Future Science OA

ISSN: 2056-5623 (Online) Journal homepage: www.tandfonline.com/journals/ifso20

Plain language summary of the ALINA study results: alectinib compared with chemotherapy after surgery in people with *ALK*-positive non-small cell lung cancer

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To cite this article: Yi-Long Wu (Prof), Rafal Dziadziuszko (Prof), Jin Seok Ahn (Prof), Fabrice Barlesi (Prof), Makoto Nishio (Prof), Dae Ho Lee (Prof), Jong-Seok Lee (Prof), Wenzhao Zhong (Prof), Hidehito Horinouchi (Dr), Weimin Mao (Prof), Maximilian Hochmair (Dr), Filippo de Marinis (Prof), Maria Rita Migliorino (Dr), Igor Bondarenko (Prof), Shun Lu (Prof), Qun Wang (Fr), Tania Ochi Lohmann (Dr), Ms Tingting Xu, Mr Andres Cardona, Ms Laura Hiles, Johannes Noe (Dr) & Benjamin J. Solomon (Prof) (2025) Plain language summary of the ALINA study results: alectinib compared with chemotherapy after surgery in people with *ALK*-positive non-small cell lung cancer, Future Science OA, 11:1, 2578145, DOI: 10.1080/20565623.2025.2578145

To link to this article: https://doi.org/10.1080/20565623.2025.2578145

Published online: 11 Nov 2025.

Plain Language Summary of Publication

Future Science OA

Plain language summary of the ALINA study results: alectinib compared with chemotherapy after surgery in people with *ALK*-positive non-small cell lung cancer

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First draft submitted: 30 July 2025; Accepted for publication: 17 October 2025

Where can I find the original article on which this summary is based?

The original article titled: 'Alectinib in Resected *ALK*-positive Non-Small Cell Lung Cancer' was published in the *New England Journal of Medicine* in April 2024. You can read the full article for free at: https://www.nejm.org/doi/abs/10.1056/NEJMoa2310532

Summary

What is this summary about?

In this article, we report the results of the ALINA study. This study looked at how well alectinib treatment worked in participants with *ALK*-positive non-small cell lung cancer (NSCLC) compared with chemotherapy after surgery.

Alectinib was given to participants who had NSCLC with a specific physical change (alteration) in the Anaplastic Lymphoma Kinase (*ALK*) gene, or *ALK*-positive NSCLC, after their cancer was completely removed by surgery.

Tyrosine kinases are proteins that are involved in a number of important processes in the body including cell growth, division and survival. An alteration in the *ALK* gene can form an ALK tyrosine kinase with uncontrolled activity, leading to cancer development.

Alectinib (ALECENSA®) is a type of drug called a 'tyrosine kinase inhibitor' that helps to control the growth and spread of *ALK*-positive NSCLC in the body. Alectinib works by blocking ALK tyrosine kinase from switching on cell growth and survival, helping to slow down cancer growth. Alectinib is already globally approved to treat people with *ALK*-positive NSCLC that has spread beyond their lungs (metastatic disease).

How was the study designed?

The ALINA study included participants aged 18 years or older who had received surgery to completely remove their *ALK*-positive NSCLC. Participants could take part if they could be given platinum-based

How to say (download PDF and double click sound icon to play sound)...

- **Alectinib:** al-EK-tin-ib
- **ALECENSA:** al-eh-SEN-sa
- **Tyrosine kinase:** TIE-ro-seen KY-nase
- **Cisplatin:** SIS-plat-in
- **Vinorelbine:** vin-oh-REL-been
- **Gemcitabine:** JEM-site-uh-been
- **Pemetrexed:** pem-eh-TREK-sed
- **Carboplatin:** CAR-bo-plat-in

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chemotherapy per local treatment guidelines. Participants who had received **systemic** anti-cancer **treatment** before could not take part.

Systemic treatment: These treatments are designed to travel throughout the body in the bloodstream.

Participants were randomly allocated to get treatment with either alectinib, twice a day for two years, or with chemotherapy, for four cycles, with each cycle lasting three weeks. Both the participant and their doctor knew which treatment they received (this is known as an open-label or unblinded study).

