



Your guide to ALUNBRIG[®] (brigatinib)

Learn how ALUNBRIG targets your specific type of lung cancer, what to expect from treatment, and more.

What is ALUNBRIG?

ALUNBRIG is a prescription medicine used to treat adults with non-small cell lung cancer (NSCLC):

- that has a certain type of abnormal anaplastic lymphoma kinase (ALK) gene, **and**
- that has spread to other parts of your body

It is not known if ALUNBRIG is safe and effective in children.

Please read the [Patient Information](#) in the full [Prescribing Information](#) and discuss with your healthcare provider.



Your doctor has decided that ALUNBRIG (brigatinib) is your next right step

This may be because you:

- Have recently learned you have ALK-positive non-small cell lung cancer (ALK+ NSCLC) that has spread to other parts of your body (“metastatic”)
- Have been receiving chemotherapy treatment for metastatic NSCLC and have just tested positive for the **anaplastic lymphoma kinase (ALK)** gene, or:
- Have known for some time that you have ALK+ metastatic NSCLC and have tried a targeted therapy that stopped working

This brochure contains **important information about your lung cancer and ALUNBRIG**, including how it works, how it’s been proven to help in clinical studies, and how you take it just once a day.

You’ll also discover where you can find support along the way, so that you never feel alone.



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About ALK+ NSCLC

What is NSCLC?

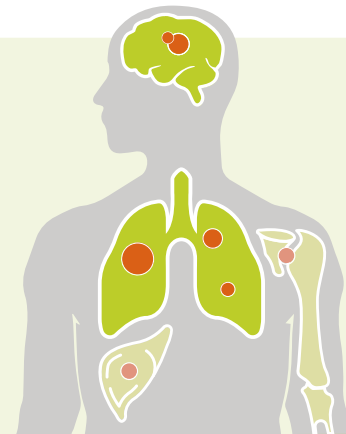
Non-small cell lung cancer, or NSCLC, is the most common type of lung cancer. It makes up about 80%–85% of lung cancer cases. NSCLC can be caused by a genetic mutation, which is an abnormal change in the genes within a cell. As a result, these cells may begin to function improperly and grow more quickly, leading to cancer in some people.

What is ALK-positive (ALK+) NSCLC?

ALK+ NSCLC is a type of NSCLC that often spreads to other parts of the body, including the liver, bones, and brain. It's **caused by a mutation in the gene that makes a protein called ALK**, which is involved in cell growth.

- About 3% to 5% of people with NSCLC have the ALK gene mutation
- ALK+ NSCLC is most frequently seen in people who never smoke or lightly smoke, as well as in younger patients

Cancer that has traveled to the brain is called brain **metastasis**. While brain metastases may be common (affecting up to 75% of people with ALK+ NSCLC at some point during their cancer journey), certain treatment approaches may help, such as **targeted therapy** options.



About ALUNBRIG (brigatinib)

What is ALUNBRIG?

ALUNBRIG is an oral prescription medicine approved for adults with ALK+ metastatic NSCLC. It is just **one tablet taken once a day, with or without food.**



**1 TABLET ONCE DAILY
WITH OR WITHOUT FOOD**

How does ALUNBRIG work?

ALUNBRIG is a targeted therapy. A targeted therapy is a type of treatment that may slow the growth and spread of cancer cells while limiting the damage to healthy cells. **ALUNBRIG targets a specific molecule called a tyrosine kinase** that is responsible for cancer cell growth in ALK+ NSCLC.

ALUNBRIG works by blocking (or “inhibiting”) the action of the tyrosine kinase. In other words, ALUNBRIG is a **tyrosine kinase inhibitor**, or **TKI**. To learn more about ALK TKIs such as ALUNBRIG, visit [cancer.gov/publications/dictionaries/cancer-terms/def/tyrosine-kinase-inhibitor](https://www.cancer.gov/publications/dictionaries/cancer-terms/def/tyrosine-kinase-inhibitor).

