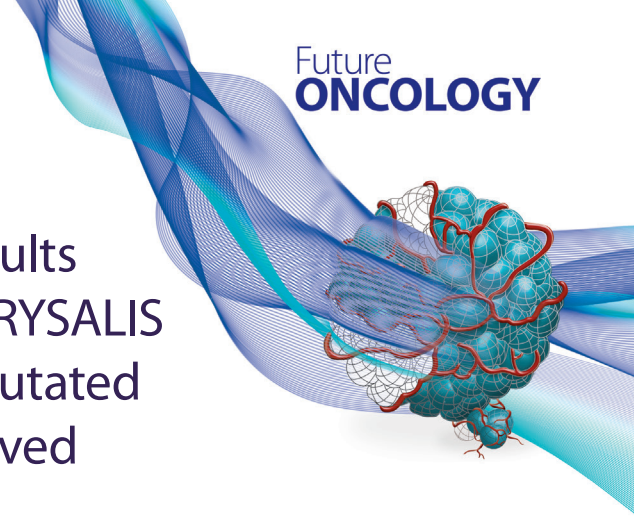
Plain Language Summary of Publication



A plain language summary of the results from the group of patients in the CHRYSALIS study with *EGFR* exon 20 insertion-mutated non-small-cell lung cancer who received amivantamab

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Summary

What is this summary about?

This is a plain language summary of an article published in the *Journal of Clinical Oncology* in 2021. It describes the first results from 1 group of patients in the **phase 1** CHRYSALIS study with **epidermal growth factor receptor** (***EGFR***) exon 20 insertion (ex20ins) **mutations**.

This part of the CHRYSALIS study (called **cohort** D) investigated the bispecific **antibody** amivantamab (brand name RYBREVANT®) in patients with non-small-cell lung cancer (NSCLC) with an *EGFR* ex20ins mutation. *EGFR* mutations are one of the most common causes of NSCLC tumors, with *EGFR* ex20ins mutations being more common among people of Asian descent. Patients who took part in this study had cancer that could not be removed by surgery, and whose cancer had worsened after receiving other forms of treatment, such as chemotherapy. Typically, patients with this type of mutation are difficult to treat or do not experience treatment response with commonly used therapies that target EGFR.

What were the results?

The CHRYSALIS study took place between May 27, 2016, and June 8, 2020, in select hospitals in the USA, Japan and South Korea. In cohort D, amivantamab showed promising results, with an **overall response rate** of 40%. This means that 4 of every 10 patients in CHRYSALIS cohort D had tumors that shrank or were no longer measurable.

How to say (double click sound icon to play sound)...

- **Amivantamab:** am-ee-VAN-tuh-mab
- **Epidermal:** ep-ee-DER-mal
- **Epithelial:** ep-ee-THEL-ee-ul
- **Mesenchymal:** meez-en-KY-mul

Phase 1: A study that looks at the effectiveness and safety of the study drug (in this case amivantamab) and identifies the amount of drug (dose) to be given in future studies.
Receptor: A protein used by cells to pass along chemical signals.
Epidermal growth factor receptor (EGFR): A protein that relays chemical signals that tell the cell to grow, divide, or survive. EGFR refers to a protein while *EGFR* refers to a gene.
Mutation: A change to the DNA sequence.
Cohort: A group of people with a shared characteristic. In the CHRYSALIS study, patients in cohort D had the same genetic mutations to their lung cancer.
Antibody: A protein produced by immune cells that identifies targets (called antigens) that can often cause infection. Antibodies identify antigens by binding them. This allows for other immune cells to remove the antigens.

Future Medicine part of fsg

Overall response rate: Percentage of patients in a study whose tumor had measurable shrinkage or was no longer detectable after receiving a medication (in this case amivantamab). This is generally defined as the sum of complete responses (tumors that are no longer detectable over a specified time period) and partial responses (measurable tumor shrinkage that is still detectable over a specified time period).

Infusion-related reaction (IRR): A side effect that may occur after receiving medicine through a vein, which commonly includes turning one's face red and/or hot, chills, difficulty breathing, nausea, chest discomfort, and vomiting.

Mesenchymal epithelial transition (MET) receptor: A protein that relays chemical signals that tell the cell to divide, spread, or survive. MET refers to a protein, while *MET* refers to a gene.

All medications carry risk of side effects, which are recorded for safety, accuracy, and transparency. Amivantamab's side effects were typically mild and included skin infections around the fingernails, rash, and **infusion-related reactions** (IRRs). IRRs most frequently occurred within the first 2 hours of the first infusion, which is when the medicine is given through a tube in the patient's vein. IRRs are common with infused antibodies, so other preventative medications were given prior to amivantamab. A slower infusion rate was also used to reduce the risk of IRRs. As a result, most reactions were mild and resolved quickly.

What do the results mean and why do they matter?

In CHRYSALIS cohort D, amivantamab demonstrated the ability to reduce the size of tumors, delay tumor growth, and delay cancer from spreading from the lung to other parts of the body, in some patients who have NSCLC with *EGFR* ex20ins mutations. The observed side effects of amivantamab were typically mild and manageable. IRRs were primarily limited to the first infusion, and certain side effects were expected due to the way that amivantamab targets cancer cells.

Based on these results, amivantamab was approved in 2021 by the US Food and Drug Administration (FDA) regulatory authority as well as in Australia (2022), Canada (2022), Switzerland (2022), and the European Union (2021) as a treatment for patients who have NSCLC with *EGFR* ex20ins mutations. Other cohorts of the CHRYSALIS clinical study are ongoing, with completion expected in early 2024. Amivantamab is also being investigated in several phase 3 studies in lung cancer studying larger groups of patients with other *EGFR* and **mesenchymal epithelial transition (*MET*)** mutations that are expected to be complete around the same time as the phase 1 CHRYSALIS study.

