If you’re fighting advanced non-squamous non-small cell lung cancer (NSCLC), you’re not alone.

If you’re interested in this clinical research study please contact:

- **All subsequent cycles every 21 days:**
  - Physical examination
  - Blood tests
  - Study treatment infusions

Tumor assessments will thereafter be performed every 12 weeks until the end of study participation.

- End of Treatment / Withdrawal:
  - Physical examination
  - Blood tests
  - Heart assessments

When the study ends, participants will be followed up by phone every 2 months.

Is there anything else that I should know?

There may be some risk and discomfort involved in taking part in a clinical research study. However, the safety of participants is our number one priority during every stage of the process.

Before the study

Every study is closely regulated and must be approved by an independent ethics committee (IEC)/Institutional Review Board (IRB) and/or Country Competent Authorities (CA), which are committees that approve research involving human beings. The committees comprise healthcare and research professionals as well as non-medical members. They review the ethics, science, medical aspects and country regulations of the clinical study and are responsible for protecting the rights, safety and wellbeing of human research participants. If you decide to join, the study will be carefully explained to you and you will be given the chance to ask questions. You will then be asked to sign an Informed Consent Document (ICD) to show that you understand what the study involves.

During the study

While the study is ongoing, a specialist team of doctors and nurses at the study center will monitor your health closely.

Like all medicines, bevacizumab, carboplatin, paclitaxel and the investigational drug can cause side effects, although not everybody experiences the same reactions. Most side effects are mild to moderate but some may be serious and require treatment or hospitalization. Reactions during or soon after bevacizumab, carboplatin or paclitaxel infusions can occur. These can include allergic type reactions, chills, fever, flu-like symptoms and other events. Rarely, infusion reactions can become serious. Other side effects can include heart problems during or after treatment, low blood cell counts, feeling tired, hair loss, neuropathy (numbness in your hands or feet), joint or muscle pain, nausea, vomiting and other effects. The study team would discuss all of the side effects that could be anticipated with you before you make the decision to participate in the study.

If you join the study and change your mind at a later date, you are free to leave the study at any time.

All patients participating in the **reflections B739-03** study will receive close care and attention during the study, and their health will be carefully monitored throughout.

Taking part in a study does not guarantee that your health will improve. Because non-squamous NSCLC is a long-term condition, you should ensure that you have regular contact with medical professionals. Keep all appointments with your healthcare team, and discuss any changes you have noticed in your symptoms.

What should I do now?

If you are interested in joining the **reflections B739-03** study or would like further information, please contact the study site staff on the number provided on the back cover of this brochure.

If you are potentially suitable for this study, you may be asked to attend a screening visit to ensure that you fully meet the study requirements. If you do meet the study requirements and want to take part, you will be asked to sign an informed consent document (ICD) to show that you understand what the study involves and agree to participate.

Thank you for your time and interest in the **reflections B739-03** study.

If you are interested in this clinical research study please contact:
A guide to the reflections B739-03 clinical research study for participants and their families

- Do you have newly diagnosed Stage IIIB or IV non-small cell lung cancer?
- Has your tumor been confirmed non-squamous non-small cell lung cancer (NSCLC) by histological or cytological test?

If the answer to these questions is ‘Yes’, then you may be interested in a clinical research study for people with non-squamous, non-small cell lung cancer.

This brochure will tell you a little about the reflections B739-03 study, as well as clinical studies in general. If you have any questions, or would like to discuss the study further, please contact the study site staff using the details provided on the back cover of this brochure.

What are clinical studies?

Clinical studies involve research of investigational drugs in people who volunteer to take part in them. All investigational drugs are researched in a number of carefully regulated clinical studies that are designed to answer questions about their safety and benefits. Every clinical research study is overseen by physicians and their research staff, and must be approved by the regulatory authorities and independent ethics committees in all countries that the study will take place in prior to starting.

Choosing to take part in a clinical trial is an important personal decision. Make sure you take as much time as you need to think about this information and remember that expressing interest does not mean you have to participate.

What is the purpose of this study?

This study is being conducted as part of a larger research program to develop a potential Biosimilar to the approved biologic bevacizumab for individuals with non-squamous NSCLC. The study will evaluate whether the investigational drug has benefits and safety characteristics that are similar to bevacizumab.

Who can take part in the reflections B739-03 study?

We are looking for patients with newly diagnosed Stage IIIB or IV NSCLC (according to the Revised International System for Staging Lung Cancer criteria of 2010) or recurrent (NSCLC) who have not received chemotherapy for metastatic disease.

In order to take part, patients must meet the following criteria:
- Men and women ≥18 years of age
- Newly diagnosed Stage IIIB or IV non-small lung Cancer (according to Revised International System for Staging Lung Cancer criteria of 2010) or recurrent non–small-cell lung cancer (NSCLC) without receiving chemotherapy for metastatic disease.
- Measurable disease according to RECIST v1.1.
- Histologically or cytologically confirmed diagnosis of predominately non-squamous NSCLC
- At least one measurable lesion as defined by Response Evaluation Criteria in Solid Tumors (RECIST v1.1.)
- For patients with recurrent disease, at least 6 months must have passed since completing adjuvant or neoadjuvant treatment.

There are some additional criteria that must be met to join the study. Before joining, all patients will have a number of screening tests to make sure the study is suitable for them.

What study treatment would I get?

Participants assigned to 1 treatment group will receive bevacizumab, and participants assigned to the other treatment group will receive the investigational drug (a potential Biosimilar to bevacizumab). All patients in the study will also have treatment with paclitaxel and carboplatin, a combination of chemotherapy agents that are commonly considered to be a standard of care for the treatment of advanced or metastatic NSCLC.

This study is double-blinded. That means neither the sponsor nor your doctors and site staff or you will know which study treatment you are receiving. This is to ensure the scientific validity of clinical trial results. It will be easy for your doctors to find out which treatment you are on if this is necessary at any point.

This study will follow a treatment and assessment schedule that is typical for your healthcare status. You may receive weekly intravenous infusions (a solution administered into your vein) of study treatment for up to 16 weeks. You will receive between 4 and 6 treatment cycles (each cycle is 3 weeks) of the treatment which will be either bevacizumab or the investigational drug and then continue with bevacizumab for as long as you and your doctor agree you are benefiting from this treatment.

What would I have to do?

During the study, you would visit the study center every three weeks for treatment and assessments.

Participation is approximately 13 months, including one month of screening and one month of follow-up. After one year, tumor assessments will be done every 12 weeks until you and your doctor decide to stop your participation in the study.

An outline of the various procedures that take place during different study visits is given below:

It is important that you attend each of your scheduled appointments.

Screening visit:
- Physical examination
- Blood tests
- Heart assessments
- Study treatment infusions
- Tumor assessments

Tumor assessments will then be performed every 6 weeks, until week 25.

Cycle 1–6 visit—day 1, 22, 43, 64, 85 and 106:
- Physical examination
- Blood tests
- Study treatment infusions

Tumor assessments will thereafter be performed every 9 weeks, until 1 year after start of treatment.

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