Who is ALUNBRIG for?

If you are an adult with ALK+ metastatic NSCLC, your doctor may prescribe ALUNBRIG if you:

- Have never tried an ALK-targeted therapy, or:
- Have tried an ALK-targeted therapy that stopped working

You should be aware that targeted therapies may cause serious side effects. For ALUNBRIG, these may include lung problems; high blood pressure; slow heart rate; vision problems; muscle pain, tenderness, and weakness; inflammation of the pancreas; liver problems; and high blood sugar.

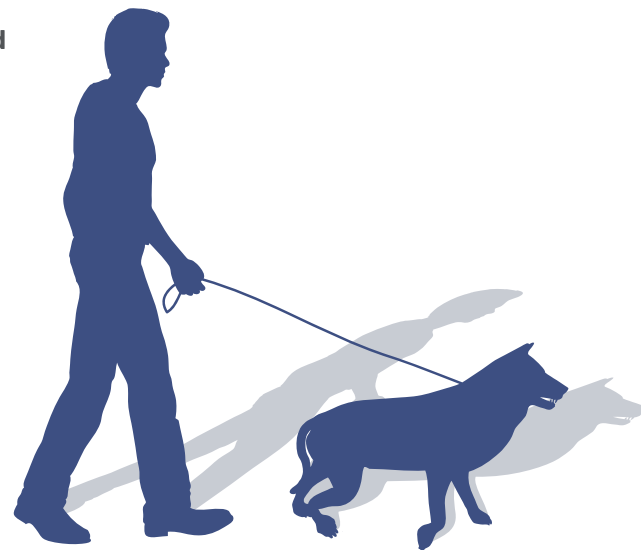
With ALUNBRIG, you may live longer without your cancer getting worse

An overview of how ALUNBRIG may help

In clinical studies, **ALUNBRIG shrank tumors in people whose ALK+ NSCLC had spread to other parts of the body, including the brain.** This benefit occurred in study participants who took ALUNBRIG as the first ALK-targeted therapy in their treatment journey, and also in study participants who took ALUNBRIG after their disease got worse on another ALK-targeted therapy called crizotinib.

See study results for:

- ALUNBRIG as **a first-line ALK-targeted therapy** on page 8
- ALUNBRIG **after another ALK-targeted therapy stopped working** on page 12



ALUNBRIG is an effective treatment that treats ALK+ metastatic NSCLC in multiple areas of the body, **including the lungs and brain**, which may delay disease progression.


ALUNBRIG[®]
BRIGATINIB
180mg | 90mg | 30mg
TABLETS

Important Safety Information for ALUNBRIG (brigatinib)

ALUNBRIG can cause serious side effects, including:

- **Lung problems. ALUNBRIG may cause severe or life-threatening swelling (inflammation) of the lungs any time during treatment and can lead to death.** These lung problems happen **especially within the first week of treatment** with ALUNBRIG. Symptoms may be similar to those symptoms from lung cancer. Tell your healthcare provider right away if you have any new or worsening symptoms, including:
 - trouble breathing or shortness of breath
 - cough with or without mucus
 - chest pain
 - fever
- **High blood pressure (hypertension).** ALUNBRIG may cause high blood pressure. Your healthcare provider will check your blood pressure before starting and during treatment with ALUNBRIG. Tell your healthcare provider right away if you get headaches, dizziness, blurred vision, chest pain or shortness of breath.
- **Slow heart rate (bradycardia).** ALUNBRIG may cause very slow heartbeats that can be severe. Your healthcare provider will check your heart rate during treatment with ALUNBRIG. Tell your healthcare provider right away if you feel dizzy, lightheaded, or faint during treatment with ALUNBRIG. Tell your healthcare provider if you take any heart or blood pressure medicines.
- **Vision problems.** ALUNBRIG may cause vision problems. Your healthcare provider may stop ALUNBRIG and refer you to an eye specialist if you develop severe vision problems during treatment with ALUNBRIG. Tell your healthcare provider right away if you have any loss of vision or any change in vision, including:
 - double vision
 - light hurting your eyes
 - seeing flashes of light
 - new or increased floaters
 - blurry vision
- **Muscle pain, tenderness, and weakness (myalgia).** ALUNBRIG may increase the level of an enzyme in your blood called creatine phosphokinase (CPK), which may be a sign of muscle damage. Your healthcare provider will do blood tests to check your blood levels of CPK during treatment with ALUNBRIG. Tell your healthcare provider right away if you get new or worsening signs and symptoms of muscle problems, including unexplained muscle pain or muscle pain that does not go away, tenderness, or weakness.
- **Inflammation of the pancreas (pancreatitis).** ALUNBRIG may increase enzymes in your blood called amylase and lipase, which may be a sign of pancreatitis. Your healthcare provider will do blood tests to check your pancreatic enzyme blood levels during treatment with ALUNBRIG. Tell your healthcare provider right away if you get new or worsening signs and symptoms of pancreatitis, including upper abdominal pain that may spread to the back and get worse with eating, weight loss, or nausea.
- **Liver problems (hepatotoxicity).** ALUNBRIG may increase the levels of bilirubin in your blood and enzymes called aspartate aminotransferase (AST) and alanine aminotransferase (ALT) in your blood, which may be a sign of liver problems. Your healthcare provider will do blood tests to check your liver during treatment with ALUNBRIG. Tell your healthcare provider right away if you get new or worsening signs or symptoms, including:
 - yellowing of your skin or the white part of your eyes
 - bleed or bruise more easily than normal
 - dark or brown (tea color) urine
 - itchy skin
 - nausea or vomiting
 - decreased appetite
 - pain on the right side of your stomach area
 - feeling tired

• **High blood sugar (hyperglycemia).** ALUNBRIG may increase your blood sugar levels. Your healthcare provider will do blood tests to check your blood sugar levels before starting and during treatment with ALUNBRIG. Your healthcare provider may need to start or change your blood sugar medicine to control your blood sugar levels. Tell your healthcare provider right away if you get new or worsening signs and symptoms of hyperglycemia, including:

- feeling very thirsty
- feeling very hungry
- feeling weak or tired
- needing to urinate more than usual
- feeling sick to your stomach
- feeling confused

The most common side effects of ALUNBRIG include diarrhea, fatigue, nausea, rash, cough, muscle pain, headache, high blood pressure, vomiting and difficulty breathing.

ALUNBRIG may cause fertility problems in males. This may affect your ability to father a child. Talk to your healthcare provider if you have concerns about fertility.

These are not all the possible side effects of ALUNBRIG. Call your doctor for medical advice about side effects. You may report side effects to the FDA at **1-800-FDA-1088**.

What should I avoid while taking ALUNBRIG?

- Limit your time in the sun during treatment with ALUNBRIG and for at least 5 days after your final dose. ALUNBRIG may make your skin sensitive to sunlight. You may burn more easily and get severe sunburns. When you are in the sun, wear a hat and protective clothing, and use a broad-spectrum sunscreen and lip balm with a Sun Protection Factor (SPF) of 30 or greater to protect against sunburn.
- Avoid eating grapefruit or drinking grapefruit juice during treatment with ALUNBRIG. Grapefruit may increase the amount of ALUNBRIG in your blood.

Before you take ALUNBRIG, tell your healthcare provider about all of your medical conditions, including if you have lung or breathing problems, high blood pressure, a slow heartbeat, or any vision problems, have or have had pancreatitis, have liver problems, have diabetes mellitus or glucose intolerance, have kidney problems or are on dialysis, are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed.