The researchers assessed if participants who were given alectinib had a longer period without their cancer returning (also known as remission) compared with participants who were given chemotherapy.

As people with NSCLC often have their cancer spread from the lungs to the brain and spinal cord (known as the central nervous system, or CNS), the researchers assessed if participants who were given alectinib had a longer period without their cancer returning in their CNS compared with participants who were given chemotherapy. The researchers also assessed how long participants lived for after starting the study.

To investigate the safety of both treatments, the percentage, type and seriousness of side effects that participants had whilst on treatment were noted. The percentage of participants who had side effects which led to the treatment dose being reduced, interrupted or stopped was also recorded.

What were the results?

In total, 257 participants took part in the study: 130 were given alectinib and 127 were given chemotherapy. Researchers found that participants who were given alectinib stayed alive and cancer-free for longer than those who were given chemotherapy. At 2 years, 94% of participants on alectinib were alive and cancer-free, compared with 64% of participants on chemotherapy. At 3 years, 89% of participants on alectinib were alive and cancer-free, compared with 54% of participants on chemotherapy.

The average amount of time that participants lived for overall could not be calculated because most of them were still alive when the results were analyzed. Participants who were given alectinib were alive and cancer-free in their CNS for longer than those who were given chemotherapy. The side effects experienced by the participants who were treated with alectinib were consistent with what we already know from previous experience with alectinib.

These results from the ALINA study support the use of alectinib after surgery in people with *ALK*-positive NSCLC and led to the approval of alectinib for use in these patients.

The ALINA study is ongoing and more results will be published in the future.

What is the purpose of this plain language summary?

The purpose of this plain language summary is to help you to understand the findings from recent research.

Alectinib is used to treat the condition under study that is discussed in this summary. Approval varies by country; please check with your local provider for more details.

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Who is this article for?

This summary was written for those who want to learn more about treatments for people with *ALK*-positive NSCLC and the results of the ALINA study.

Who sponsored this study?

F. Hoffmann-La Roche Ltd/Genentech, Inc. **sponsored** the ALINA study, provided the study drugs and collaborated with the academic authors on the collection, analysis and interpretation of the data.

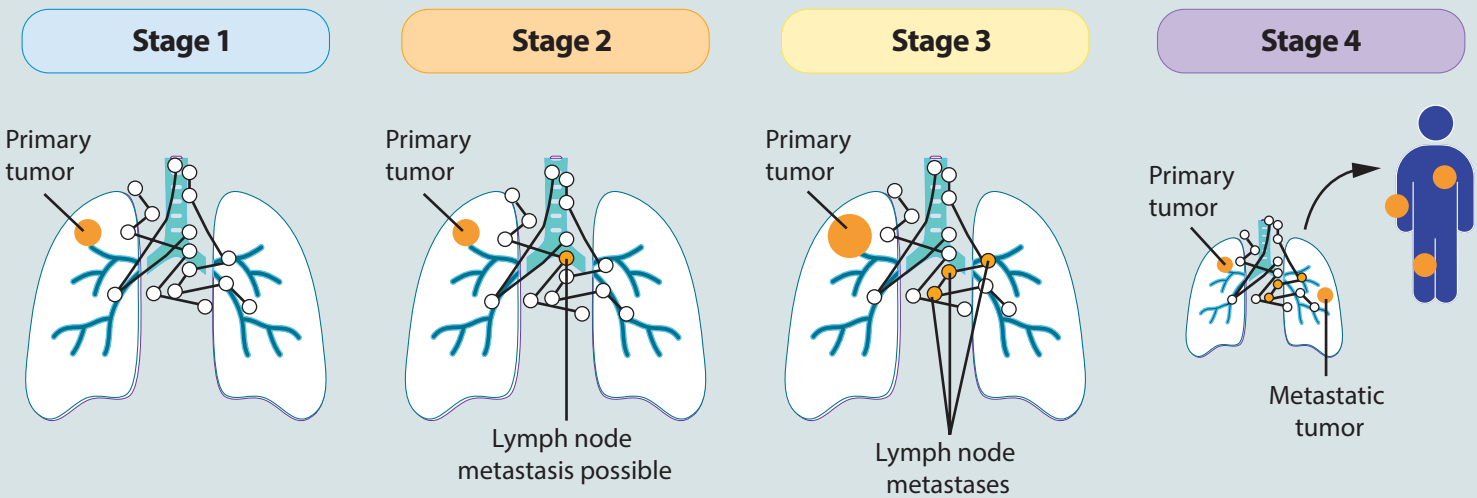
Sponsor: A company or organization that oversees and pays for a clinical research study. The sponsor also collects and analyzes the information from the study.

