



LIBTAYO works with your immune system to help treat advanced NSCLC



Patient portrayal.

What is LIBTAYO?

LIBTAYO (Lib-TIE-oh) is a prescription medicine used to treat people with a type of lung cancer called non-small cell lung cancer (NSCLC). LIBTAYO may be used as your first treatment when your lung cancer has not spread outside your chest (locally advanced lung cancer) and you cannot have surgery or chemotherapy with radiation, or your lung cancer has spread to other areas of your body (metastatic lung cancer), and your tumor tests positive for high “PD-L1,” and your tumor does not have an abnormal “EGFR,” “ALK,” or “ROS1” gene.

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

Important Safety Information

What is the most important information I should know about LIBTAYO?

LIBTAYO is a medicine that may treat certain cancers by working with your immune system. LIBTAYO can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work. These problems can sometimes become severe or life-threatening and can lead to death. You can have more than one of these problems at the same time. These problems may happen anytime during treatment or even after your treatment has ended.

Please see additional Important Safety Information throughout and [click here for full Prescribing Information](#), including [Medication Guide](#).

Understanding your treatment with LIBTAYO

Your treatment team has given you this brochure because you have been prescribed or are considering treatment with LIBTAYO. The information in this brochure is not meant to take the place of talking with your doctor, nurse, or other healthcare providers. Always talk with your doctor if you have any questions about your treatment or any side effects that may occur.

As you begin your treatment, there can be a lot of information and many details to keep track of. Learning the facts and staying informed are key parts of living with advanced non–small cell lung cancer (NSCLC). This guide was designed to help you understand your treatment with LIBTAYO, which treats people with NSCLC that has spread or cannot be cured by surgery or chemotherapy with radiation. It also provides suggested questions you can ask your doctor, along with plenty of space to take notes during your conversation.

This guide will provide you with important information including:

- Information to help you understand advanced NSCLC and the different types of NSCLC
- The ways NSCLC, including advanced NSCLC, can be treated and the types of doctors who treat it
- Information about LIBTAYO, including what you can expect from treatment and the resources that are available to you while you are taking LIBTAYO

Important Safety Information (continued)

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including:

- **Lung problems:** cough, shortness of breath, or chest pain
- **Intestinal problems:** diarrhea (loose stools) or more frequent bowel movements than usual, stools that are black, tarry, sticky or have blood or mucus, or severe stomach-area (abdomen) pain or tenderness
- **Liver problems:** yellowing of your skin or the whites of your eyes, severe nausea or vomiting, pain on the right side of your stomach area (abdomen), dark urine (tea colored), or bleeding or bruising more easily than normal

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About advanced NSCLC

Learn about a type of cancer called non-small cell lung cancer (NSCLC), including advanced NSCLC, and how it is diagnosed.



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Patient portrayal.

ABOUT ADVANCED NSCLC

TREATING ADVANCED NSCLC

TREATMENT WITH LIBTAYO

What is NSCLC?

Lung cancer is the second-most diagnosed cancer in both men and women in the United States. Non-small cell lung cancer (NSCLC) is cancer that starts in the lungs. Unlike normal cells, cancer cells grow without order or control, destroying the healthy lung tissue around them.

How is NSCLC diagnosed?

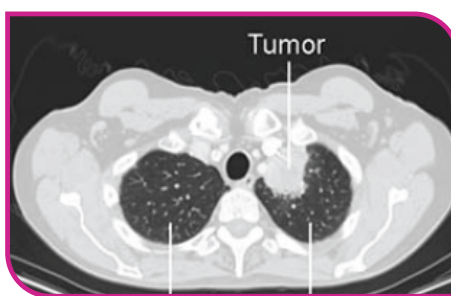
Your doctor will perform a number of tests in order to make a diagnosis. The first test is usually a painless chest X-ray that can show larger tumors, but may miss smaller or harder-to-find tumors. If something of concern is found on an X-ray or if you need a more detailed test, a CT (computed tomography) scan (kum-PYOO-ted toh-MAH-gruh-fee skan), is typically ordered.

A CT scan uses X-ray beams and a computer to create an image of the inside of your body. CT scans can find smaller tumors that may not be found by chest X-rays and can provide more detailed information about them. CT scans can also help identify enlarged lymph nodes* where a tumor may have spread.

Chest X-ray



CT scan of the lungs



Adapted with permission from LUNgevity Foundation, 2021.

