INSIGHT2

This brochure contains information about a clinical research study that may be of interest to people in your patient community

We are looking for people diagnosed with *EGFR*-mutant non-small cell lung cancer (NSCLC) that has become resistant to previous treatment.

They may be eligible to participate in a clinical research study investigating a potential future treatment.

EMD SERONO

About the INSIGHT 2 study

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The INSIGHT 2 study is being conducted to assess an investigational drug as part of a novel treatment combination for people diagnosed with *EGFR*-mutant NSCLC that has developed resistance to a previous treatment with an EGFR inhibitor called osimertinib.

The results of a previous clinical research study suggest that the investigational drug might be effective against *EGFR*-mutant NSCLC cells that are resistant to an EGFR inhibitor (like osimertinib) because of certain alterations in a gene called *MET*.[1] However, additional research is needed to confirm these findings.

Reference

1. Wu Y, et al. *Lancet Respir Med* 2020;8:1132–1143.

What is the purpose of the study?

This study will expand on previous clinical research to evaluate the potential efficacy of the investigational drug (how well it works) in patients with *EGFR*-mutant NSCLC based on how tumors respond to the drug. It will also look at how long tumors might respond for and the safety of the investigational drug, such as any side-effects that may occur.

Before taking part in the INSIGHT 2 study, participants will need to have a small amount of tumor tissue and blood tested to check for alterations in the *MET* gene in their cancer cells. The tumor tissue test can be done using a recent sample from a previous biopsy, if available. Both tumor tissue and blood samples should be taken after the cancer has developed resistance to the previous treatment, osimertinib.

The study will include up to 120 people from countries around the world

Who can take part in the INSIGHT 2 study?

People may be able to take part in the study if they:

- are 18 years of age or older
- have been diagnosed with advanced NSCLC that has a mutation in a gene called *EGFR*
- were previously treated with a drug called osimertinib, which initially worked but the cancer returned during treatment
- are willing to have a recent tumor tissue sample tested or have a new biopsy (tumor tissue and blood sample) taken prior to study participation

Other criteria also apply.

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What will happen during the study?

The study will involve study center visits every 3–6 weeks.

Study assessments will include:

- physical examinations
- measurement of vital signs
- Eastern Cooperative Oncology Group performance status
- brain imaging
- electrocardiogram (ECG)
- blood samples
- urine samples
- pregnancy tests
- collection of a tumor tissue sample at prescreening, unless a sufficiently recent sample is available
- tumor evaluation by computed tomography (CT), magnetic resonance imaging (MRI), or another scanning technique

Study overview

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The study treatment will continue until the cancer progresses, unacceptable side-effects are experienced, or a participant chooses to withdraw from the study or stops treatment for another reason.

The investigational drug and study-related care will be provided at no cost to the participant.

Prescreening period

(before the screening period starts)

- Tumor tissue and blood will be tested to see if the participant's tumor has an alteration in the *MET* gene, called *MET* amplification

Screening period

(up to 4 weeks)

- There will be a study center visit to check if the participant can join the study

Study treatment period

If the participant can join the study and they wish to take part, they will start the study treatment period. During this period:

- Participants will take both osimertinib and the investigational drug daily by mouth, after food
- There will be study center visits once every three weeks (or once every six weeks after the first nine months)
- Participants will have various study assessments and health checks

Follow-up period

Follow-up will begin when participants stop taking the investigational drug.

- There will be two study center visits, two weeks and one month after the last dose of the investigational drug is taken
- There will also be follow-up telephone calls or study center visits every three months after the last dose of the investigational drug is taken, until the end of the study

Next steps

We would be grateful if you would consider discussing this study with your patient community. If any of the patients in your community would like to learn more about the study, please ask them to contact the study team using the details below.

Thank you for considering the INSIGHT 2 study.

Contact information

For more information visit:
www.clinicaltrials.targeting-met.com

EMD Serono is an affiliate of Merck KGaA, Darmstadt, Germany.

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