

Patient Information Sheet and Informed Consent Form for HER2 Testing

Patient Information Sheet for HER2 Testing

Title of the Study: An Open-label, Randomized, Multicenter Phase III Clinical Trial of SHR-A1811 Versus Investigator-selected Chemotherapy for Platinum-resistant Relapsed Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer

Study Number: GSP 402-301 (SHR-A1811-315_Extension)

Sponsor: Glenmark Specialty SA., Place du Port, CH-2000 Neuchâtel, Switzerland.

Introduction

This HER2 assay is related to the study titled “An Open-label, Randomized, Multicenter Phase III Clinical Trial of SHR-A1811 Versus Investigator-selected Chemotherapy for Platinum-resistant Relapsed Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer”. The study is sponsored by Glenmark Specialty S.A. and the local Sponsor is Glenmark Pharmaceuticals Ltd. The study Sponsor pays the cost for this HER2 testing.

We ask that you allow testing of your tumor tissue sample to determine if your tumor tissue has certain characteristics (i.e., HER2 expression), also known as biomarkers. These biomarkers may indicate that your disease/condition is more or less responsive to SHR-A1811, an investigational drug used for tumors that express HER2 receptors. The results of the HER2 test will determine your eligibility for the study (mentioned above) to some extent.

You will be asked to attend a consultation lasting approximately one hour. You will be asked to give a biological sample (tumor tissue) and undergo a procedure (such as a biopsy) that may differ from routine medical tests. After that, you will need to wait regarding 7 to 14 days to find out if your HER2 test result makes you eligible to take part in the study.

This HER2 test does not involve any changes to your present treatment and is only used to determine your eligibility for the study. The benefit of participating in this HER2 test is to know if you are eligible for this study and/or to help your physician decide your further treatment option(s).

Whether or not to take a HER2 test depends entirely on your voluntariness. You may refuse to take part in this without loss of your medical or other benefits. Even if you now agree to take part in HER2 testing, you can still change your mind prior the biopsy is completed and will not lose the medical or other benefits you are entitled to. Kindly read this form carefully and do not rush. If you have any questions regarding HER2 testing, you can ask the study physician or researcher. If you have text or details that you don't know, the study physician or researcher will explain it to you. The research team consists of the study physician, nurses, and other people working with the study physician.

You can take an unsigned informed consent form with you and consider it carefully or discuss it with a family member or friend prior making a decision.

If you agree to take part in this HER2 test, you must sign this informed consent form prior undergoing any procedure.

What is the aim of HER2 testing?

The results of HER2 testing will determine to some extent whether you are eligible to take part in the study (the title of the study is mentioned in first page of this document) that includes patients

with platinum-resistant relapsed epithelial ovarian, fallopian tube or primary peritoneal cancer with HER2 expression. If your HER2 test shows that your tumor tissue sample does not express HER2 receptors, you will generally not be eligible for this study. If HER2 testing shows HER2 receptor expression in your tumor tissue sample, the study physician will review additional study needs to determine if you are eligible for the study.

The study physician will discuss your HER2 test results with you. If the results show that you are eligible to take part in the study, the study physician will additionally give you with a separate informed consent document that describes the study and obtain your consent for your participation in the study. Whether or not to take part in the study is entirely on your voluntariness.

How long does it take to complete a HER2 test?

You may be asked to attend a visit that lasts about 1 hour. After that, it will take about 7 to 14 days for your HER2 test report availability.

How many people will take part in the study?

The study is being performed in multiple countries which includes India, Australia and others. About 30 research institutions in India are planned to take part in the study, with regarding 250 people planned to be tested for HER2, and finally about 50 people from India will take part in the study.

What happens at the time of this HER2 test?

You will need to undergo a tumor biopsy or give previously archived biopsies of tumor tissue (no less than 6 pieces) for testing of HER2 expression.

Are there any special instructions for this HER2 test?

No special instructions are needed for this HER2 test.

What are the possible risks and discomforts of this HER2 test?

If the test can be done with tissue collected from your previous surgery or biopsy, there are no known possible physical risks or discomforts.

Although, if it is determined that another biopsy is needed, there may be risks and discomfort. Kindly read this section carefully to ensure you know the risks and discomfort associated with the procedure.