A biopsy is the usual way to confirm an NSCLC diagnosis. Small pieces of tissue or fluids are removed from the body and examined under a microscope by a doctor called a pathologist. The biopsy procedure not only confirms the presence of cancer but typically determines the type of NSCLC as well.

*Lymph nodes are like filters that remove germs. They contain immune cells that can help fight infection.

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Injection 350 mg

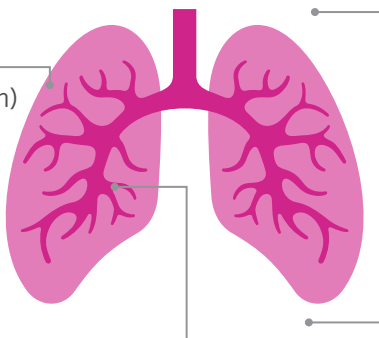
Types of NSCLC

Non-small cell lung cancer (NSCLC) is the most common type of lung cancer. About 85% of lung cancers are NSCLC. It typically grows and spreads more slowly.

Types of NSCLC that are the most commonly diagnosed:

Adenocarcinoma

(A-deh-noh-KAR-sih-NOH-muh) begins in cells of glands that normally secrete substances such as mucus and are often found in an outer area of the lungs.



Large cell carcinoma

(... sel KAR-sih-NOH-muh) can occur in any part of the lungs and tends to grow and spread faster than adenocarcinoma or squamous cell carcinoma.

Squamous cell carcinoma

(SKWAY-mus sel KAR-sih-NOH-muh) begins in the flat cells that line the passages of the respiratory tract and are found in the center of the lungs next to an air tube (bronchus).

Important Safety Information (continued)

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including (continued):

- **Hormone gland problems:** headache that will not go away or unusual headaches, eye sensitivity to light, eye problems, rapid heartbeat, increased sweating, extreme tiredness, weight gain or weight loss, feeling more hungry or thirsty than usual, urinating more often than usual, hair loss, feeling cold, constipation, your voice gets deeper, dizziness or fainting, or changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness
- **Kidney problems:** decrease in your amount of urine, blood in your urine, swelling of your ankles, or loss of appetite

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What is staging and why is it important?

After an NSCLC diagnosis, one of the first steps doctors will take is to try to determine the size of the cancer and areas of the body where it is located. This is called staging. The stage of NSCLC mainly describes the size of the tumor and if it has spread to other areas of the body. The lower the stage number, the less advanced the cancer is.

There are different staging systems for different cancers, but the most common is the numbered cancer staging system that identifies 5 possible cancer stages:

Stage 0: Cancer cells are located in the lining of the airways and have not spread.

Stage 1: The cancer is still small and has not spread outside the lungs or to the lymph nodes.*

Stage 2: The cancer may be larger than in stage 1 or may have spread to the lymph nodes* near where the cancer started.

Stages continued on the next page >

*Lymph nodes are like filters that remove germs. They contain immune cells that can help fight infection.



It is important for doctors to determine the stage of your cancer so they can understand how advanced the cancer is in order to develop your treatment plan.

Important Safety Information (continued)

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including (continued):

- **Skin problems:** rash, itching, skin blistering or peeling, painful sores or ulcers in mouth or nose, throat, or genital area, fever or flu-like symptoms, or swollen lymph nodes

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What is staging and why is it important? (continued)

Stage 3: The cancer may have spread to lymph nodes* farther away from where it started within the chest. The cancer has not spread to other parts of the body and may be larger than those in stage 2. It is sometimes referred to as locally advanced NSCLC.

Stage 4: The most advanced form of cancer. In stage 4 cancer, the disease is called metastatic NSCLC, which means that the cancer has spread to other organs such as the other lung, brain, liver, or to other parts of the body.

What is advanced NSCLC?

When NSCLC is diagnosed as stage 3 or stage 4, it is considered advanced.

There are 2 forms: Locally advanced NSCLC and metastatic NSCLC

- Locally advanced NSCLC, when NSCLC is diagnosed as stage 3, occurs when the cancer may have spread to the lymph nodes* farther away from where it started within the chest. The cancer has not spread to other parts of the body and may be larger than those in stage 2
- Metastatic NSCLC, when NSCLC is diagnosed as stage 4, occurs when the cancer has spread to other organs such as the other lung, brain, liver, or to other parts of the body

*Lymph nodes are like filters that remove germs. They contain immune cells that can help fight infection.

