

Study Title for Study Participants: Targeted Treatment for Advanced Squamous Cell Lung Cancer

Official Study Title for Internet Search on http://www.ClinicalTrials.gov:

S1400, "A Biomarker-Driven Master Protocol for Previously Treated Squamous Cell Lung Cancer"
S1400B, "A Phase II Study of GDC-0032 (Taselisib) for Previously Treated PI3K Positive Patients with Stage IV Squamous Cell Lung Cancer (Lung-MAP Sub-Study)" *(Revised 12/1/14) (Revised 4/22/15) (Revised11/18/15)*

What is the usual approach to my lung cancer?

Squamous cell lung cancers make up about one-fourth of non-small cell lung cancer. Various chemotherapy drugs have been shown to improve survival for patients with advanced squamous lung cancer. Most patients will be treated at first with cisplatin or carboplatin in combination with a second chemotherapy drug such as gemcitabine, paclitaxel, docetaxel, or vinorelbine. In addition, an immunotherapy drug called nivolumab was recently FDA approved for patients with squamous lung cancer who previously received chemotherapy. *(Paragraph Revised 4/22/15)*

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

Your other choices may include:

- **You may choose to have the usual approach described above**
- **You may choose to take part in a different study, if one is available**
- **You may choose to get comfort care, also called palliative care. This type of care helps reduce pain, tiredness, appetite problems and other problems caused by the cancer. It does not treat the cancer directly, but instead tries to improve how you feel. Comfort care tries to keep you as active and comfortable as possible.**

Why is this study being done?

There are several investigational treatments that are being tested in various sub-studies as part of this study. You will have already received the information on your biomarker testing. You have been assigned to this treatment study because your tumor sample had changes in genes and proteins called the PI3K biomarker. The purpose of this sub-study is to look at the effects (good and bad) of GDC-0032 (taselisib). GDC-0032 (taselisib) is investigational for this study. GDC-0032 may or may not shrink your cancer and it could also cause side effects. *(Paragraph Revised11/18/15)*

There will be about 40 patients taking part in this study. *(Revised 4/22/15) (Revised11/18/15)*

What are the study groups?

You have been assigned to this sub-study because your tumor sample had the PI3K biomarker. This sub-study is a single arm study. *(Revised11/18/15)*

The study drug GDC-0032 is taken by mouth. Due to a potential interaction with GDC-0032, you should avoid consuming grapefruits or grapefruit juice and consult with your study doctor before taking any new medication or herbal supplement. *(Revised11/18/15)*

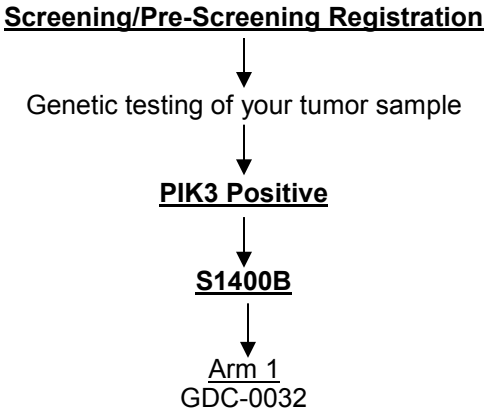
(Deleted11/18/15)

The target treatment on this study is described in the table below:

Arm	Drug	How often is it given?	How is it given?	What days is it given on?	What is the cycle duration?
1	GDC-0032 (Taselisib) *(Revised 4/22/15)*	Every day	By mouth	Daily	21 days

(Table Revised11/18/15)

Another way to find out what may happen to you during the study is to read the chart below. Start reading at the top of the chart and read down, following the arrows.



(Revised 12/1/14) (Revised 4/22/15) (Revised11/18/15)

How long will I be in this study?

You will receive treatment until your disease worsens. After you are finished taking study treatment, the study doctor will continue to watch you for side effects and follow your condition for 3 years from the time you started treatment. *(Revised11/18/15)* At the follow up visits you will have a physical exam, blood tests, and scans. Your doctor may give you other tests or procedures if they think they are needed.

Should your disease worsen, you have the option to participate in a different sub-study. As before, the new sub-study that you will be offered will depend on a combination of the results of the previous testing done on your tumor sample and the sub-studies available. If your tumor has multiple biomarkers with sub-studies designed for them, you will be assigned to one of the sub-studies randomly (by chance). There is a sub-study available if your tumor does not have any additional biomarkers being tested or you were not eligible to participate in other sub-studies. If you do not have any of the biomarkers being tested and have had prior immunotherapy treatment (such as nivolumab) you will not be eligible. *(Paragraph Added 7/19/16)*

What extra tests and procedures will I have if I take part in this study?