All studies have risks, which includes risks that may make you feel uncomfortable or that may harm you. You may experience these risks or discomforts when participating in HER2 testing. If you experience any of these problems at the time of your HER2 testing, it's important to let your research team know. The research team will monitor you for risk or discomfort at the time of HER2 testing. Although, the research team is not clear regarding all the effects that your participation in this HER2 test may have on you. These effects can be mild or severe. In some cases, these effects can be long-term or permanent and can even be life-threatening.

Here are the risks or discomfort that are most likely to happen to you when you take part in this HER2 test.

As soon as symptoms and side effects appear, it is important to report them to the study team in a timely manner.

Tumor biopsy (if needed): There may be some temporary pain or discomfort in the area where the tissue was removed at the time of the procedure and sometime afterwards. You may also

experience some bruising around the biopsy site in the next few days. In rare cases, possible bleeding or infection at the biopsy puncture site may occur; if the puncture site is in the lungs, it may cause pneumothorax; puncture may cause new metastases of the tumor; inadequate tumor tissue sampling at the time of biopsy may lead to test failure and not determine your HER2 status properly. This list does not include all risks or discomforts.

What are the possible benefits of this HER2 test?

HER2 testing is for research aims only to assess if HER2 status in your tumor makes you eligible for the study. There is no direct benefit to participating in HER2 testing. Although, the detail gained from the HER2 testing may be helpful to decide further treatment option(s) for your tumor.

If I don't want to take part in this HER2 test, what are my options?

If you wish to take part in the study, you must complete the HER2 testing process described in this informed consent document to confirm your eligibility to take part in the study. If you do not agree with this HER2 test, you will not be able to take part in this study. Although, even if you agree to take part in this HER2 test, you may not meet the other needs to take part in this study.

What if I get injured at the time of a HER2 test?

When the HER2 test will use a tissue sample that has been taken from you previously such as archived tissue sample, so if you agree to take part, you will not be at risk of injury.

If a study-related injury occurs as a result of your participation in this clinical study and you act in accordance with the instructions of the study physician, you will receive the necessary medical treatment.

The Sponsor gives liability insurance for this study, and the Sponsor will bear both treatment-related costs and corresponding financial compensation for any damages related to the trial, except for medical malpractice.

What happens if I agree to have a HER2 test and then choose not to continue?

If you agree to take part, you are free to change your mind prior the biopsy and test. Your decision will not result in loss of your medical or other benefits. If you are considering withdrawing from HER2 testing, tell your study physician.

Sometimes the study physician or Sponsor may decide to exclude you from HER2 testing, even if you do not agree, if:

- You are unable or unwilling to follow the instructions of the research team;
- HER2 testing is not in your best interest in the opinion of the study physician, or you are no longer eligible to take part;
- HER2 testing or research is stopped by the Sponsor, Institutional Review Board (IRB)/Independent Ethics Committee (IEC) (a group of people reviewing research to protect your rights), or government/regulatory authority.

What is the cost if I agree to take part in this HER2 test?

This HER2 test is completely free of charge, and if biopsy collection is needed according to the research process, the biopsy operation cost will be borne by the Sponsor. There is no cost to you or your insurance company.

Will I get paid for this HER2 test?

You will not be compensated for participating in this HER2 test.

If you need to complete a tumor biopsy, you will be given with travel and/or food fee of Rs. as applicable for the situation.

Sponsors can use the detail obtained from HER2 testing to develop products or processes and profit from them. You will not receive fees or any products developed in this study. All products and processes developed using the detail obtained from HER2 testing, which includes your sample, are owned by the Sponsor.

What happens to my personal details?

At the time of this HER2 testing, your personal data, especially medical outcomes, is collected, stored and evaluated. You have the right to be informed and to have the data corrected if there is updated details regarding the data that has already been collected. In order to verify research operations and data, medical records related to clinical trials containing your personal details and informed consent forms signed by you may be disclosed by the investigator to the Ethics Committee or Institutional Review Board, inspectors of national or foreign regulatory authorities and Sponsors for research or regulatory aims. These people (inspectors/monitors) are also responsible for maintaining the privacy of your details. Sponsors have access to research information at the time of and after this HER2 testing. If you do not agree to the above data protection terms, you will not be able to take part in this HER2 testing.