Important Safety Information (continued)

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including (continued):

- **Problems can also happen in other organs and tissues. These are not all of the signs and symptoms of immune system problems that can happen with LIBTAYO. Call or see your healthcare provider right away for any new or worsening signs or symptoms, which may include:** chest pain, irregular heartbeat, shortness of breath or swelling of ankles, confusion, sleepiness, memory problems,

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Questions for your doctor

Below are questions you can ask your doctor to help you understand your advanced NSCLC diagnosis better. Use this page to take notes during your conversation.

How does NSCLC differ from the other types of lung cancer?

What type of advanced NSCLC do I have?

How does the stage of my lung cancer help decide the best type of treatment?

What other tests will I need before we can decide on treatment?

Important Safety Information (continued)

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including (continued):

- Problems can also happen in other organs and tissues. These are not all of the signs and symptoms of immune system problems that can happen with LIBTAYO. Call or see your healthcare provider right away for any new or worsening signs or symptoms, which may include (continued): changes in mood or behavior, stiff neck, balance problems, tingling or numbness of the arms or legs, double vision, blurry vision,

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Treating advanced NSCLC

This next section provides an overview of the types of doctors who treat NSCLC, including advanced NSCLC, and some of the treatment options.



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Patient portrayal.

ABOUT ADVANCED NSCLC

TREATING ADVANCED NSCLC

TREATMENT WITH LIBTAYO

Who treats NSCLC, including advanced NSCLC?

The following specialized doctors may be involved in your care and can help determine the right treatment options for you.

- **Thoracic surgeons:** Doctors who treat diseases of the lungs and chest with surgery
- **Radiation oncologists:** Doctors who treat cancer with radiation therapy
- **Oncologists:** Doctors who treat cancer with medicines such as chemotherapy, targeted therapy, and immunotherapy
- **Pulmonologists:** Doctors who diagnose and treat diseases of the respiratory system including the lungs and other organs that help you breathe

Many other specialists may be involved in your care as well, including nurse practitioners, nurses, respiratory therapists, psychologists, social workers, rehabilitation specialists, and other healthcare professionals.



Don't be afraid to ask the people on your team what their roles are and what part of your care or treatment they will be providing. Knowing how your care team works and how they communicate with one another will help you and your loved ones better understand your treatment and who can best address any issues or concerns you may have.

Important Safety Information (continued)

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including (continued):

- **Problems can also happen in other organs and tissues. These are not all of the signs and symptoms of immune system problems that can happen with LIBTAYO. Call or see your healthcare provider right away for any new or worsening signs or symptoms, which may include (continued):** sensitivity to light, eye pain, changes in eyesight, persistent or severe muscle pain or weakness, muscle cramps, low red blood cells, or bruising

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How is NSCLC treated?

The treatment options for NSCLC are based mainly on the stage and extent of the cancer. Other factors, such as your overall health and lung function, as well as certain traits of the cancer itself, are also important.



Surgery is an operation to remove tumors. It is most commonly used in early-stage NSCLC.



Radiation therapy is a type of cancer treatment that uses beams of intense energy, most often X-rays, to kill cancer cells and shrink tumors. Radiation therapy is given by a radiation oncologist.



Chemotherapy is a form of systemic drug therapy (a type of drug that moves through the body) that kills cells that divide or grow too fast. These include cancer cells but may also include normal cells. Chemotherapy may be used before or after surgery, in combination with radiation therapy, targeted therapies, immunotherapies, and/or other agents.

Chemoradiation therapy is a combination of chemotherapy and radiation therapy.

Important Safety Information (continued)

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including (continued):

- **Infusion reactions that can sometimes be severe.** Signs and symptoms of infusion reactions may include: nausea, chills or shaking, itching or rash, flushing, shortness of breath or wheezing, dizziness, feel like passing out, fever, back or neck pain, or facial swelling

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How is NSCLC treated? (continued)

The treatment options for NSCLC are based mainly on the stage and extent of the cancer. Other factors, such as your overall health and lung function, as well as certain traits of the cancer itself, are also important.



Targeted therapies are a form of systemic drug therapy aimed at certain changes that make cancer cells different (abnormal). These therapies work by interfering with specific “targets” that are involved in the growth, progression, and spread of cancer cells.



Immunotherapy is a form of systemic drug therapy that may help your immune system fight cancer. Your body might not attack cancer because the cancer cells have developed ways to avoid the immune system and keep growing. Immunotherapy helps the immune system recognize, attack, and kill the cancer cells. Immunotherapy is given by an oncologist and often used during the advanced stages (stages 3 and 4). It is not chemotherapy.

