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## Navigating NSCLC: A biomarker testing guide & glossary

XALKORI is a prescription medicine used to treat people with non-small cell lung cancer (NSCLC) that has spread to other parts of the body and is caused by a defect in either a gene called ALK (anaplastic lymphoma kinase) or a gene called ROS1. It is not known if XALKORI is safe and effective in children.

Please see Important Safety Information on pages 4-5.  
Click for the [full Prescribing Information](#) and [Patient Information](#) or visit [XALKORI.com](#).

## ■ How genetics is changing the fight against non-small cell lung cancer (NSCLC)

In the past, most people with non-small cell lung cancer (NSCLC) were treated with a standard, broad approach. But today, breakthroughs in genetics have revealed new insights about what causes some tumors to grow. These discoveries are sparking a change in how your doctor may treat your NSCLC. It all begins with a test.



## ■ Biomarker testing can help guide treatment decisions

### **Biomarker testing and biomarker-driven treatments**

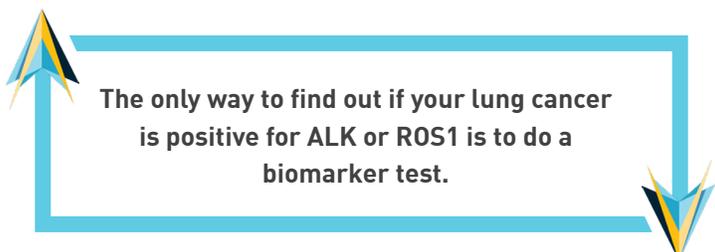
As scientists study cancer cells at the molecular level, they are finding genetic changes or defects that are common to certain types of cancer. In some cases, these defects are what make the cells grow and multiply abnormally. Biomarkers are the signs of these genetic defects. Biomarker-driven therapies are believed to work by blocking the activity of the defective gene that is making the cancer grow.

By testing a sample of your tumor for biomarkers, doctors can learn if your cancer has one of these defects — and then use that information to recommend specific treatment options. Biomarker testing may also be referred to as molecular profiling, a tumor marker test, molecular testing or mutation profiling.

## ■ The ALK and ROS1 fusion genes

Everyone has the ALK and ROS1 genes in their cells. But when a part of the ALK or the ROS1 gene breaks off and reattaches the wrong way, it becomes a fusion gene. This may cause the cell to multiply out of control, resulting in cancer growth.

The specific types of lung cancer that test positive for the ALK or ROS1 fusion genes are called ALK-positive (ALK+) or ROS1-positive (ROS1+), depending on which gene is abnormal.



**The only way to find out if your lung cancer is positive for ALK or ROS1 is to do a biomarker test.**

Your doctor may test for many biomarkers at once or test for one or more of the most common NSCLC biomarkers.

It's important to know that if you test positive for ALK, you typically would not test positive for ROS1, and vice versa. But both of them are thought to play a critical role in the growth of some NSCLCs.

About 3% to 5% of people with NSCLC test ALK+ and about 1% to 2% test ROS1+. These numbers may seem small, but not if you are one of them.

## ■ The ALK and ROS1 fusion genes (continued)

### Who can have ALK+ or ROS1+ NSCLC?

The short answer is there is no one “type” of person who has it. Men and women with NSCLC who tested ALK+ or ROS1+ for clinical trials were of various ethnicities and a wide age range. Some had smoked, though most had never smoked. While some people may be more likely to carry either altered gene, there is no true way to know without getting tested.

### What’s involved in testing?



Your doctor needs a tissue sample, or biopsy, of the tumor. If there’s enough tissue from a previous biopsy, that sample could be used. If not, another biopsy would be needed. Once the tissue is sent to the lab, most results come back within two weeks.

If you have any questions about biomarker testing or whether your tumor may be positive for ALK or ROS1, talk to your doctor.

## ■ About XALKORI

XALKORI is a prescription medicine used to treat people with non-small cell lung cancer (NSCLC) that has spread to other parts of the body and is caused by a defect in either a gene called ALK (anaplastic lymphoma kinase) or a gene called ROS1. It is not known if XALKORI is safe and effective in children.

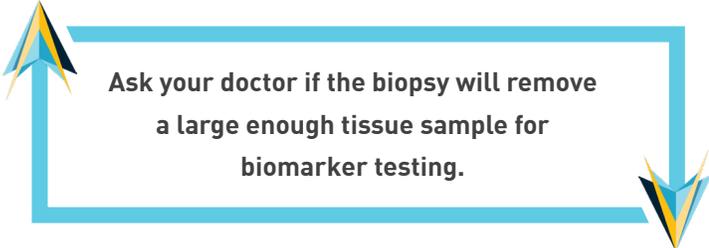
**In 2011, XALKORI became the first medication for people who test ALK+ and have NSCLC that has spread to other parts of the body (metastatic).**

**Today, it also treats those who test ROS1+.** By blocking the action of the abnormal ALK or ROS1 gene, XALKORI may shrink or slow the growth of the cancer for a certain length of time.