Most of the exams, tests, and procedures you will have are part of the usual approach for your cancer. However, there are some extra exams, tests, and/or procedures that you will need to have if you take part in this study. *(Added11/18/15)*

Before you begin the study:

- Brain CT or MRI (to check if your cancer may have spread to your brain)
- *(Deleted11/18/15)*
- Blood tests to assess your fasting blood sugar levels and pancreas functions *(Added 12/1/14)*

Note: You might receive the above tests even if you were not on the study as part of your cancer treatment.

You will have a CT or MRI done before you begin the study and then approximately every 6 weeks until your disease worsens. *(Added11/18/15)* Your doctor will review the CT scans or other radiographic scans done to check on your tumors on a regular basis. These scans will also be sent to a central location for review. This central review is part of a total study analysis only. Information of your scans from the central review will not be sent back to you or your doctor.

If the exams, tests, and procedures show that you can take part in the study, and you choose to take part, then you will need the following extra tests. They are not part of the usual approach for your type of cancer. *(Added11/18/15)*

During the study: *(Section added 12/1/14) (Revised11/18/15)*

- Blood tests to assess your fasting blood sugar levels and pancreas functions

The blood test for your glucose levels will be done after treatment. The blood test to assess your blood sugar levels and pancreatic functions will be done before you begin the study and approximately on Day 1 of each cycle. *(Revised 4/22/15)*

Neither you nor your health care plan/insurance carrier will be billed for the following tests for this study:

- Blood tests to assess fasting blood sugar (Hb1Ac test only)
- Blood tests to assess pancreas functions (Amylase and Lipase tests)
  (Added 4/22/15) (Revised11/18/15)

What possible risks can I expect from taking part in this study?

If you choose to take part in this study, there is a risk that you may:

- **Lose time at work or home and spend more time in the hospital or doctor's office than usual**
- **Be asked sensitive or private questions which you normally do not discuss**

The treatment used in this study may affect how different parts of your body work such as your liver, kidneys, heart, and blood. The study doctor will be testing your blood and will let you know if changes occur that may affect your health.

There is also a risk that you could have side effects.

Here are important points about side effects:

- **The study doctors do not know who will or will not have side effects.**
- **Some side effects may go away soon, some may last a long time, or some may never go away.**
- **Some side effects may interfere with your ability to have children.**
- **Some side effects may be serious and may even result in death.**

Here are important points about how you and the study doctor can make side effects less of a problem:

- **Tell the study doctor if you notice or feel anything different so they can see if you are having a side effect.**
- **The study doctor may be able to treat some side effects.**
- **The study doctor may adjust the study drugs to try to reduce side effects.**

The tables provided below show the most common and the most serious side effects that researchers know about related to GDC-0032. There might be other side effects that researchers do not yet know about. If important new side effects are found, the study doctor will discuss these with you.

COMMON, SOME MAY BE SERIOUS **In 100 people receiving GDC-0032, more than 20 and up to 100 may have:** *(Table Replaced 12/1/14) (Table Replaced 7/19/16)*
• **Diarrhea, nausea** • **Tiredness** • **Loss of appetite**

OCCASIONAL, SOME MAY BE SERIOUS **In 100 people receiving GDC-0032, from 4 to 20 may have**: *(Table Replaced 12/1/14) (Table Replaced 4/22/15) (Table Updated 7/19/16)*
• **Pain** • **Dry mouth, skin** • **Heartburn, vomiting** • **Sores in mouth which may cause difficulty swallowing** • **Changes in taste** • **Itching, rash**

RARE, AND SERIOUS **In 100 people receiving GDC-0032, 3 or fewer may have:** *(Table Replaced 12/1/14) (Table Replaced 4/22/15) (Table Updated 7/19/16)*
• **Swelling of the lungs which may cause shortness of breath**

(Deleted11/18/15)

(Paragraph Deleted11/18/15)

Let your study doctor know of any questions you have about possible side effects. You can ask the study doctor questions about side effects at any time.

Reproductive risks: You should not get pregnant, breastfeed, or father a baby while in this study as the drugs used in this study could be very damaging to an unborn baby. Women who receive GDC-0032 should use effective contraception during the period of the trial and for at least 7 months after completion of treatment. *(Added 12/1/14)* Check with the study doctor about what types of birth control, or pregnancy prevention, to use while in this study.

What possible benefits can I expect from taking part in this study?

It is not possible to know at this time if the study drug/study approach is better than the usual approach, so this study may or may not help you. This study will help researchers learn things that will help people in the future.

Can I stop taking part in this study?

Yes. You can decide to stop at any time. If you decide to stop for any reason, it is important to let the study doctor know as soon as possible so you can stop safely. If you stop, you can decide whether or not to let the study doctor continue to provide your medical information to the organization running the study.