Immunotherapy can cause your immune system to attack normal organs and tissues in your body, which may cause serious side effects.

Important Safety Information (continued)

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including (continued):

- **Rejection of a transplanted organ.** Your healthcare provider should tell you what signs and symptoms you should report and monitor you, depending on the type of organ transplant that you have had

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Finding treatment through biomarker testing

Biomarker testing is an important part of understanding your unique advanced NSCLC diagnosis. It is used in advanced stages of NSCLC and involves testing tumor tissue for mutations or abnormalities in the DNA and levels of specific proteins in, or on the surface of, the tumor. Biomarkers tell your doctor that a mutation or abnormality may be present and may lead to a better understanding of which treatment to use and how you may respond to treatment.

What are the types of biomarkers?

There are many different biomarker tests that may help you and your doctor decide the most appropriate treatment options to help treat your advanced NSCLC. Your doctor may test you for more than one biomarker. Below are some of the most common types of biomarkers.

ALK

Anaplastic lymphoma kinase
(A-nuh-PLAS-tik lim-FOH-muh KY-nays)

NTRK

Neurotrophic tyrosine receptor kinase
(NOOR-oh-TROH-fik TY-ruh-seen
reh-SEP-ter KY-nays)

BRAF

B-Raf proto-oncogene, serine/threonine kinase
(b-raf prow-tuh-aang-kow-jeen, sr-een/
three-uh-need KY-nays)

PD-L1

Programmed death ligand 1
(prow-gramd deth li-gand wuhn)

EGFR

Epidermal growth factor receptor
(eh-pih-DER-mul grothe FAK-ter reh-SEP-ter)

ROS1

ROS proto-oncogene 1, receptor tyrosine kinase
(ros prow-tuh-aang-kow-jeen wuhn, reh-SEP-ter
TY-ruh-seen KY-nays)

Important Safety Information (continued)

Call or see your healthcare provider right away if you develop any symptoms of the following problems or these symptoms get worse (continued):

- **Complications, including graft-versus-host disease (GVHD), in people who have received a bone marrow (stem cell) transplant that uses donor stem cells (allogeneic).** These complications can be serious and can lead to death. These complications may happen if you underwent transplantation either before or after being treated with LIBTAYO. Your healthcare provider will monitor you for these complications

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Finding treatment through biomarker testing (continued)

Immunotherapy biomarkers

Some treatment options depend on the presence or absence of biomarkers. Biomarker testing is used to determine if you may have a mutation or an abnormality that is treatable or to measure your **programmed death ligand 1 (PD-L1)** level. The results of these tests help determine whether any of the FDA-approved targeted therapies or immunotherapies may be right for your treatment plan. If you test negative for mutations or abnormalities such as EGFR, ALK, ROS1, or BRAF biomarkers and have a high PD-L1 level (greater than or equal to 50%), immunotherapy may be recommended. While there are different types of biomarkers, PD-L1 is currently used to help decide whether your advanced NSCLC may respond to treatment with immunotherapy.

PD-L1 is a protein that acts as a kind of “brake” to keep the body’s immune responses under control. PD-L1 binds to another protein found on T cells called programmed death receptor-1 (PD-1). This binding keeps T cells from killing normal cells and cancer cells that contain PD-L1.



It is important to know your biomarker status. Biomarker testing allows for cancer treatment to be personalized to your biomarker type. Biomarker testing requires a sample of the tumor tissue. Your doctor will do a biopsy to take a sample of the tumor tissue. Be sure to discuss with your doctor that enough tissue is removed so that all necessary biomarker tests can be performed. This will help you find the most appropriate treatment for your advanced NSCLC.

Important Safety Information (continued)

Getting medical treatment right away may help keep these problems from becoming more serious. Your healthcare provider will check you for these problems during your treatment with LIBTAYO. Your healthcare provider may treat you with corticosteroid or hormone replacement medicines. Your healthcare provider may also need to delay or completely stop treatment with LIBTAYO if you have severe side effects.

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Questions for your doctor

Below are questions you can ask your doctor to help you understand your advanced NSCLC diagnosis better. Use this page to take notes during your conversation.

Who are the members of my healthcare team and what are their roles?

What is my biomarker status?

Based on my biomarker status, which treatment is best for me?

What is my PD-L1 status?