What are the different stages of lung cancer?

- Non-small cell lung cancer (NSCLC) is the most common type of lung cancer. NSCLC usually grows in the tissues lining the lungs but can also spread to **lymph nodes** near the lungs and other organs in the body.
- The stage of people's cancer gives information on the size of their cancer and how much their cancer has spread in the body.
- Around 50% of people with NSCLC are diagnosed with early-stage disease, when tumors are small and have not spread or have only spread to areas near the lungs (stage 1–2 disease), or when tumors are larger, have increased in number or have spread further to parts of the body surrounding the lungs (stage 3 disease).

Lymph nodes: Small bean-shaped areas of tissue that are part of the immune system and filter fluid to help protect the body from infections.

- This study included participants with stage 1–3 *ALK*-positive NSCLC who had their cancer completely removed by surgery. The American Joint Committee on Cancer and Union for International Cancer Control (AJCC 7th edition) staging categories were used to categorize the stage of cancer that participants had, as they were the most appropriate staging categories available at the time of the study.



What is *ALK*-positive NSCLC?

Gene: A section of DNA that has instructions for making the body.
Gene alteration: A specific physical change in the gene making it different from what is found in healthy cells.

- NSCLC is the most common type of lung cancer.
- *ALK*-positive NSCLC is a specific type of NSCLC caused by an **alteration** in the *ALK* **gene**.
- Approximately 4–5% of people with NSCLC have an alteration in the *ALK* gene.
- The *ALK* gene codes for a protein called ALK tyrosine kinase. Alterations in the *ALK* gene can form an ALK tyrosine kinase with uncontrolled cell division and growth. This means that instead of following the usual cell division and growth pattern, cells with *ALK* alterations form a tumor.
- Compared with people who have NSCLC without *ALK* alterations, people with *ALK*-positive NSCLC tend to:

» be younger.

» have no smoking history.

» have more advanced disease (cancer that has spread to distant parts of the body).

» be at higher risk of getting cancer in the brain (this happens in up to half of people with *ALK*-positive NSCLC).

How is *ALK*-positive NSCLC diagnosed?

Biopsy: A medical procedure in which a small piece of tissue, skin, liver or tumour is removed from the body by a doctor for further tests.

To diagnose *ALK*-positive NSCLC, doctors collect a sample of cancer from people with NSCLC (known as taking a **biopsy**) to test if their cancer has alterations in the *ALK* gene or to test for presence of ALK tyrosine kinase.

Some investigations include brain scans to check if the *ALK*-positive NSCLC has spread to the brain.

What is alectinib?

- Alectinib is taken by mouth, as a pill, twice a day by people with *ALK*-positive NSCLC.
- Alectinib is a type of drug called a tyrosine kinase inhibitor (TKI).
- Alectinib directly targets the altered ALK protein and blocks the uncontrolled tyrosine kinase activity. This slows down the speed in which cancer cells multiply and can help to stop tumours from growing in some people with lung cancer, including in people with lung cancer that has spread to other parts of the body, such as the brain and spinal cord (also known as the central nervous system or CNS).
- Based on the results from the ALINA study, alectinib was approved for treating people with *ALK*-positive NSCLC after they had received surgery.
  - » Alectinib is the first (and currently the only) ALK inhibitor that is approved after surgery for people with *ALK*-positive NSCLC.
- Alectinib is also already approved as a first step in treatment in people with *ALK*-positive NSCLC who are unable to receive surgery due to the wide spread of their cancer.

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How are people treated for *ALK*-positive resectable NSCLC?