Who should read this article?

Patients, their families, and health care teams involved with patients who have NSCLC with *EGFR* ex20ins mutations.

Who sponsored this clinical study?

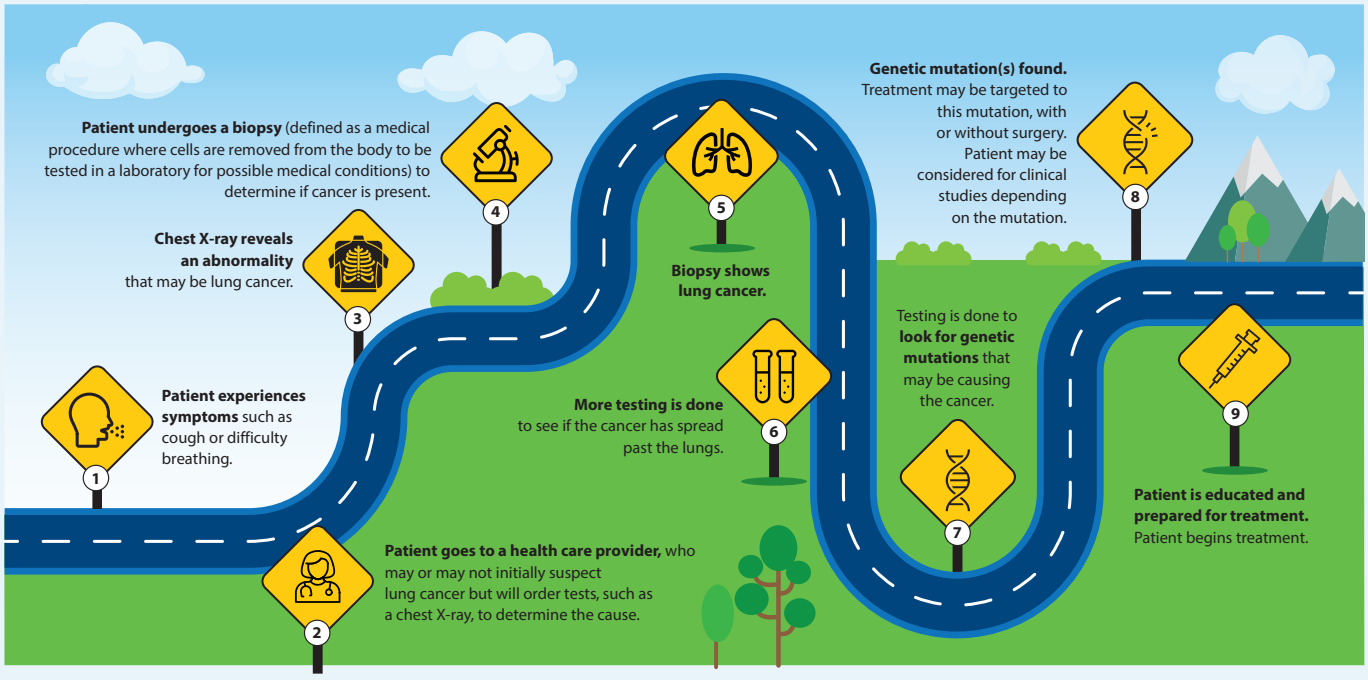
The pharmaceutical company Janssen Biotech, the manufacturer of amivantamab, funded and conducted this clinical study.

Why is it important to understand the journey of patients with lung cancer?

Every patient is different and will have a different journey towards a diagnosis of lung cancer. Understanding the patient journey for someone with lung cancer is important because it helps health care providers, researchers, and caregivers better meet the needs of patients and improve their care. For some patients, the journey may start with experiencing a cough or difficulty breathing that they report to their health care team. Doctors may not suspect lung cancer right away, especially if the patient is young and has never smoked. However, patients can undergo tests to determine if they have lung cancer.