- ALUNBRIG can harm your unborn baby. Your healthcare provider will determine whether or not you are pregnant before you start treatment with ALUNBRIG. Tell your healthcare provider right away if you become pregnant during treatment with ALUNBRIG or think you may be pregnant.
 - **Females** who are able to become pregnant should use effective birth control during treatment with ALUNBRIG and for at least 4 months after the final dose of ALUNBRIG. Talk to your healthcare provider about birth control choices that are right for you during treatment with ALUNBRIG.
 - **Males** who have female partners who are able to become pregnant should use effective birth control during treatment with ALUNBRIG and for at least 3 months after the final dose of ALUNBRIG.
- It is not known if ALUNBRIG passes into your breast milk. Do not breastfeed during treatment with ALUNBRIG and for 1 week after the final dose of ALUNBRIG.

Tell your healthcare provider about all the medicines you take, including prescription medicines, over-the-counter medicines, vitamins, or herbal supplements.

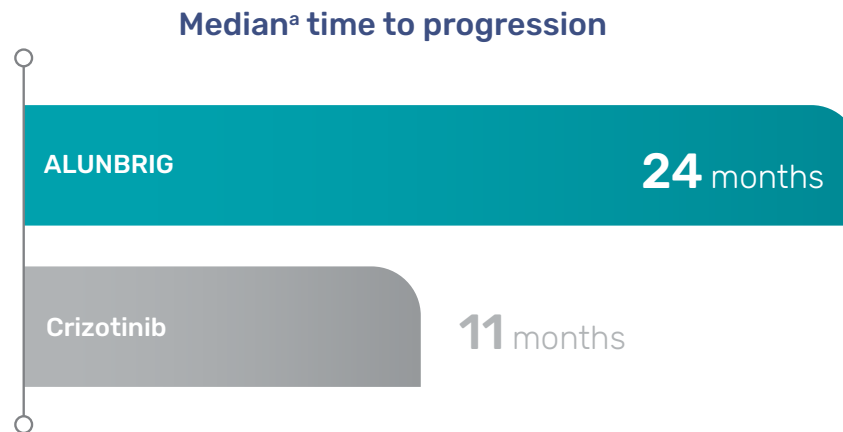


How ALUNBRIG (brigatinib) may help as a first-line ALK-targeted therapy

In a clinical study of people taking ALUNBRIG as the first ALK-targeted therapy in their treatment journey, ALUNBRIG was:

Proven to extend time to disease progression...

- People went **twice as long** without their disease getting worse or spreading further vs those taking crizotinib:



The study was carried out by a group of independent researchers. They did not know which patients were given which therapy and had nothing to gain from how they assessed either drug.

^aMedian is not the same as average. Median is the middle number in a set of measurements arranged from lowest to highest.

^bStatistically significant means that a result is unlikely to be due to chance.

The results shown on pages 8-10 are from a clinical study that compared ALUNBRIG to crizotinib (another ALK-targeted therapy) in 275 people with ALK+ metastatic NSCLC who had not yet been treated with an ALK-targeted therapy. The study participants were split into two groups: **137** of them received the recommended dosing regimen of ALUNBRIG (90 mg orally once daily for 7 days, followed by an increase to 180 mg once daily), and **138** of them received crizotinib 250 mg orally twice daily.

...and proven to shrink tumors in the body and the brain.

- Overall, the number of people who responded to ALUNBRIG was **higher** than the number who responded to crizotinib:

74% of people taking ALUNBRIG saw their tumors shrink
(101 out of 137)
**vs 62% (85 out of 138) taking crizotinib—
a difference that's considered statistically significant.^b**

The researchers also evaluated a smaller group of **41 patients with brain metastases**.

- The number of people with brain metastases at the start of the study who responded to ALUNBRIG was **3x higher** than the number of people who responded to crizotinib:

78% of people taking ALUNBRIG saw their tumors shrink
(14 out of 18)
vs 26% (6 out of 23) taking crizotinib.