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

The study doctor may take you out of the study:

- If your health changes and the study is no longer in your best interest
- If new information becomes available
- If you do not follow the study rules
- If the study is stopped by the sponsor, IRB or FDA.

What are my rights in this study?

Taking part in this study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

For questions about your rights while in this study, call the _____ *(insert name of center)* Institutional Review Board at _____ *(insert telephone number). (Note to Local Investigator: Contact information for patient representatives or other individuals at a local institution who are not on the IRB or research team but take calls regarding clinical trial questions can also be listed here.)*

What are the costs of taking part in this study?

The GDC-0032 will be supplied at no charge while you take part in this study. The cost of getting the GDC-0032 ready and giving it to you is not paid by the study sponsor so you or your insurance company may have to pay for this. It is possible that the GDC-0032 may not continue to be supplied while you are on the study. Although not likely, if this occurs, your study doctor will talk to you about your options.

You and/or your health plan/insurance company will need to pay for all of the other costs of treating your cancer while in this study, including the cost of tests, procedures, or medicines to manage any side effects, unless you are told that certain tests are supplied at no charge. Before you decide to be in the study, you should check with your health plan or insurance company to find out exactly what they will pay for.

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

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

If you are injured or hurt as a result of taking part in this study and need medical treatment, please tell your study doctor. The study sponsors will not offer to pay for medical treatment for injury. Your insurance company may not be willing to pay for study-related injury. If you have no insurance, you would be responsible for any costs.

If you feel this injury was a result of medical error, you keep all your legal rights to receive payment for this even though you are in a study.

Who will see my medical information?

Your privacy is very important to us and the researchers will make every effort to protect it. Your information may be given out if required by law. For example, certain states require doctors to report to health boards if they find a disease like tuberculosis. However, the researchers will do their best to make sure that any information that is released will not identify you. Some of your health information, and/or information about your specimen, from this study will be kept in a central database for research. Your name or contact information will not be put in the database.

There are organizations that may inspect your records. These organizations are required to make sure your information is kept private, unless required by law to provide information. Some of these organizations are:

- The study sponsor, SWOG, and the drug company supporting the treatment sub-study you are on.
- The Institutional Review Board, IRB, is a group of people who review the research with the goal of protecting the people who take part in the study.
- The Food and Drug Administration (FDA) and the National Cancer Institute (NCI) in the U.S., and similar ones if other countries are involved in the study *(Revised 12/1/14)*.

- TRIAD-Your medical images with clinical study data (e.g., the treatment Group you are assigned to, etc.) will be transferred to the Ohio State University in Columbus, Ohio. Your medical images will be reviewed by physicians at this organization as part of the study analysis for this trial. In addition, information gained from this study may be used in the future for additional research and only that data would be provided to other scientist for future research. Your name, and any other information that could be used to identify you personally, will not be included. *(Added 12/1/14)*

Where can I get more information?

You may visit the NCI Web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

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.

[Note to Informed Consent Authors: The above paragraph complies with the new FDA regulation found at 21CFR50.25 (c) and must be included verbatim in all informed consent documents. The text in this paragraph cannot be revised *(Added 12/1/14)*

Who can answer my questions about this study?

You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact the study doctor _____ *(insert name of study doctor[s])* at _____ *(insert telephone number).*

This section is about optional studies you can choose to take part in

This part of the consent form is about optional studies that you can choose to take part in. You will not get health benefits from any of these studies. The researchers leading this optional study hope the results will help other people with cancer in the future.

The results will not be added to your medical records, nor will you or your study doctor know the results.

You will not be billed for these optional studies. You can still take part in the main study even if you say 'no' to any or all of these studies. If you sign up for but cannot complete any of the studies for any reason, you can still take part in the main study.

Circle your choice of "yes" or "no" for each of the following studies.

(Deleted 12/1/14)

1. Optional Additional Biopsy and Optional Sample Collections for Laboratory Studies and/or Biobanking for Possible Future Studies

Researchers are trying to learn more about cancer, diabetes, and other health problems. Much of this research is done using samples from your tissue, blood, urine, or other fluids. Through these studies, researchers hope to find new ways to prevent, detect, treat, or cure health problems. Some of these studies may be about genes. Genes carry information about features that are found in you and in people who are related to you. Researchers are interested in the way that genes affect how your body responds to treatment.

If you choose to take part in this part of the study, the researchers would also like to ask your permission to store and use your samples and health information for medical research. The research that may be done is unknown at this time. Storing samples for future studies is called "biobanking". The Biobank is being run by SWOG and supported by the National Cancer Institute.

WHAT IS INVOLVED?