Getting tested is the only way for your doctor to know if XALKORI might be an option for you.



**The attached glossary can help you understand medical language that you may come across during your treatment journey.**



**Ask your doctor if the biopsy will remove a large enough tissue sample for biomarker testing.**

## ■ Important Safety Information

**XALKORI® (crizotinib) may cause serious side effects, some of which may include:**

**Liver problems** — XALKORI may cause life-threatening liver injury that may lead to death. Your healthcare provider should do blood tests at least every month to check your liver during treatment with XALKORI. Tell your healthcare provider right away if you get any of the following new or worsening symptoms:

- yellowing of your skin or the white part of your eyes
- severe tiredness
- dark or brown (tea color) urine
- nausea or vomiting
- decreased appetite
- pain on the right side of your stomach
- bleed or bruise more easily than normal
- itching

**Lung problems (pneumonitis)** — XALKORI may cause life-threatening lung problems that may lead to death. 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 mucous
- fever

**Heart problems** — XALKORI may cause very slow, very fast, or abnormal heartbeats. Your healthcare provider may check your heart during treatment with XALKORI. Tell your healthcare provider right away if you feel dizzy or faint or have abnormal heartbeats. Tell your healthcare provider if you take any heart or blood pressure medicines.

**Vision problems** — Vision problems are common with XALKORI. These problems usually happen within 1 week of starting treatment with XALKORI. Vision problems with XALKORI can be severe and may cause partial or complete loss of vision in one or both eyes. Your healthcare provider may stop XALKORI and refer you to an eye healthcare provider if you develop severe vision problems during treatment with XALKORI. Tell your healthcare provider right away if you have any loss of vision or any change in vision, including:

- double vision
- seeing flashes of light
- blurry vision
- light hurting your eyes
- new or increased floaters

**Before you take XALKORI, tell your healthcare provider if you:**

- have heart problems, including a condition called long QT syndrome
- have liver or kidney problems
- have vision or eye problems
- have any other medical conditions

## ■ Important Safety Information (continued)

### Before you take XALKORI® (crizotinib), tell your healthcare provider if you:

- are pregnant, or plan to become pregnant. XALKORI can harm your unborn baby.
  - **Females** who are able to become pregnant should use effective birth control during treatment with XALKORI and for at least 45 days after the final dose of XALKORI.
  - **Males** who have female partners who can become pregnant should use condoms during treatment with XALKORI and for at least 90 days after the final dose of XALKORI.
- Talk to your healthcare provider about birth control methods that may be right for you.
- If you or your partner becomes pregnant, tell your healthcare provider right away.
- are breastfeeding or plan to breastfeed. It is not known if XALKORI passes into your breast milk. Do not breastfeed during treatment with XALKORI and for 45 days after the final dose. Talk to your healthcare provider about the best way to feed your baby during this time.

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

You should not drink grapefruit juice or eat grapefruit during treatment with XALKORI. It may increase the amount of XALKORI in your blood to a harmful level.

The most common side effects of XALKORI include:

- vision problems
- nausea
- diarrhea
- vomiting
- swelling of your hands, feet, face, and eyes
- constipation
- increased liver function blood test results
- tiredness
- decreased appetite
- upper respiratory infection
- dizziness
- feeling of numbness or tingling in the extremities

XALKORI can cause changes in your vision, dizziness, and tiredness. If you have these symptoms avoid driving a car, using machinery, or doing anything that needs you to be alert.

XALKORI may cause decreased fertility. In females, this could affect your ability to become pregnant. In males, this could affect your ability to father a child.

These are not all of the possible side effects of XALKORI. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

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**ALK gene:**

ALK stands for anaplastic lymphoma kinase. Everyone has the ALK gene in their cells. When a part of the ALK gene breaks off and reattaches in the wrong way, it becomes an abnormal ALK gene, also known as an ALK fusion gene. This can lead to cancer cell growth and tumor survival.

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**ALK+ NSCLC:**

A type of non-small cell lung cancer (NSCLC) where an ALK fusion gene is present. Also written as ALK-positive NSCLC.

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**Biomarker:**

A tumor biomarker is a molecule that indicates there is a change in a tumor cell's genes that may be related to the development or spread of cancer. A biomarker may help a doctor choose a specific treatment plan for a patient based on the characteristics of his or her cancer. Also called a molecular marker.