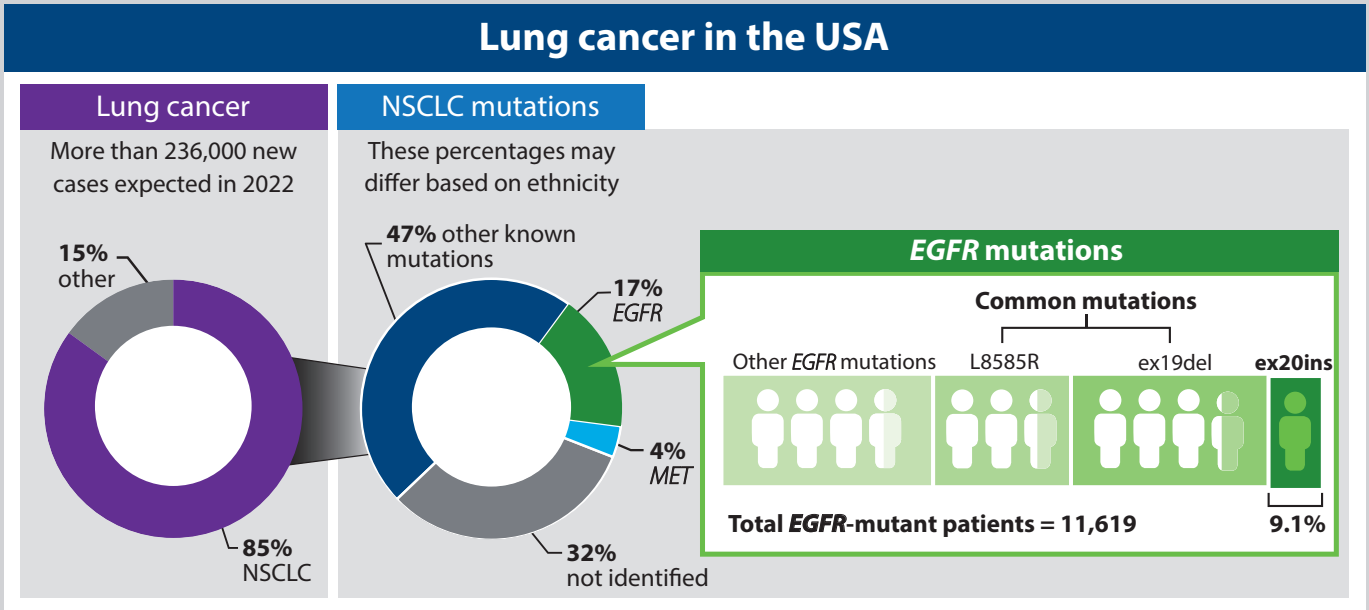
The understanding of what causes lung cancer, who is at risk, and how to treat it has greatly increased in the last 5 to 10 years due to advances in science and medical research. For example, it was previously thought that lung cancer is a disease that occurred only in older patients who smoke a lot. However, today we know that certain types of lung cancer occur more often in younger people who do not smoke, and these types of lung cancer are linked to certain mutations in DNA.

Technologies that read the DNA code (called sequencing) can uncover changes (called mutations) in DNA that can cause cancer. Researchers have used this information to create medicines that target tumors with these mutations and mark them to be killed. Amivantamab is a type of treatment called a 'targeted therapy'. Targeted therapies are made to kill cancer cells with the aim of avoiding normal healthy cells.



What is *EGFR*-mutated NSCLC?

NSCLC is the most common type of lung cancer. Mutations in a gene, called *EGFR*, have been identified as being one of the most common causes of NSCLC. EGFR is found on the surface of both normal cells and cancer cells. Mutations in the *EGFR* gene can cause uncontrolled cell growth, leading to cancer. When a patient is diagnosed with lung cancer, their doctor can use information about the mutations that are causing their cancer to select the most appropriate targeted therapy.