If you agree to take part, here is what will happen next:

1) Your specimens may be stored in the Biobank, along with samples from other people who take part. These specimens may include:
    - *(Deleted 4/22/15)*
    - About 1 tablespoon of blood will be collected from a vein in your arm (at the same time as other study blood tests) on Weeks 4, 7, 10, and again if your cancer gets worse. *(Revised 4/22/15)*
    - A sample of tissue will be collected from an optional extra biopsy if your cancer gets worse after treatment on this study. Common side effects of a biopsy are a small amount of bleeding at the time of the procedure, pain and bruising at the biopsy site, which can be treated with regular pain medications.

      Rarely, an infection can occur. Rarely, patients may experience partial lung collapse that may require a chest tube or breathing machine. You will sign a separate consent form before the biopsy is taken. This will be a standard surgical consent form from the institution where the biopsy procedure takes place. The samples will be kept until they are used up.

2) Qualified researchers can submit a request to use the materials stored in the Biobanks. A science committee at the clinical trials organization, and/or the National Cancer Institute, will review each request. There will also be an ethics review to ensure that the request is necessary and proper. Researchers will not be given your name or any other information that could directly identify you.
3) Neither you nor your study doctor will be notified when research will be conducted or given reports or other information about any research that is done using your samples.

4) Some of your genetic and health information may be placed in central databases that may be public, along with information from many other people. Information that could directly identify you will not be included.

(Deleted 12/1/14)

WHAT ARE THE POSSIBLE RISKS?

1) There is a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you.
2) There is a risk that someone could trace the information in a central database back to you. Even without your name or other identifiers, your genetic information is unique to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information.
3) In some cases, this information could be used to make it harder for you to get or keep a job or insurance. There are laws against the misuse of genetic information, but they may not give full protection. There can also be a risk in knowing genetic information. The Genetic Information Nondiscrimination Act of 2008, also referred to as GINA, was passed by Congress to protect Americans from such discrimination. The law prevents discrimination from health insurers and employers. This law does not cover life insurance, disability insurance and long-term care insurance. New health information about inherited traits that might affect you or your blood relatives could be found during a study. The researchers believe the chance these things will happen is very small, but cannot promise that they will not occur.

HOW WILL INFORMATION ABOUT ME BE KEPT PRIVATE?

Your privacy is very important to the researchers and they will make every effort to protect it. Here are just a few of the steps they will take:

1) When your samples are sent to the researchers, no information identifying you (such as your name) will be sent. Samples will be identified by a unique code only.
2) The list that links the unique code to your name will be kept separate from your sample and health information. Any Biobank and SWOG staff with access to the list must sign an agreement to keep your identity confidential.
3) Researchers to whom SWOG sends your sample and information will not know who you are. They must also sign an agreement that they will not try to find out who you are.
4) Information that identifies you will not be given to anyone, unless required by law.
5) If research results are published, your name and other personal information will not be used.

WHAT ARE THE POSSIBLE BENEFITS?

You will not benefit from taking part.

The researchers, using the samples from you and others, might make discoveries that could help people in the future.

ARE THERE ANY COSTS OR PAYMENTS?

Neither you nor your health care plan/insurance carrier will be billed for the collection or testing of the tumor tissue or blood samples that will be used for this study. *(Revised11/18/15)*. You will not be paid for taking part. If any of the research leads to new tests, drugs, or other commercial products, you will not share in any profits.

WHAT IF I CHANGE MY MIND?

If you decide you no longer want your samples to be used, you can call the study doctor, _____, *(insert name of study doctor for main trial)* at _____ *(insert telephone number of study doctor for main trial)* who will let the researchers know. Then, any sample that remains in the bank will no longer be used. Samples or related information that have already been given to or used by researchers will not be returned.

WHAT IF I HAVE MORE QUESTIONS?

If you have questions about the use of your samples for research, contact the study doctor, _____, *(insert name of study doctor for main trial)*, at _____ *(insert telephone number of study doctor for main trial)*.

Please circle your answer to show whether or not you would like to take part in each option:

SAMPLES FOR FUTURE RESEARCH STUDIES:

1. **My tumor tissue and related information may be kept in a Biobank for use in future health research.**

   YES NO

2. **My blood samples and related information may be kept in a Biobank for use in future health research.**

   YES NO

(Revised 4/22/15)

This is the end of the section about optional studies.

My Signature Agreeing to Take Part in the Main Study

I have read this consent form or had it read to me. I have discussed it with the study doctor and my questions have been answered. I will be given a signed copy of this form. I agree to take part in the main study and any additional studies where I circled 'yes'.

Participant's signature *(Deleted 12/1/14)*_____

Date of signature_____