Important Safety Information (continued)

Before you receive LIBTAYO, tell your healthcare provider about all your medical conditions, including if you:

- have immune system problems such as Crohn's disease, ulcerative colitis, or lupus

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Starting treatment with LIBTAYO

You and your doctor have decided that LIBTAYO is an appropriate treatment option. This section will help you understand:

- What LIBTAYO is
- How LIBTAYO works with your immune system to help fight advanced NSCLC
- Results from the LIBTAYO clinical trial
- How you will receive treatment with LIBTAYO
- What you can expect from treatment, including the possible side effects

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Patient portrayal.

What is LIBTAYO?

LIBTAYO (Lib-TIE-oh) is a prescription medicine that may be used as your first treatment for non–small cell lung cancer (NSCLC) that has not spread outside your chest and you cannot have surgery or chemotherapy with radiation or has spread to other areas of your body. LIBTAYO is a type of immunotherapy called a programmed death receptor-1 (PD-1) inhibitor. LIBTAYO is not chemotherapy or radiation therapy.

LIBTAYO may be right for people with advanced NSCLC who have tumors that test positive for high PD-L1 and the tumor does not have an abnormal EGFR, ALK, or ROS1 gene, and whose NSCLC:



**Has not spread outside the chest
(locally advanced lung cancer)**



AND

Cannot have surgery or chemotherapy with radiation

OR



**Has spread to other areas of the body
(metastatic lung cancer)**



Biomarker testing is needed before you start treatment. Biomarker testing helps determine if treatment with LIBTAYO is appropriate for you based on your PD-L1 levels and if you tested negative for abnormal EGFR, ALK, or ROS1 genes.

ALK=anaplastic lymphoma kinase; EGFR=epidermal growth factor receptor; PD-L1=programmed death ligand 1; ROS1=ROS proto-oncogene 1, receptor tyrosine kinase.

Important Safety Information (continued)

Before you receive LIBTAYO, tell your healthcare provider about all your medical conditions, including if you (continued):

- have received an organ transplant

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LIBTAYO works with your immune system to help treat advanced NSCLC

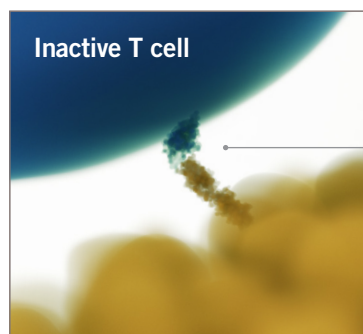
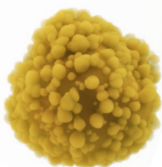
Your immune system defends your body against disease.



T cell

Certain white blood cells (**T cells**) are an important part of your immune system. Their job is to find and fight infections and kill **cancer cells**. T cells have a protein on the cell surface called **PD-1**, or programmed death receptor-1, that is involved in normal T-cell function.

Cancer cell



Inactive T cell

Some cancer cells are able to hide from the immune system to prevent the attack from T cells. **When proteins on cancer cells bind to the PD-1 receptor on T cells, this binding makes the T cell inactive and stops it from killing the cancer cell.**

PD-1 receptor binding to the cancer cell protein

Important Safety Information (continued)

Before you receive LIBTAYO, tell your healthcare provider about all your medical conditions, including if you (continued):

- have received or plan to receive a stem cell transplant that uses donor stem cells (allogeneic)

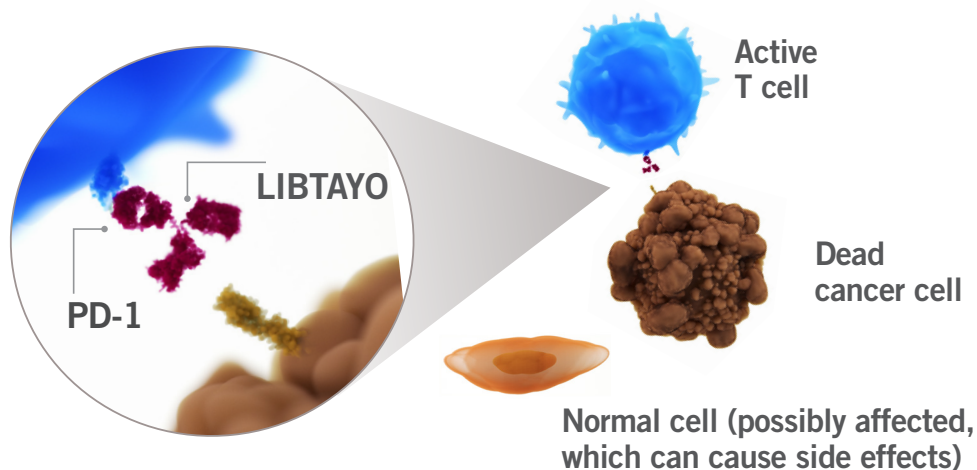
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LIBTAYO works with your immune system to help treat advanced NSCLC (continued)

LIBTAYO is a treatment that works by blocking PD-1, to inhibit binding with the cancer cell protein. The T cell then remains active, so it can attack and kill the cancer cell.