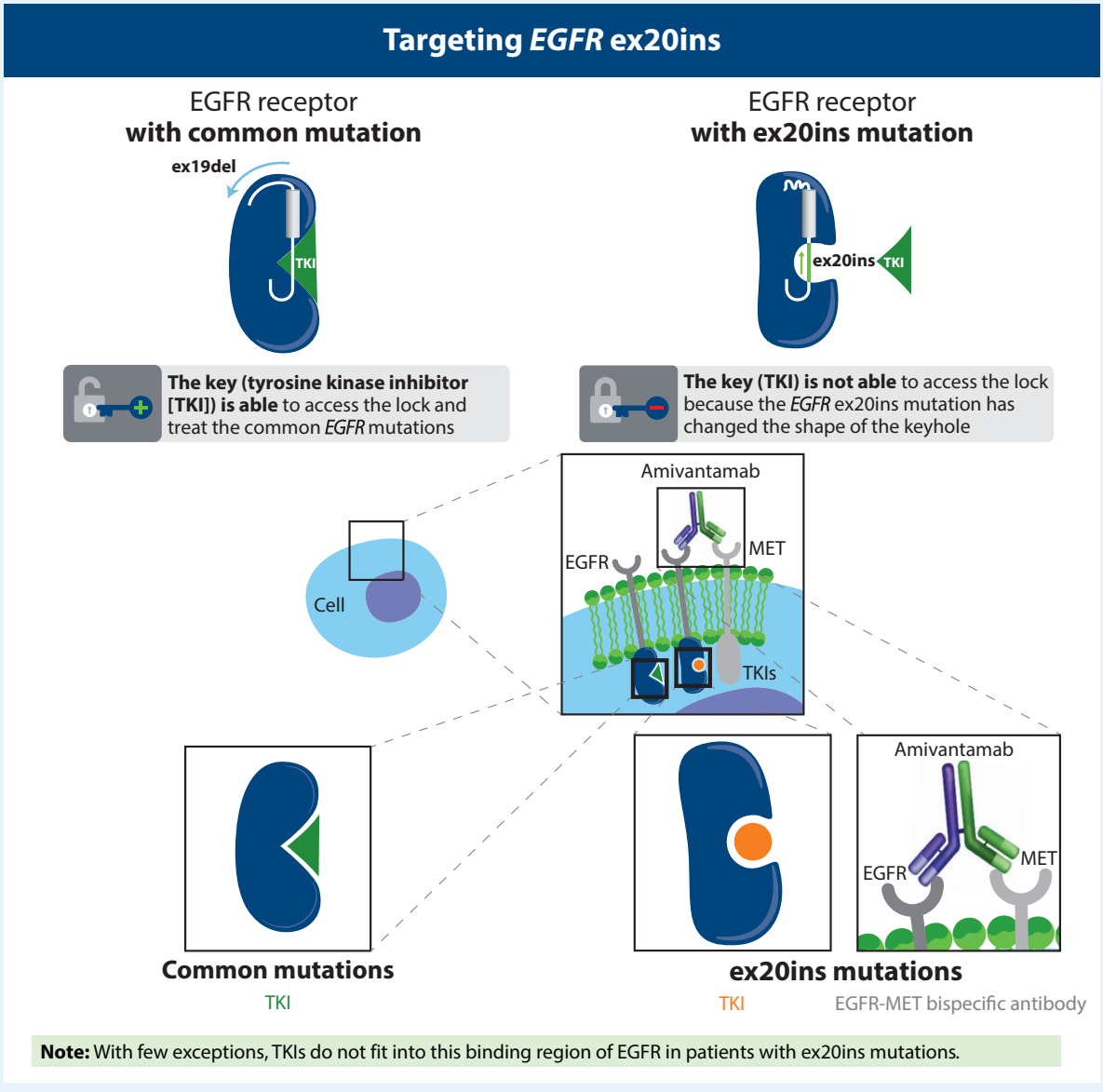


How is late-stage *EGFR*-mutated NSCLC usually treated?

At diagnosis, lung cancer may be present only in the lungs (called early-stage disease) or may have spread outside the lungs to other parts of the body (called **metastatic** or **late-stage disease**). Early-stage disease is often treated with surgery, and sometimes medicines before or after surgery. Late-stage disease may be treated with targeted therapies, therapies that modify the immune system to help fight cancer (called immunotherapy) and/or chemotherapy. The type of therapy chosen depends on what the mutations in the cancer are, where the cancer is in the body, and other health factors. Patients may be treated with targeted therapies that block the activity of the mutant EGFR receptor. The action of these targeted therapies is like inserting a key into a lock. This prevents (or 'locks') the mutated EGFR from telling the cancer cells to grow and multiply.

Metastasis: The spread of cancer from where the cancer began to grow to other parts of the body. The metastasis of cancer often indicates the cancer has become an advanced (or late-stage) disease.

Late-stage disease: Also referred to as advanced disease, where the cancer has spread from its original location in the body (for example, if lung cancer spreads beyond the lung).



Many patients with common *EGFR* mutations can be treated with EGFR tyrosine kinase **inhibitors** (TKIs). However, patients with *EGFR* ex20ins mutations tend to have less treatment response to currently available EGFR TKIs. This is because there is a difference in the shape of the EGFR receptor when *EGFR* ex20ins mutations are present. These mutations change how well TKIs work. Normally, the TKIs act as 'keys' that fit into the EGFR receptors to turn them off or 'lock' them, but for patients with *EGFR* ex20ins mutations, the shape of the keyhole is different, so EGFR TKIs (the 'key') cannot access it. As a result, patients with *EGFR* ex20ins mutations benefit less from these targeted therapies and have worse outcomes compared to patients with common *EGFR* mutations.

Inhibitor: A molecule or protein that prevents the function of its target.

Mutations in other genes including the one for the MET receptor are also found in NSCLC. In addition to *EGFR* ex20ins mutations, these can reduce the cancer's response to treatment.

What is amivantamab?

Amivantamab acts as another type of 'key' that can bypass the misshapen keyhole created by *EGFR* ex20ins, 'locking' the receptor, and reducing the signal that causes the growth of cancer cells. Amivantamab also 'locks' the MET receptor by preventing it from sending signals. This receptor is often used by cancer cells to survive the effects of EGFR TKIs.

Amivantamab is a bispecific antibody, meaning it binds to both EGFR and MET receptors.

Amivantamab boosts the body's immune response to kill cancer cells and to promote cancer cell death, which is different from chemotherapy. Therefore, there may be different side effects with amivantamab treatment.

Amivantamab is a medicine administered by a health care team in a vein (via intravenous infusion) and targets both EGFR and MET receptors. It was approved for use in 2021 in the USA and the European Union, and in 2022 in Australia, Canada, and Switzerland as a treatment for patients who have NSCLC with *EGFR* ex20ins mutations.

What was the CHRYSALIS study looking at?

CHRYSALIS was a phase 1 clinical study that evaluated amivantamab as a medicinal treatment for patients who have NSCLC. The CHRYSALIS study was designed to determine the recommended phase 2 dose of amivantamab. The recommended phase 2 dose is the amount of a medicine that doctors think is both safe and has the highest chance of helping patients in the clinical study based on what has been learned from earlier testing. The CHRYSALIS study has several cohorts, each testing the effects of amivantamab on different types of *EGFR* and *MET* mutations.

This plain language summary reports the results from the original article published in the *Journal of Clinical Oncology* in 2021 and focuses on the CHRYSALIS study cohort D that tested the effects of amivantamab in patients with NSCLC containing *EGFR* ex20ins mutations.

Who were the patients?

Researchers collected demographic information about each patient at the beginning of the study in accordance with good clinical practice guidelines.

In total, 362 patients were enrolled across all parts of the CHRYSALIS study between May 27, 2016, and June 8, 2020. In cohort D, the safety (or side effects) of amivantamab was assessed in 114 patients with *EGFR* ex20ins mutations (also called the safety group). Of these 114 patients, the response to treatment of amivantamab was examined in 81 patients (also called the efficacy group). These 81 patients were evaluated for amivantamab treatment response because they completed at least 3 **follow-up** visits with their doctor by the time of the clinical cutoff, which is the deadline to include data for analysis. Data from the remaining 33 patients was not included in the analysis of the efficacy group.

Follow-up: A follow-up visit is when a patient goes back to the doctor after receiving treatment to check on how the patient is feeling and how well the treatment is working.
Median overall survival: Amount of time from the start of treatment to where half of the patients are still alive.
Median progression-free survival: Amount of time where half of the patients' cancer did not worsen (progressive disease).
Median duration of response: Length of time from the start of treatment to where half of the patients had complete responses – defined as tumors that are no longer detectable over a specified time period – and partial responses – defined as measurable tumor shrinkage that is still detectable over a specified time period.
Progressive disease: tumor size increased and/or may have gone to other parts of the body (the cancer may have metastasized).