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**Biomarker-driven therapy:**

A type of treatment that is designed to block the action of abnormal genes or proteins that may be contributing to cancer growth. For people whose tumors test positive for a certain biomarker, it may be possible to base their treatment plan on this biomarker.

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**Biomarker testing or Molecular profiling:**

A process that allows doctors to analyze tumors to look for changes that may be contributing to cancer growth. This type of test helps a doctor develop a treatment plan for a patient. Also called a tumor marker test, molecular testing, or mutation profiling.

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**Biopsy:**

The removal of cells or tissue for study under a microscope to look for signs of disease.

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**Carcinoma:**

A cancer that begins in a specific area of the skin's tissue or in the lining of the internal organs.

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**Chemotherapy:**

A cancer treatment that may work by stopping or slowing the growth of fast-dividing cancer cells.

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**Chromosome:**

A strand of DNA that contains genes and is found in the center of cells.

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**Clinical trial:**

A research study meant to test new medical approaches. In cancer, a clinical trial may test new ways to find, diagnose, and treat cancer.

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**DNA:**

The genetic information passed on from parent to child. DNA is found within cells.

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**Gene:**

A short piece of DNA that “tells” cells what to do.

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**Median time period:**

In a cancer treatment study, it often means that half of the patients responded to a treatment for at least a specific amount of time, and half responded for less than that specific amount of time.

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**Metastatic:**

Having to do with metastasis, which is the spread of cancer from where it started to other places in the body.

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**Non-small cell lung cancer (NSCLC):**

A group of lung cancers that are named for the kinds of cells found in the cancer and how the cells look under a microscope. Non-small cell lung cancer is the most common kind of lung cancer.

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**Patient Prescribing Information:**

A version of a medicine’s label or package insert that is written in language meant to be understood by patients.

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**ROS1 gene:**

Everyone has the ROS1 gene in their cells. When a part of the ROS1 gene breaks off and reattaches in the wrong way, it becomes an abnormal ROS1 gene, also known as a ROS1 fusion gene. This can lead to cancer cell growth and tumor survival.

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**ROS1+ NSCLC:**

A type of non-small cell lung cancer (NSCLC) where a ROS1 fusion gene is present. Also written as ROS1-positive NSCLC.

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**Specialty pharmacy provider:**

A pharmacy that focuses on providing medicines for patients with complex diseases, like cancer. Specialty pharmacies handle medicines that are often not stocked at regular neighborhood pharmacies.

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**Tumor:**

A mass of tissue that is caused by abnormal growth of cells or by cells that live longer than normal.

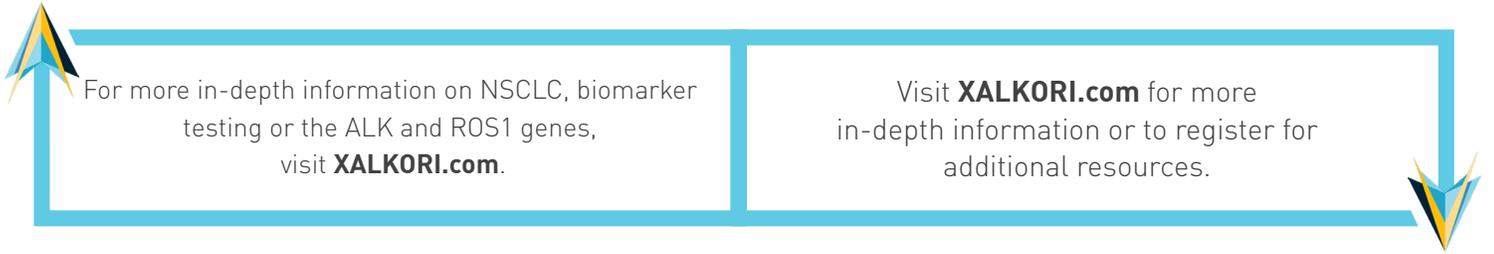
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EXPLORE  
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## ■ Getting the most out of your XALKORI® (crizotinib) treatment

**Remember:** always follow your doctor's instructions exactly, and be sure to report any side effects you may experience right away.

A decorative graphic consisting of a light blue rectangular frame. On the left side, a stylized arrow points upwards. On the right side, a stylized arrow points downwards. The frame is divided into two sections by a vertical line.

For more in-depth information on NSCLC, biomarker testing or the ALK and ROS1 genes, visit **XALKORI.com**.

Visit **XALKORI.com** for more in-depth information or to register for additional resources.



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