- First, surgery is carried out to completely remove their **resectable cancer**. Types of surgery include a lobectomy, sleeve lobectomy, bilobectomy or pneumonectomy.
- After the cancer is removed by surgery, people are given further treatment, such as **platinum-based chemotherapy**, to remove any cancer cells that may still be left and to help lower the risk of the cancer coming back.
- **Five years after receiving chemotherapy**:

About **71%** of people with stage 1 NSCLC are alive

About **36%** of people with stage 3 NSCLC are alive

- However, **cancer can return** for many, even after chemotherapy:

About **45%** of people with stage 1 NSCLC have their cancer return within 5 years or do not survive because of it

About **76%** of people with stage 3 NSCLC have their cancer return within 5 years or do not survive because of it

- When NSCLC returns, it often spreads (also known as metastasis) to other parts of the body, including the CNS. Results from previous studies show that people with *ALK*-positive NSCLC are at high risk of their cancer spreading to the CNS.
- Chemotherapy removes both cancer cells and normal cells, so it can cause side effects that are hard to manage and can lower people's quality of life. These include hair loss, nausea and damage to nerves or kidneys.
- Therefore, medicines which specifically target ALK, such as alectinib, may be a better treatment option after surgery than chemotherapy for people with *ALK*-positive NSCLC.

Resectable cancer: Cancer that can be completely removed with surgery.
Platinum-based chemotherapy: A type of cancer treatment that uses drugs that have the chemical element platinum.

Why was the ALINA study carried out?

Alectinib has shown benefit in people with advanced *ALK*-positive NSCLC, including in those who have *ALK*-positive NSCLC that has spread beyond the lungs, in three phase 3 studies.

Based on these results, alectinib is a preferred first treatment for people with advanced *ALK*-positive NSCLC in international guidelines.

Study phases

Phase 1	Phase 2	Phase 3
Test how safe a new treatment is in a small number of people who do not have the disease	Test how well a new treatment works and how safe it is in people who have a certain disease	Test how well a new treatment works and how safe it is in a lot of people who have a certain disease

The ALINA study was carried out to compare the effects of alectinib with chemotherapy after surgery in people with *ALK*-positive resectable NSCLC. The study also aimed to find out if the benefits of alectinib seen in people with advanced *ALK*-positive NSCLC also apply in people with early-stage *ALK*-positive NSCLC whose cancer had been completely removed by surgery.

What kind of study is ALINA?

The ALINA study is:

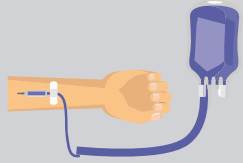
- A phase 3 study (alectinib had been tested in several hundreds of people with *ALK*-positive NSCLC before this study. Alectinib had shown beneficial results in these people).
- A randomized study (the medicines that participants took were chosen by chance. This helped to make it more likely that the two treatment groups were comparable and included similar participants in terms of their stage of cancer, and race.
- An open-label study (everyone involved, including the participant and their study doctor, knew which medicine the participant received).

How was the ALINA study carried out?

- Participants were randomly assigned to 1 of 2 treatment groups:

Alectinib group
Pills, twice a day
for up to 2 years

Chemotherapy group
Infusion into the vein, for 4 cycles
with every cycle lasting 3 weeks



Treatment with alectinib was planned to continue for 2 years unless the participant's cancer came back or they decided to stop treatment for other reasons, such as due to side effects that could not be managed

For participants who were given platinum-based chemotherapy, the available options were cisplatin plus either vinorelbine, gemcitabine or pemetrexed.
For participants who did not tolerate cisplatin, carboplatin was used

- Participants received alectinib or platinum-based chemotherapy treatment 4 to 12 weeks after they had surgery to remove any remaining cancer that could not be seen.
- If a participant's cancer returned, their treatment options, including if they would need to be taken off the study, were decided with their study doctor separately from this study.
- The ALINA study is ongoing. Here, we present the results from the study's first analysis.

Who took part in the ALINA study?