Patients who were eligible to participate had late-stage NSCLC, which has spread outside the lungs (metastasized) to other parts of the body, and could not be treated with surgery. Their mutations were confirmed by genetic sequencing of DNA from their tumor. Their cancer had also worsened despite previous chemotherapy and patients were unable or did not want to receive chemotherapy. Patients were healthy enough to perform light activities, such as cooking and light housework.

What was evaluated in the study?

Response to treatment (efficacy) was defined as patients whose tumors were not measurable, decreased in size, or had not increased in size, and whose cancer had not spread. Patients in the efficacy group were also evaluated for **median overall survival**, **median progression-free survival**, and **median duration of response** to treatment with amivantamab. Side effects were monitored and recorded, including those expected with infused medicines.

The results from the safety group were analyzed on June 8, 2020, while the results from the efficacy group were analyzed on October 8, 2020, after additional follow-up.

Participants in the CHRYSALIS study

Participating countries:

Characteristics of efficacy group (81 participants)

Female
59%
Over half of the participants were female

Median age, years
62
Range (42–84)
Ages of the participants ranged from 42–84 years

Smoking history
No **53%**
Yes **47%**
Over half of the participants had no history of smoking

Race
Asian 49%
White 37%
Black 2%
Chose not to disclose 11%
Almost half of the participants were Asian

Note: The median is the middle value of a set of numbers.

How much amivantamab was given to patients?

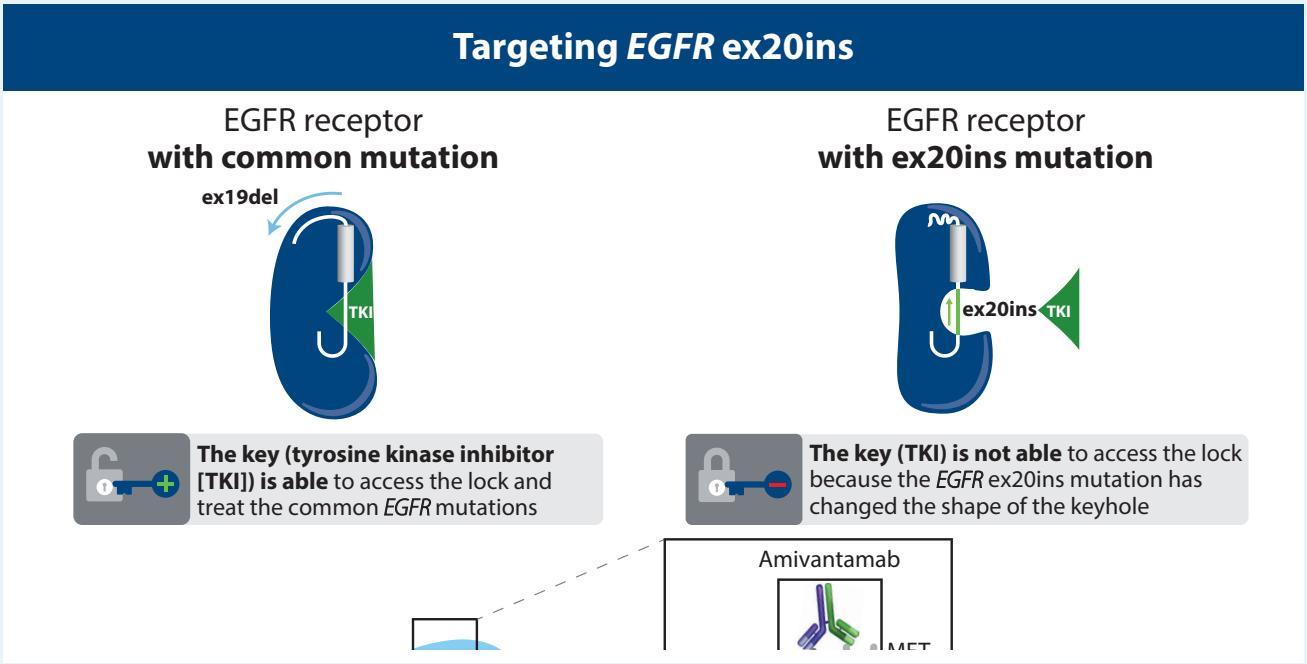
The amount of amivantamab given to patients was based on a range of different factors, such as body weight, how long amivantamab stayed in the body, and how it left the body. These factors were used to estimate the degree to which amivantamab was killing tumor cells in the patient's body along with the side effects that this individual could experience.

How was amivantamab given to patients?

Amivantamab was administered by a member of the health care team via intravenous infusion, which is a continuous flow of medicine into the vein. Treatment with amivantamab was divided into 4-week periods (cycles). For the first 4-week cycle, patients were given amivantamab once per week. The first dose was split so that part of the dose was given on the first day (350 mg) and the rest was given on the second day (700 mg for patients who weighed less than 175 pounds [less than 80 kg] or 1050 mg for patients who weighed at least 175 pounds [at least 80 kg]).

The purpose of giving amivantamab in this way was to reduce the risk of a side effect known as an IRR. Patients were informed about IRR symptoms, such as fever, chills, headache, rash, or difficulty breathing, and were advised to report them as soon as possible to their health care team. Patients were also given other medications, such as steroids, antihistamines, and antipyretics, in addition to their dosage of amivantamab during the first 2 days, in order to help reduce or prevent the likelihood of IRRs occurring.