LIBTAYO can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work. These problems can sometimes become severe or life-threatening and can lead to death. These problems may happen anytime during treatment or even after your treatment has ended.



Important Safety Information (continued)

Before you receive LIBTAYO, tell your healthcare provider about all your medical conditions, including if you (continued):

- have a condition that affects your nervous system, such as myasthenia gravis or Guillain-Barré syndrome
- are pregnant or plan to become pregnant. LIBTAYO can harm your unborn baby

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In a study, LIBTAYO was proven to help patients live longer versus chemotherapy

LIBTAYO was studied in a clinical trial that compared patients with advanced NSCLC who received LIBTAYO at 350 mg every 3 weeks with those who received chemotherapy containing platinum. The study was designed to include patients if their tumor tested positive for the biomarker PD-L1 at a level greater than or equal to 50% and if they did not have abnormal EGFR, ALK, or ROS1 genes. A total of 710 patients were included in the study.

Median overall survival (OS)*



*Median overall survival (OS) is the time in a trial—expressed in months or years—when half of the patients are still living.

- Results showed that 248 out of 356 patients (70%) taking LIBTAYO were alive, compared with 213 out of 354 patients (60%) taking chemotherapy

LIBTAYO will not work for everyone.

Important Safety Information (continued)

Before you receive LIBTAYO, tell your healthcare provider about all your medical conditions, including if you (continued):

Females who are able to become pregnant:

- Your healthcare provider will give you a pregnancy test before you start treatment

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In a study, LIBTAYO was proven to help patients live longer versus chemotherapy (continued)

LIBTAYO reduced the risk of cancer spreading, growing, or getting worse by 41% compared with chemotherapy.

- **Half of the patients on LIBTAYO were alive without their cancer spreading, growing, or getting worse at 6.2 months, compared with 5.6 months for patients on chemotherapy**
- **Cancer had not progressed in 155 out of 356 patients (43%) taking LIBTAYO compared with 92 out of 354 patients (26%) taking chemotherapy**

LIBTAYO will not work for everyone.

Important Safety Information (continued)

Before you receive LIBTAYO, tell your healthcare provider about all your medical conditions, including if you (continued):

Females who are able to become pregnant (continued):

- You should use an effective method of birth control during your treatment and for at least 4 months after your last dose of LIBTAYO. Talk with your healthcare provider about birth control methods that you can use during this time
- Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with LIBTAYO
- are breastfeeding or plan to breastfeed. It is not known if LIBTAYO passes into your breast milk. Do not breastfeed during treatment and for at least 4 months after the last dose of LIBTAYO

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What are the most common side effects of LIBTAYO?

- **LIBTAYO can cause serious side effects**, including those described on pages 26 to 29 and in the [Medication Guide](#)
- The most common side effects you may experience with LIBTAYO include **muscle or bone pain, tiredness, rash, and diarrhea**
- These are not all the possible side effects of LIBTAYO

In a study, the most common side effects reported in the 355 patients with advanced NSCLC taking LIBTAYO were:



Muscle or bone pain

92 out of 355 patients (26%) experienced muscle or bone pain



Rash

53 out of 355 patients (15%) experienced having a rash



Anemia

53 out of 355 patients (15%) experienced anemia (low red blood cell count)



Tiredness

50 out of 355 patients (14%) experienced tiredness

Most common side effects continued on the next page >

Please review “What is the most important information I should know about LIBTAYO?” on pages 26 to 29 and in the [Medication Guide](#). Getting medical treatment right away may help keep these problems from becoming more serious.