Participants could take part in the ALINA study if they:

- Were aged 18 years or older.
- Had *ALK*-positive NSCLC.
- Had stage 1 (tumors of size 4 cm or larger) to stage 3 NSCLC (AJCC 7th edition) that had been completely removed by surgery.
- Could be given platinum-based chemotherapy, per local guidelines.
- Had a good level of functioning (level 0–1) in a **5-level measurement scale**

A **5-level measurement scale** is used by doctors to describe people's level of functioning in terms of how well they can care for themselves and carry out daily activities e.g., walking and working. Higher numbers in this scale are for people who have greater disability.

Participants could not take part in the ALINA study if they:

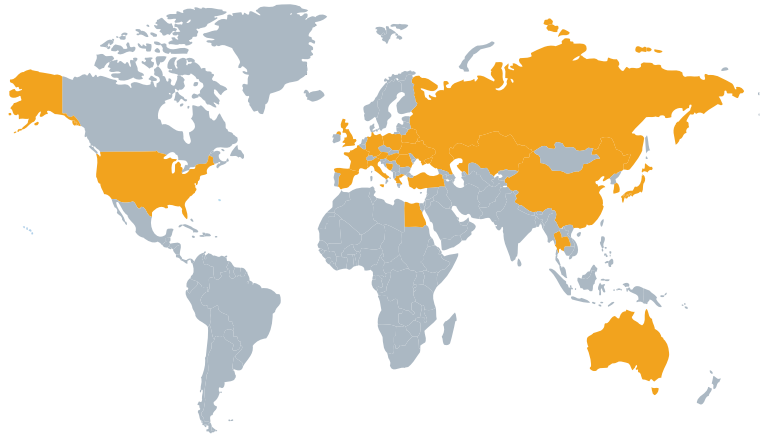
- Had received systemic anti-cancer treatment, including ALK-targeting treatment, before the study.
- Were given or required **radiotherapy** treatment after their lung cancer surgery.
- Had liver disease.
- Were pregnant or breastfeeding.

Radiotherapy: A cancer treatment that uses high energy rays to remove cancer cells.

Full criteria are available online at: https://www.nejm.org/doi/full/10.1056/NEJMoa2310532

The characteristics of participants included in each treatment group were similar:

Participants were enrolled from 113 sites across 26 different countries:



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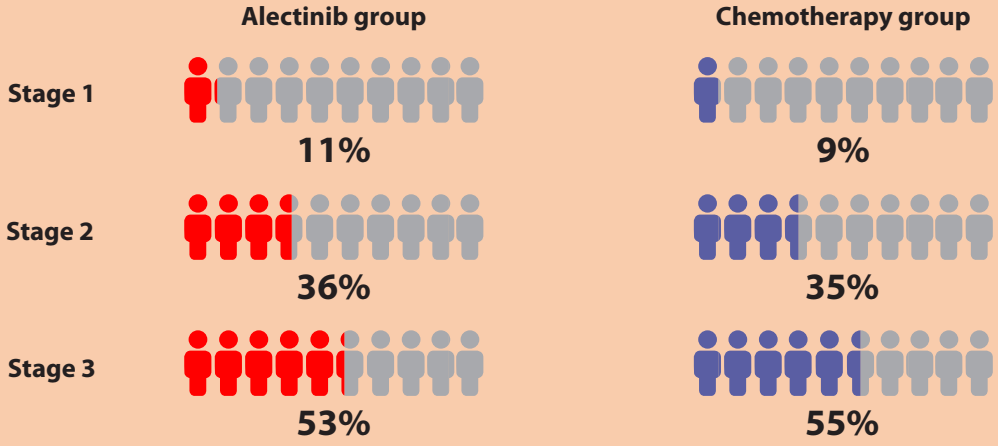
Taiwan
Thailand
Turkey
Ukraine
United Kingdom
United States of America

- 65% of participants in the alectinib group and 55% in the chemotherapy group had never smoked.
- There was a balance of participants with different disease stages of *ALK*-positive NSCLC in the alectinib and chemotherapy groups:



- There was a similar percentage of Asian and non-Asian participants in the two treatment groups:

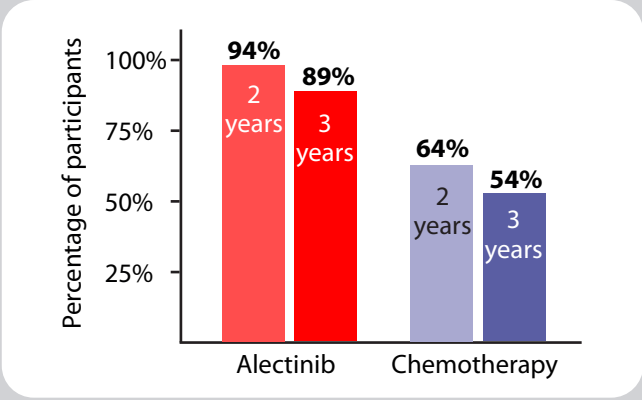
What were the overall results of the study?

The researchers compared the following results between the two treatment groups:

- How long participants stayed alive and cancer-free for.
- How long participants stayed alive for.
- How long participants stayed alive and free from CNS-related cancer for.
- The side effects that participants experienced.

Alectinib worked better at stopping cancer from coming back than chemotherapy. Age, disease stage and smoking did not affect this result.

Percentage of alive and cancer-free participants in each group after starting the study medicine



76%

- Overall, there was a 76% reduction in the risk of the **cancer coming back or of death** in participants who received alectinib compared with those who received chemotherapy.

- There was not enough information to answer how long participants lived for on average after starting the ALINA study. This was because most participants in the study were still alive when the results were analyzed.

78%

- There was a 78% reduction in the risk of **cancer coming back in the CNS or of death** in participants who took alectinib compared with chemotherapy.

What were the most common side effects?

- Information on the safety of the study medicines was available from 128 of the 130 participants who received alectinib and from 120 of the 127 participants who received chemotherapy.
- Even though participants took alectinib for much longer (about 2 years) than chemotherapy (about 2 months), the percentage of side effects was similar between the two. Most side effects were mild to moderate.
- In the **alectinib group:**

At least one side effect was reported by **98%** of participants

The two most common side effects occurring in 10% of participants or more were:

» **43%** increase in creatine kinase levels, which can happen due to stress or injury to muscles

» **42%** constipation

Side effects considered to be related to alectinib treatment by the participant's physician were reported in **94%** of participants.

- In the **chemotherapy group:**

At least one side effect was reported by **93%** of participants

The two most common side effects were:

» **73%** nausea

» **29%** decreased appetite

Side effects considered to be related to chemotherapy treatment by the participant's physician were reported in **89%** of participants.

- Most side effects were not serious (i.e., they were not life-threatening, did not need hospital care via hospitalization or did not cause lasting issues).

Alectinib group

Serious side effects were reported in **13%** of participants

Chemotherapy group

Serious side effects were reported in **8%** of participants

» All serious side effects related to alectinib went away (participants recovered from these serious side effects).

» There were no deaths due to side effects in participants in either treatment group.

Alectinib group

Side effects led to the treatment dose being reduced in **26%** of participants

Side effects led to the treatment dose being interrupted in **27%** of participants

Side effects led to the treatment being stopped in **6%** of participants

Chemotherapy group

Side effects led to the treatment dose being reduced in **10%** of participants

Side effects led to the treatment dose being interrupted in **18%** of participants

Side effects led to the treatment being stopped in **13%** of participants

The side effects observed with alectinib were similar to the ones seen in other studies of alectinib.

What do the results of the study mean?

- The results of the ALINA study show that participants with *ALK*-positive NSCLC who received alectinib after surgery are living cancer-free for longer than those who received chemotherapy.
- These results led to approval of alectinib in people with *ALK*-positive NSCLC after surgery.
- The results from ALINA support the need for testing for *ALK* alterations across all disease stages of NSCLC, to allow the early identification of people who can receive alectinib.
- Although alectinib was given for two years in ALINA, more results from this study and other studies in people with *ALK*-positive NSCLC are needed to find out how long alectinib should be given for ideally.
- Also, participants in ALINA will need to be observed for longer to see if alectinib helps them to live longer than with chemotherapy and if there are any long-term side effects with both treatments.
- An important point about the open-label design of the ALINA study is that both doctors and participants knew if alectinib or chemotherapy was being given, which may have affected the results. However, this design was needed to compare results and understand how two very different types of treatment (alectinib as a pill and chemotherapy as an infusion through the vein) affected participants without making it too difficult for them.
- Further study to see if alectinib and chemotherapy together works better than alectinib alone in people with *ALK*-positive NSCLC will be useful.