- Of those who responded to ALUNBRIG, **64%** (9 out of 14) maintained that response for **2 years or longer**



During the same study, 131 people completed a quality-of-life^a questionnaire

ALK+ mNSCLC patients reported on how they functioned physically, emotionally, and socially, and on the severity of their symptoms

Both groups reported that their cancer eventually impacted their quality of life, but ALUNBRIG patients reported a longer time until their symptoms worsened.

The median time to symptoms getting worse



This means half of the people who took ALUNBRIG saw their symptoms get worse before 26.7 months, and half saw their symptoms get worse after 26.7 months.

The results of this survey weren't originally part of the study. People also knew which medicine they were taking during the study. This means that they may have marked their quality-of-life improvements as higher than they actually were.

Learn how ALUNBRIG helped when taken after another ALK inhibitor on pages 12-13.

^aQuality of life was assessed with the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire, or EORTC QLQ-C30. This 30-item questionnaire is used to measure health-related quality of life in people with cancer—specifically, how their disease and treatment are affecting them physically (eg, side effects and ability to be active), psychologically (eg, mental and emotional challenges), and socially (eg, impact on interacting with family and friends).

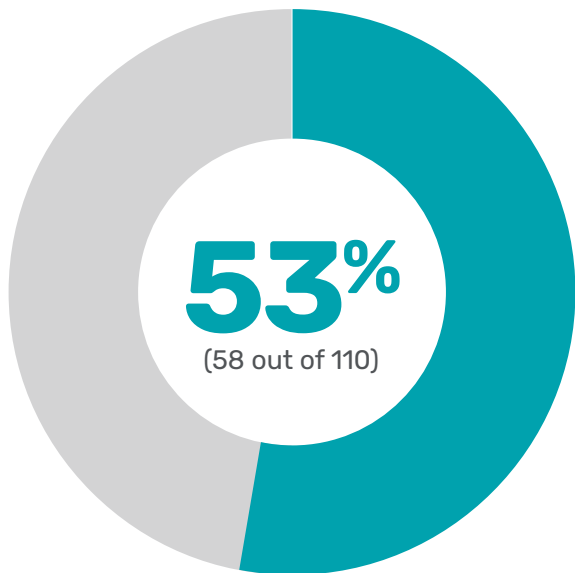
Notes

How ALUNBRIG (brigatinib) may help after another ALK-targeted therapy stops working

In a clinical study of people previously treated with an ALK-targeted therapy called crizotinib, the recommended dosing regimen of ALUNBRIG was:

Proven to shrink tumors in the body...

- **More than half** (53%, or 58 out of 110) of people taking ALUNBRIG **saw their tumors shrink**, and their response to treatment lasted a **median of 13.8 months**:



People whose tumors shrank with ALUNBRIG^a

- 4.5% (5 out of 110) had a complete response
- 48% (53 out of 110) had a partial response

Response lasted a median of 13.8 months



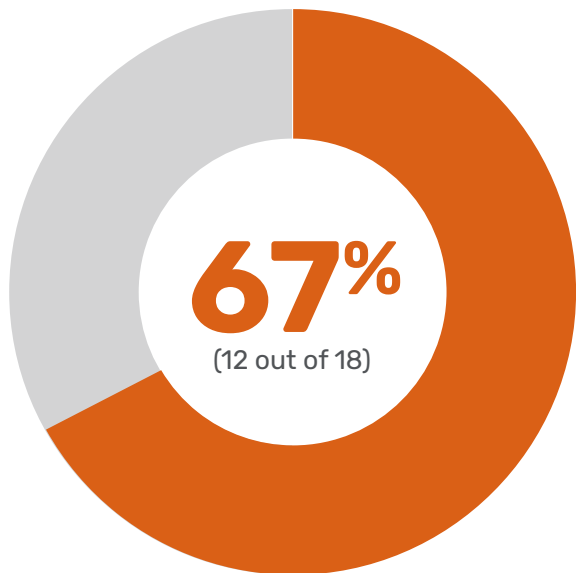
People whose tumors did not respond to ALUNBRIG (47%)

^aOverall response rate is defined as the proportion of patients who have a response to therapy, meaning that their tumors have shrunk by a certain amount (a partial response) or have disappeared (a complete response).