After the first 4 weeks of the study, amivantamab was then given alone, without the other medicines, twice a week.

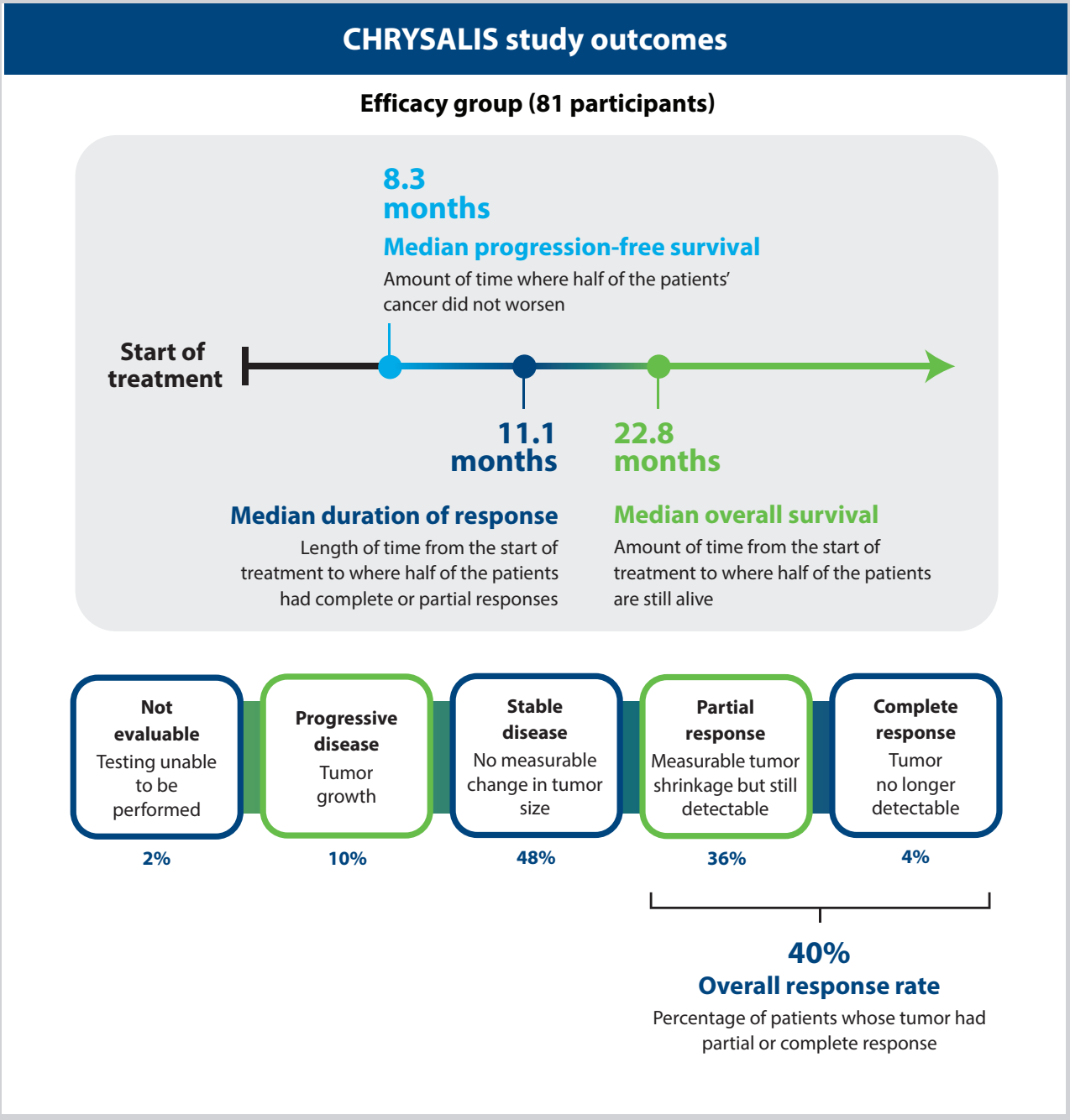


How did researchers measure the effectiveness of amivantamab?

Medical imaging was used to take pictures of the inside of the body to show tumors and their locations. Changes in the size and number of tumors in the lung and elsewhere in the body were measured before and after treatment with amivantamab.

What were the overall results of the study?

The overall response rate was 40% (32 of 81 patients). This represents the percentage of study patients whose tumor had measurable shrinkage or was no longer detectable after receiving a medication (in this case amivantamab). This is generally defined as the sum of complete responses (tumors that are no longer detectable over a specified time period) and partial responses (measurable tumor shrinkage that is still detectable over a specified time period). 39 patients (48%) had stable disease, 8 patients (approximately 10%) had **progressive disease**, and 2 patients (2%) could not be evaluated. Median duration of response was 11.1 months from the start of the treatment, median progression-free survival was 8.3 months, and median overall survival was 22.8 months. These data show amivantamab had a treatment effect on the improvement of NSCLC with *EGFR* ex20ins mutations. This study is ongoing, and the final results will be reported after the study is complete.



What were the most common side effects?

A side effect is an unwanted or unintentional reaction to a medicine or treatment. Patients and caregivers were educated on the common side effects of amivantamab treatment and were advised to work closely with their health care team to better identify and timely manage IRRs. Some of amivantamab's common side effects, including rash and skin infections around the fingernails, are known to occur when EGFR and MET receptors are blocked. These side effects happen because these receptors are also present in normal cells, such as skin cells. All side effects in the CHRYSALIS study were grouped by type and severity, and then examined to determine whether the side effects led to treatment changes or to a stoppage of treatment with amivantamab.