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What are the most common side effects of LIBTAYO? (continued)

- **LIBTAYO can cause serious side effects**, including those described on pages 26 to 29 and in the [Medication Guide](#)
- The most common side effects you may experience with LIBTAYO include **muscle or bone pain, tiredness, rash, and diarrhea**
- These are not all the possible side effects of LIBTAYO

In a study, the most common side effects reported in the 355 patients with advanced NSCLC taking LIBTAYO were:



Loss of appetite

43 out of 355 patients (12%) experienced loss of appetite



Pneumonia

39 out of 355 patients (11%) experienced pneumonia



Cough

39 out of 355 patients (11%) experienced cough

Please review “What is the most important information I should know about LIBTAYO?” on pages 26 to 29 and in the [Medication Guide](#). Getting medical treatment right away may help keep these problems from becoming more serious.



Talk with your healthcare team anytime you have questions or concerns. Your healthcare team will watch for side effects as well during your treatment with LIBTAYO. They may decide to pause or stop your treatment with LIBTAYO due to side effects, or treat you with other medicines to help with these side effects.

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How will I receive LIBTAYO?

LIBTAYO is a medicine prescribed by a doctor. It is given in a hospital or clinic as a 30-minute intravenous (IV) infusion. This means that it enters the body through a vein.

What is the schedule for infusions of LIBTAYO?

1) 350 mg IV infusion



2) For 30 minutes



3) Every 3 weeks



- LIBTAYO is an IV infusion given over 30 minutes
- Treatment with LIBTAYO happens once every 3 weeks
- Infusion reactions may happen while you are receiving the drug. Infusion (IV) reactions can sometimes be severe. Signs of these problems may include nausea, chills or shaking, itching or rash, flushing, shortness of breath or wheezing, dizziness, feel like passing out, fever, back or neck pain, and facial swelling. Tell your doctor right away if you start to experience any of these symptoms
- Your healthcare provider will decide how many treatments you will need
- Your healthcare provider will do blood tests to check you for side effects



It is important to continue treatment as prescribed by your doctor. If you miss any appointments, call your healthcare provider as soon as possible to discuss your treatment plan.

Please see Important Safety Information throughout and [click here for full Prescribing Information](#), including [Medication Guide](#).

 **LIBTAYO**[®]
(cemiplimab-rwlc)
Injection 350 mg

Information about infusions with LIBTAYO

Below are questions you can ask your doctor to help you prepare for your treatments with LIBTAYO.

Is there anything you need to know from me prior to my first infusion?

Is there any type of follow-up after each infusion?

How will you track my progress?

What are my treatment goals?

Important Safety Information (continued)

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

Please see additional Important Safety Information throughout and [click here for full Prescribing Information](#), including [Medication Guide](#).



What is the most important information I should know about LIBTAYO?

LIBTAYO is a medicine that may treat certain types of cancers by working with your immune system. LIBTAYO can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work. These problems can sometimes become severe or life-threatening and can lead to death. You can have more than one of these problems at the same time. These problems may happen anytime during treatment or even after your treatment has ended.

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including:

Lung problems

- Cough
- Shortness of breath
- Chest pain

Intestinal problems

- Diarrhea (loose stools) or more frequent bowel movements than usual
- Stools that are black, tarry, or sticky, or that have blood or mucus
- Severe stomach-area (abdomen) pain or tenderness

Liver problems

- Yellowing of your skin or the whites of your eyes
- Severe nausea or vomiting
- Pain on the right side of your stomach-area (abdomen)
- Dark urine (tea colored)
- Bleeding or bruising more easily than normal

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What is the most important information I should know about LIBTAYO? (continued)

Hormone gland problems

- Headache that will not go away or unusual headaches
- Eye sensitivity to light
- Eye problems
- Rapid heartbeat
- Increased sweating
- Extreme tiredness
- Weight gain or weight loss
- Feeling more hungry or thirsty than usual
- Urinating more often than usual
- Hair loss
- Feeling cold
- Constipation
- Your voice gets deeper
- Dizziness or fainting
- Changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness

Kidney problems

- Decrease in your amount of urine
- Blood in your urine
- Swelling of your ankles
- Loss of appetite

Skin problems

- Rash
- Itching
- Skin blistering or peeling
- Painful sores or ulcers in mouth or nose, throat, or genital area
- Fever or flu-like symptoms
- Swollen lymph nodes

Please see additional Important Safety Information throughout and [click here for full Prescribing Information](#), including [Medication Guide](#).