The results shown on pages 12-13 are from a clinical study that evaluated ALUNBRIG at the recommended dosing regimen in 110 people with ALK+ metastatic NSCLC who had been previously treated with crizotinib and their disease progressed; 18 of these people had brain metastases at the start of the study. The recommended dosing regimen of ALUNBRIG is 90 mg once daily for 7 days, followed by an increase to 180 mg once daily.

...and proven to shrink tumors in the brain.

- **67%** (12 out of 18) of the people with brain tumors at the start of the study **saw their brain tumors shrink** in response to ALUNBRIG
- Of those who responded to ALUNBRIG, **50%** (6 out of 12) maintained that response for **6 months or longer**, and **25%** (3 out of 12) maintained that response for **12 months or longer**



- **People whose brain tumors shrank with ALUNBRIG^a**
 - Response lasted for at least 6 months for 6 out of 12 people**
 - Response lasted for at least 12 months for 3 out of 12 people**
- People whose brain tumors did not respond to ALUNBRIG (33%)

In the same clinical study, 112 people with ALK+ metastatic NSCLC received 90 mg of ALUNBRIG once daily without increasing their dose to 180 mg on Day 8; 26 of these people had brain metastases at the start of the study. To view those results in the body and the brain, please visit [ALUNBRIG.com](https://www.alunbrig.com).



How to take ALUNBRIG (brigatinib)

Your healthcare provider will start you on **ALUNBRIG at a dose of 90 mg once daily for the first 7 days** of treatment. If you tolerate this dose of ALUNBRIG well, your healthcare provider may **increase your dose to 180 mg once daily from Day 8 onward**.

ALUNBRIG is:



Just **one tablet** per day



Taken **with or without** food

Take ALUNBRIG exactly as your healthcare provider tells you to take it. Do not change your dose or stop taking ALUNBRIG unless your healthcare provider tells you to.



If you miss a dose or vomit after taking a dose of ALUNBRIG:

- Do not take the missed dose or an extra dose
- Take your next dose at your regular time

Other important information

- Swallow ALUNBRIG tablets whole. Do not crush or chew tablets
- Keep ALUNBRIG and any other medicines you may be taking out of the reach of children
- Store ALUNBRIG at a room temperature of 68°F to 77°F (20°C to 25°C)
- Avoid grapefruit and grapefruit juice because it may increase the amount of ALUNBRIG in your blood
- Limit sun exposure while taking ALUNBRIG and for at least 5 days after you stop taking it. When outdoors, wear a hat and protective clothing and use a broad-spectrum sunscreen and lip balm

Possible side effects of ALUNBRIG

Side effects can happen with any medication, so it's always important to know what they are. By learning the possible side effects of ALUNBRIG now, you will **be ready to ask for help with managing them** if you have any side effects later.

Serious side effects of ALUNBRIG include lung problems; high blood pressure; slow heart rate; vision problems; muscle pain, tenderness, and weakness; inflammation of the pancreas; liver problems; and high blood sugar.

The most common side effects of ALUNBRIG include diarrhea, fatigue, nausea, rash, cough, muscle pain, headache, high blood pressure, vomiting, and difficulty breathing.

Remember, side effects can often be managed with the help of your healthcare team. If you develop certain side effects, your healthcare provider may change or temporarily stop your dose until those side effects are under control. If your side effects continue, your healthcare provider may decide to permanently stop your treatment.



Questions or concerns? You have a healthcare team you can turn to for help

Many healthcare providers make up the team who will guide you throughout your treatment. In addition to your primary care doctor and oncologists, they include lung and heart specialists, nurses, and more.

Here are some common questions people have at the start of treatment that a healthcare team can help answer:

What can I do to prepare for treatment with ALUNBRIG (brigatinib)?