The most common side effect of amivantamab was an IRR. Most IRRs were considered mild. The side effects were better managed by giving medications prior to amivantamab treatment, lowering the dose of amivantamab, or temporarily stopping amivantamab treatment. Other common side effects included rash, skin infections around the fingernails, muscle and joint pain, shortness of breath, nausea, fatigue, swelling, redness and swelling in the mouth, cough, constipation, and vomiting. Severe side effects, which are those that require significant medical care or hospitalization, were experienced by 40 patients in the safety group. The severe side effects experienced included low blood potassium levels, rash, blood clots in the lung, diarrhea, and low numbers of white blood cells. For 15 patients (13%), the dose of amivantamab was lowered, and for 5 patients (4%) treatment was temporarily or permanently stopped to manage these side effects. Overall, amivantamab's side effects were manageable and predictable.

CHRYSALIS study side effects

Most common side effects included:

Rash

86%
of patients

Severe reactions (4%)

Infusion-related reactions (IRRs)

66%
of patients

Severe reactions (3%)

Nail infections

45%
of patients

Severe reactions (1%)

Dose management

Dose reduced

13%

Patients who had their dose reduced due to a treatment-related side effect

Stopped amivantamab

4%

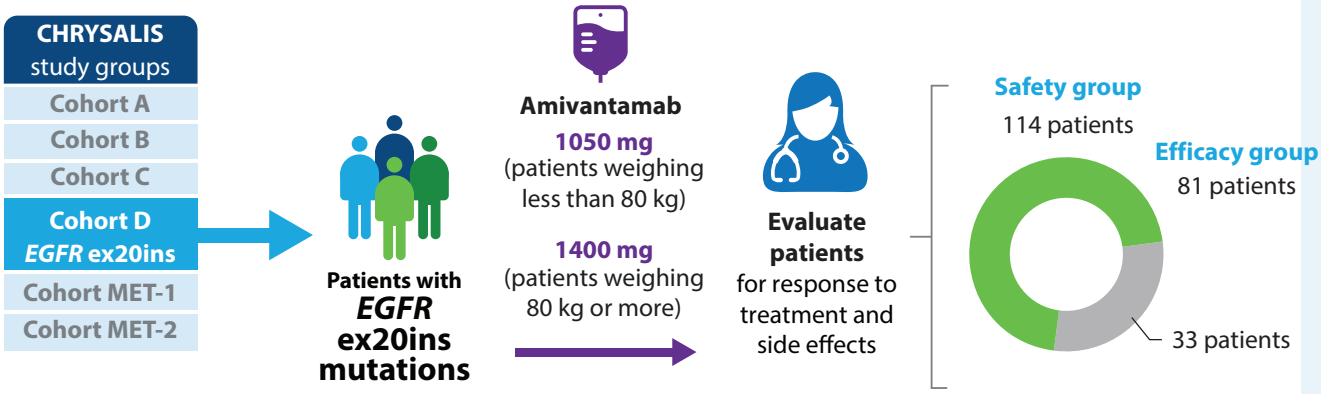
Patients who permanently discontinued amivantamab due to a treatment-related side effect

What is an IRR?

IRRs are common side effects caused by infused medicines that are similar to an immune response (antibodies). Amivantamab is an antibody given by intravenous infusion, so it was expected that IRRs might occur. IRRs in the CHRYSALIS study commonly occurred on the first day of treatment, usually within the first 2 hours of amivantamab treatment. IRRs were uncommon on the second day and rarely occurred after that. The main IRRs observed were fever, rash, and nausea.

What was done to reduce or prevent side effects?

CHRYSALIS study design: patients with ex20ins mutations



Note: Patients with other NSCLC mutations were evaluated in different groups within the CHRYSALIS study.

Note: 33 patients were excluded from the efficacy group because they did not have 3 follow-up visits with their doctor.

Rash is a common side effect of EGFR inhibitors, including amivantamab

Rash can impact patients' quality of life in different ways

Preventive measures can be used to reduce rash symptoms

Education

- Rash is expected and frequently happens with treatments that block EGFR, including amivantamab
- Rash may start at any time and might remain for the duration of treatment and can range from mild to severe
- There are various ways to reduce rash symptoms before and during treatment

Dermatology

- Notify your dermatologist when you begin treatment with an EGFR inhibitor
- If you do not have a dermatologist, consider adding one to your health care team
- Inform your doctor or dermatologist of any rash, unusual appearance of the skin, or lack of improvement within 2 weeks so they can determine its severity

Preventive measures and management

- Since rash can appear soon after treatment, consider ways to prevent and manage rash before the first dose and during treatment
  - **Before:** Limit sun exposure by using broad UVA/UVB sunscreen and wearing sun-protective clothing, and take oral antibiotics
  - **During:** Limit shower time and use gentle cleansers, use alcohol-free calming cream for dry skin, use topical low-dose corticosteroids or topical antibiotics, and take oral antibiotics

Note: These materials are for educational purposes only. Please seek your physician's advice for treatment recommendations.

What do the results of this study mean?

Amivantamab is the first bispecific antibody that has been able to reduce the size of tumors, delay tumor growth, and delay cancer from spreading from the lung to other parts of the body, in some patients who have NSCLC with *EGFR* ex20ins genetic mutations.