Where can readers find more information on this study?

The original article titled: 'Alectinib in Resected *ALK*-positive Non-Small Cell Lung Cancer' was published in the *New England Journal of Medicine*. You can read the full article for free at: https://www.nejm.org/doi/full/10.1056/NEJMoa2310532

Original citation:
Wu, Y.L., *et al.* 2024. Alectinib in resected *ALK*-positive non–small-cell lung cancer. *New England Journal of Medicine* 390(14), 1265–1276.

You can read more about the ALINA study (NCT03456076) on the following website: https://clinicaltrials.gov/study/NCT03456076

For more patient-driven and patient-oriented resources and more information on *ALK*-positive lung cancer, you can access the following websites:

- www.alkpositive.org
- https://www.alkpositive.org.uk/
- https://www.facebook.com/ALKpositiveEurope/

If you are a current or former participant of the ALINA study and have any questions about the results, please contact your doctor or study centre.

Acknowledgments

The authors would like to thank all the participants, their families, study investigators, clinical site staff and the ALINA study team past and present.

Disclosure statement

Prof Yi-Long Wu: research funding with Boehringer Ingelheim, Roche, Pfizer and Bristol-Myers Squibb; consultancy with AstraZeneca, Roche, Boehringer Ingelheim and Takeda; advisory board for AstraZeneca, Roche, Boehringer Ingelheim and Takeda; honoraria from AstraZeneca, Roche, Pfizer, Boehringer Ingelheim, MSD Oncology, Bristol-Myers Squibb, Hengrui Pharmaceutical and BeiGene Beijing. Prof Rafal Dziadziuszko: advisory/consultancy fees with Roche, Pfizer, AstraZeneca, Novartis, Merck Sharp & Dohme, Takeda and GlaxoSmithKline; honoraria from Roche, AstraZeneca and Amgen; participation in Data Safety Monitoring Boards/advisory boards for Roche,