How can possible side effects of ALUNBRIG be managed?

How long does it take for ALUNBRIG to start working?

Are there any side effects that I should call you about right away?

What does my long-term treatment plan look like?

What support services are available to me?

To help keep track of the healthcare providers on your care team and other important information, download the **Patient Treatment Guide** by scanning the QR code.



Support and resources

Take some time to explore these online resources and revisit certain terms used in this brochure. Learning as much as you can about ALK+ NSCLC can help you be an active participant in your treatment decisions and care.

Support groups

ALK Positive
alkpositive.org

GO₂ for Lung Cancer
go2.org
(800) 298-2436

LUNGeivity
lungevity.org
(844) 360-5864

American Cancer Society
cancer.org
(800) 227-2345

Cancer Support Community
cancersupportcommunity.org
(888) 793-9355

Living with ALK
livingwithalk.com

Lung Cancer Foundation of America
lcfamerica.org
(323) 741-4713

CancerCare
cancercares.org
(800) 813-4673

National Cancer Institute
cancer.gov
(800) 422-6237

The manufacturer does not endorse these organizations. The online resources are provided for informational purposes only and are not to replace the medical advice of your healthcare providers.

Glossary

ALK – A gene that makes a protein called anaplastic lymphoma kinase, or ALK, which is involved in cell growth. Mutated or genetically changed forms of the ALK gene and protein have been found in some types of cancer, such as NSCLC.

Median – The middle number in a set of measurements arranged from lowest to highest.

Metastasis – The spread of cancer from the original site to another part of the body.

Targeted therapy – A type of treatment that can inhibit or slow the disease growth, progression, and spread of cancer by attacking specific types of cancer cells, with less damage to normal cells. Some targeted therapies block the action of certain enzymes, proteins, or other molecules involved in the growth and spread of cancer cells.



From finding financial assistance that may be right for you to understanding your disease, Takeda Oncology Here2Assist® can provide the information you need throughout your treatment.

Takeda Oncology Here2Assist:

- ▶ Works with your insurance company to help you get started on your medication
- ▶ Identifies available financial assistance that may be right for you
- ▶ May help get you started on treatment if there is a delay in insurance coverage determination
- ▶ Connects you to additional support services and resources
- ▶ Identifies specialty pharmacies to help fill and ship your prescriptions appropriately
- ▶ Conducts regular follow-up calls with you
- ▶ Sends you status updates and reminders via text message*
- ▶ Connects you with nurse navigators to support your product education journey



ACCESS SUPPORT: Once you're enrolled, Takeda Oncology Here2Assist case managers can work with you and your healthcare provider to determine your coverage options, and provide additional support throughout your Takeda Oncology treatment.



FINANCIAL ASSISTANCE: If you need assistance affording your medication, Takeda Oncology Here2Assist can help identify financial assistance programs that may be able to help you with the cost of your treatment.



HELPFUL RESOURCES: Takeda Oncology Here2Assist case managers can provide information about additional resources that may help address day-to-day concerns associated with your treatment.



To learn more about Takeda Oncology Here2Assist, call to speak with a case manager at 1-844-817-6468, Option 2, or scan the QR code to visit www.Here2Assist.com. **Let's Talk.** We're available Monday-Friday, 8AM-8PM ET. To learn more about Takeda Oncology Here2Assist, visit www.Here2Assist.com/patient/home

*Patients will need to enroll in the texting program to receive text messages.

Learn more about living with ALK+ metastatic NSCLC

To learn from another person's experience with ALUNBRIG (brigatinib),
use your phone to scan the QR code.



To request or download additional resources, sign up for our
free Patient Information Kit at [ALUNBRIG.com/resources](https://alunbrig.com/resources).

To learn more, visit [ALUNBRIG.com](https://alunbrig.com).

Please read the [Patient Information](#) in the full [Prescribing Information](#) and discuss with your healthcare provider.



ONCOLOGY

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