In this HER2 testing, your blood, urine, tumor tissue, and other biological samples will be coded, meaning they will have a “code” instead of using your name or any other personal details of you. Data collected through sample detection will also be saved and analyzed using coding. Only your study physician or someone else authorized by the study physician can identify your name by the code.

How can I get more details regarding the study or findings?

A description of this study will be available on website <https://ctri.nic.in/Clinicaltrials>. You can search this website at any time. This website will not include details that can identify you. At most, the website will include a summary of the study results after the study is completed.

Who to call with questions?

If you have any questions, concerns, or complaints regarding any part of the HER2 testing process, you should ask to speak with a study physician or a member of the study team who will assist you.

The data controller of this study is the Sponsor of this study. If you have any questions regarding your personal data protection rights as a participant in this study, or if you have any complaints regarding the use of your personal details, kindly contact the study physician or the study team. They will be able to refer your questions directly to the Sponsor's data protection officer or the Sponsor's data representative as needed.

Name of the Study Physician: _____

Phone: _____

If you have any questions regarding your rights as a research participant, kindly contact the below mentioned person:

Ethics Committee: _____

Phone: _____

Informed Consent for HER2 Testing

Title of the Study: An Open-label, Randomized, Multicenter Phase III Clinical Trial of SHR-A1811 Versus Investigator-selected Chemotherapy for Platinum-resistant Relapsed Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer

Study Number: GSP 402-301 (SHR-A1811-315_Extension)

Subject's Initials: _____ Name of the Subject: _____

Date of Birth/Age: _____

Subject's Address: _____

Qualification: _____

Occupation: Student/ Self-Employed/ Service/ House-wife/Others

(Kindly tick as proper)

Annual Income of the subject: _____

Details of Nominee (s):

Nominee's Name: _____

Nominee's Address: _____

Relation to Subject: _____

Kindly initial box (Subject)

(i) I agree that I have read (or, if I can't, a member of the research team has read it to me) and know the informed consent document for HER2 testing mentioned above and have the chance to ask questions. I have enough time to read this informed consent document. I also had the chance to ask regarding the details of HER2 testing and decide whether to take part.

(ii) I know that participation in HER2 testing will require processing (which includes collection, use, transfer, storage, analysis, and reporting) of my personal detail regarding the privacy of personal detail. I know and consent to the processing of my personal details within or outside the country of my residence for healthcare, medical research, and/or regulatory aims.

- (iii) I know that my consent to participation is voluntary, and I can stop participating in HER2 testing or take informed consent to the processing of my personal detail at any time. I don't need to give any reason, and my normal medical and legal rights will not be affected. Although, even if I take my informed consent to the processing, personal details retained at that time may be saved for the aim of complying with laws and regulations and maintaining the integrity of the research. I also know that my biological samples may not be destroyed because they may no longer be traced back to me, may have been used.
- (iv) I consent to the study team visiting my medical history, which includes details from my medical record and test results, as well as any medical treatment I received at the time of HER2 testing, and to contact my physician or any other medical care giver treating me for such details if necessary.
- (v) I know that the Sponsor and/or others working on the Sponsor's behalf, the Institutional Review Board (IRB) or Ethics Committee (IEC), and regulatory authorities may need access to personal details regarding me generated at the study site or collected by the research team for HER2 testing. I agree that they have access to my personal details.
- (vi) Signing this informed consent document does not constitute a waiver of any legal rights. I was told that I would receive a signed and dated copy of that document.
- (vii) I agree to take part in the HER2 testing described in this document.

☐☐☐☐☐

Signature (or Thumb impression) of the Subject/Legally Acceptable Representative: _____

Date: ____/____/____

Name of the Signatory: _____

Signature of the Investigator: _____

Date: ____/____/____

Name of the Study Investigator: _____

Witness's Signature: _____

Date: ____/____/____

Witness's Name: _____

A copy of the Patient Information Sheet and the completed Informed Consent Form for HER2 testing will be provided to the participant or their attendant.