AstraZeneca, Amgen, Pfizer, Merck Sharp & Dohme and Eli Lilly; received drug sample from Novartis and Pfizer. Prof Jin Seok Ahn: advisory board for Roche; advisory role with Pharmbio Korea, Guardant Health, Yuhan, ImmuneOncia, Therapex, Daiichi Sankyo Korea and Pfizer; coordinating PI with Yuhan; local PI with Roche and Yuhan; honoraria from LG Chemical, Pfizer, Roche, BC World Pharmaceutical, Yuhan, Hanmi, Novartis, JW Pharmaceutical, Amgen, Boehringer Ingelheim, Menarini, Kyowa Kirin, AstraZeneca, Bayer, Lilly, Takeda, Boryung, Samyang, Nokwon Medical and Bayer. Prof Fabrice Barlesi: institutional financial interests, personal financial interests and non-financial interests with AbbVie, ACEA, Amgen, AstraZeneca, Bayer, Bristol-Myers Squibb, Boehringer Ingelheim, Eisai, Eli Lilly Oncology, Roche, Genentech, Ipsen, Ignyta, Innate Pharma, Loxo, Novartis, Medimmune, Merck, MSD and Pierre Fabre. Prof Makoto Nishio: consulting fees with Ono Pharmaceuticals, Chugai Pharmaceutical, Taiho Pharmaceutical, Bristol Myers Squibb, Daiichi Sankyo, Lilly, AstraZeneca, MSD, AbbVie, Takeda, Pfizer, Boehringer Ingelheim, Novartis, Nippon Kayaku, Merck and Janssen. Prof Dae Ho Lee: advisory board for ST Cube and Abion; member of board of directors for ST Cube; invited speaker for AstraZeneca, Boehringer-Ingelheim, Bristol-Myers Squibb, Eli Lilly, ChongKeunDang, Janssen, MSD, Novartis, Ono, Pfizer, Roche, ST Cube, AbbVie and Abion. Prof Jong-Seok Lee: no conflicts of interest. Prof Wenzhao Zhong: no conflicts of interest. Dr Hidehito Horinouchi: lecturer fees with AbbVie, Amgen, AstraZeneca, BMS, Chugai/Roche, Kyowa-Kirin, Lilly, MSD, Novartis, Ono and Taiho; research expenses with AbbVie, Amgen, AstraZeneca, BMS, Chugai/Roche, Daiichi-Sankyo, MSD and Ono. Prof Weimin Mao: no conflicts of interest. Dr Maximilian Hochmair: advisory board for BMS, Roche, MSD, Lilly, Amgen and Takeda; consultancy with Roche, BMS, MSD, Lilly, Amgen and Takeda; speaker's bureau for BMS, Roche, MSD, Lilly, Amgen and Takeda. Prof Filippo de Marinis: invited speaker for Roche and MSD; advisory board for AstraZeneca, Pfizer, Roche-Genentech, Daichii, BMS, Novartis, Takeda, Eli Lilly, Mirati, Merck, MSD, Regeneron and Xcover; PI with AbbVie, Ariad, AstraZeneca, Blue Medicine, GSK, Incyte, Mirati, Takeda, Novartis, MSD, Sanofi, PharmaMar and Takeda. Dr Maria Rita Migliorino: advisory board for AstraZeneca, Novartis Pharma, Roche and Takeda Oncology; speaker grants with AstraZeneca, Novartis Pharma, Roche and Takeda Oncology. Prof Igor Bondarenko: no conflicts of interest. Prof Shun Lu: advisory role with AstraZeneca, Pfizer, Hutchison MediPharma, ZaiLab, GenomiCare, Novartis, Yuhan Corporation, Menarini, Mirati Therapeutics Inc., Daiichi Sankyo, Inc., D3 Bio Limited, Simcere, Takeda and Roche; invited speaker for AstraZeneca, Roche and Hansoh; member of board of directors for Innovent Biologics, Inc.; research grant with AstraZeneca, Hutchison, BMS, Heng Rui Beigene, Roche and Hansoh; speaker's bureau for AstraZeneca, Roche and Hansoh. Dr Qun Wang: no conflicts of interest. Dr Tania Ochi Lohmann: employee at F. Hoffmann-La Roche Ltd. Ms Tingting Xu: employee at F. Hoffmann-La Roche Ltd. Mr Andres Cardona: stocks/shares with F. Hoffmann-La Roche Ltd; employee at F. Hoffmann-La Roche Ltd. Ms Laura Hiles: stocks/shares with F. Hoffmann-La Roche Ltd; employee at F. Hoffmann-La Roche Ltd. Dr Johannes Noe: stocks/shares with F. Hoffmann-La Roche Ltd; employee at F. Hoffmann-La Roche Ltd. Prof Benjamin J. Solomon: member of board of directors for the International Association for the Study of Lung Cancer (IASLC), Thoracic Oncology Group of Australasia (TOGA) and Cancer Council of Victoria; honoraria from AstraZeneca, Merck Sharp & Dohme, Roche/Genentech, Pfizer, Amgen and Sanofi; consulting or advisory role with Bristol-Myers Squibb, Merck Sharp & Dohme, AstraZeneca, Pfizer, Roche/Genentech, Amgen, Lilly, BeiGene, Takeda, GSK and Janssen. The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

Medical writing support was provided by Tahmina S. Alam, MA, of Ashfield MedComms, an Inizio company, and was funded by F. Hoffmann-La Roche Ltd.

Patient reviewers on this PLSP have received honorarium from *Future Oncology* for their review work but have no other relevant financial relationships to disclose.

Peer reviewers on this manuscript have no relevant financial or other relationships to disclose.

Funding

F. Hoffmann-La Roche Ltd/Genentech, Inc. sponsored the ALINA study, provided the study drugs and collaborated with the academic authors on the collection, analysis and interpretation of the data.

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