The side effects of amivantamab were typically mild, manageable, primarily limited to the first infusion, and consistent with the expectations of blocking EGFR and MET receptors. Most patients (96%) did not stop amivantamab due to side effects. Education on side effects, with guidance to report them to their health care team, may help patients and caregivers prepare for and minimize these side effects.

Amivantamab is a treatment option for patients who have NSCLC with *EGFR* ex20ins mutations whose disease has worsened despite previous treatment with chemotherapy.

Studies are ongoing to see if amivantamab can be used to treat patients who have NSCLC with other types of *EGFR* or *MET* mutations other than ex20ins mutations in the other cohorts of the CHRYSALIS study.

DNA sequencing is a necessary first step to identify *EGFR* ex20ins genetic mutations so that patients receive targeted and appropriate treatment options tailored to their individual needs. Medications such as amivantamab can be considered as an option.

What are the limitations of this study?

Like most studies, there are limitations that may impact the interpretation of findings presented here. Potential limitations are listed below.

- Only patients who had *EGFR* exon20ins mutations previously treated with platinum-based chemotherapy and who were followed long enough were included in cohort D, meaning that there were additional patients with *EGFR* ex20ins mutations enrolled in the CHRYSALIS study who were not included in this analysis
- This study did not include a group that was not treated with amivantamab as a comparison (control arm), so all patients were selected for the study (not randomly assigned). The study called PAPILLON (in which patients were randomly assigned treatment) will address how much antitumor activity is due to amivantamab versus platinum-based chemotherapy
- Not all *EGFR* exon20ins mutations were detectable due to the limitations of the methods of detection and availability of adequate DNA
- Patients with cancer that has spread to the brain were not included in cohort D. The activity of amivantamab in patients with cancer that has spread to the brain is being explored in other studies

As with any medicine, patients should discuss the treatment options as well as the benefits, risks, and limitations with their health care provider to make an informed decision.

Educational resources

Learn about the National Comprehensive Cancer Network (NCCN), as well as the European Society for Medical Oncology (ESMO) guidelines for treating NSCLC. These guidelines help doctors best care for their patients and help patients make informed decisions regarding their care. NCCN and ESMO guidelines for patients can be found at:

- https://www.esmo.org/for-patients/patient-guides/non-small-cell-lung-cancer (ESMO)
- https://www.nccn.org/patients/guidelines/content/PDF/lung-metastatic-patient.pdf (NCCN – late-stage NSCLC)

Where can I find more information?

The full title of the publication in the *Journal of Clinical Oncology* is "Amivantamab in EGFR Exon 20 Insertion-Mutated Non-Small-Cell Lung Cancer Progressing on Platinum Chemotherapy: Initial Results From the CHRYSALIS Phase I Study".

You can read the original article at: https://ascopubs.org/doi/full/10.1200/JCO.21.00662

Park K, Haura EB, Leighl NB *et al.* Amivantamab in EGFR Exon 20 Insertion-Mutated Non-Small-Cell Lung Cancer Progressing on Platinum Chemotherapy: Initial Results From the CHRYSALIS Phase I Study. *J. Clin. Oncol.* 39(30), 3391–3402 (2021).

You can read more about the CHRYSALIS study at the following websites:

- https://www.clinicaltrials.gov/ct2/show/NCT02609776
- Type the EudraCT Identifier '2018-003908-38' into the search bar at: https://www.clinicaltrialsregister.eu/ctr-search/search
- US Food & Drug Administration: https://www.fda.gov/
- European Cancer Patient Coalition: https://ecpc.org/

More information about clinical studies in general can be found at: https://www.clinicaltrials.gov/ct2/about-studies/learn

More information on NSCLC can be found at the following sources used to develop this plain language summary:

- Non-Small Cell Lung Cancer: Epidemiology, Screening, Diagnosis, and Treatment: https://pubmed.ncbi.nlm.nih.gov/31378236/
- Lung Cancer Diagnosed in the Young Is Associated With Enrichment for Targetable Genomic Alterations and Poor Prognosis: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4819418/
- Lung Cancer: https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00312-3/fulltext
- Targeted Therapies for Lung Cancer: https://www.lung.org/lung-health-diseases/lung-disease-lookup/lung-cancer/treatment/types-of-treatment/targeted-therapies

More information on amivantamab can be found at the following sources:

- Amivantamab Prescribing Information: https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/RYBREVANT-pi.pdf
- A Novel Bispecific Antibody Targeting EGFR and cMet Is Effective Against EGFR Inhibitor-Resistant Lung Tumors: https://pubmed.ncbi.nlm.nih.gov/27216193/

More information on adverse events related to EGFR inhibitors can be found at the following sources used to develop this plain language summary:

- Prevention and Management of Acneiform Rash Associated With EGFR Inhibitor Therapy: A Systematic Review and Meta-Analysis: https://onlinelibrary.wiley.com/doi/10.1111/ajco.13740
- Current Recommendations and Novel Strategies for the Management of Skin Toxicities Related to Anti-EGFR Therapies in Patients with Metastatic Colorectal Cancer: https://pubmed.ncbi.nlm.nih.gov/31264159/
- A National Survey of Medical Oncologist's Opinions and Perceptions for Managing Rash Among mCRC Patients Treated With Panitumumab: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6522609/
- Dougherty L, et al. Practical Guide for Infusion-related Reaction (IRR) Management With Amivantamab for EGFR Exon 20 Insertion Mutation Non-Small Cell Lung Cancer (NSCLC): A Nurse's View. Poster presented at: *Oncology Nursing Society,* May 27–April 1, 2022; Anaheim, CA, USA.

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