What is the most important information I should know about LIBTAYO? (continued)

Problems can also happen in other organs and tissues. These are not all of the signs and symptoms of immune system problems that can happen with LIBTAYO. Call or see your healthcare provider right away for any new or worsening signs or symptoms which may include:

- Chest pain, irregular heartbeat, shortness of breath or swelling of ankles
- Confusion, sleepiness, memory problems, changes in mood or behavior, stiff neck, balance problems, tingling or numbness of the arms or legs
- Double vision, blurry vision, sensitivity to light, eye pain, changes in eyesight
- Persistent or severe muscle pain or weakness, muscle cramps
- Low red blood cells, bruising

Infusion reactions that can sometimes be severe. Sign and symptoms of infusion reactions may include:

- Nausea
- Chills or shaking
- Itching or rash
- Flushing
- Shortness of breath or wheezing
- Dizziness
- Feel like passing out
- Fever
- Back or neck pain
- Facial swelling

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What is the most important information I should know about LIBTAYO? (continued)

Rejection of a transplanted organ. Your healthcare provider should tell you what signs and symptoms you should report and monitor you, depending on the type of organ transplant that you have had.

Complications, including graft-versus-host disease (GVHD), in people who have received a bone marrow (stem cell) transplant that uses donor stem cells (allogeneic). These complications can be serious and can lead to death. These complications may happen if you underwent transplantation either before or after being treated with LIBTAYO. Your healthcare provider will monitor you for these complications.

Getting medical treatment right away may help keep these problems from becoming more serious. Your healthcare provider will check you for these problems during your treatment with LIBTAYO. Your healthcare provider may treat you with corticosteroid or hormone replacement medicines. Your healthcare provider may also need to delay or completely stop treatment with LIBTAYO if you have severe side effects.

Please see additional Important Safety Information throughout and [click here for full Prescribing Information](#), including [Medication Guide](#).

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Questions for your doctor

Below are questions you can ask your doctor to better understand treatment with LIBTAYO, including possible side effects. Use this page to take notes during your conversation.

What are the side effects that can occur while taking LIBTAYO?

Are there tips you can offer to help manage side effects from LIBTAYO?

What treatment goals do you have for me with LIBTAYO?

What should I expect from treatment with LIBTAYO?

Important Safety Information (continued)

The most common side effects of LIBTAYO include muscle or bone pain, tiredness, rash, and diarrhea. These are not all the possible side effects of LIBTAYO. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. You may also report side effects to Regeneron Pharmaceuticals and Sanofi at 1-877-542-8296.

Please see additional Important Safety Information throughout and [click here for full Prescribing Information](#), including [Medication Guide](#).



LIBTAYO Surround[®] Patient Support Program



LIBTAYO Surround is here to help. Your doctor is your trusted source for information about your condition and treatment. LIBTAYO Surround may be able to provide you with resources and support to assist you.



LIBTAYO Surround Commercial Copay Program*

You may be eligible to pay as little as \$0 per month with the LIBTAYO Surround Commercial Copay Program.



LIBTAYO Surround Patient Assistance Program[†]

You may be eligible to receive LIBTAYO at no cost.



Other resources

LIBTAYO Surround can help you look for other ways to afford your medicine.



Nurse support

Nurse Advocates are available whenever you need more information and to support you throughout your treatment journey.



To enroll, talk to your doctor or call LIBTAYO Surround at 1.877.LIBTAYO (1.877.542.8296), select option 1, Monday–Friday, 8:00 AM–8:00 PM Eastern Time, or visit LIBTAYO.com.

*This program is not valid for prescriptions covered by or submitted for reimbursement under Medicare, Medicaid, Veterans Affairs/Department of Defense, TRICARE, or similar federal or state programs. Not a debit card program. The program does not cover or provide support for supplies, procedures, or any physician-related service associated with LIBTAYO. General non-product-specific copays, coinsurance, or insurance deductibles are not covered. Additional program conditions may apply.

[†]Additional criteria for financial need apply.

Please see Important Safety Information throughout and [click here for full Prescribing Information](#), including [Medication Guide](#).



LIBTAYO Patient Starter Kit

Starting a new treatment is not always easy. That is why we created the **LIBTAYO Patient Starter Kit** to help support you as you begin your treatment. The materials provided are not meant to replace the advice from your doctor. Always speak with your doctor about any questions you have about treatment with LIBTAYO.

LIBTAYO Patient Starter Kit includes the following items:

LIBTAYO patient brochure: In this brochure, you will find information about treatment with LIBTAYO and other helpful resources.



LIBTAYO Surround[®] patient overview brochure: If you are eligible, LIBTAYO Surround may help you with financial support for LIBTAYO.

Messenger bag: Whether you are going about your day or heading to an appointment, you can use this bag to carry all the items you need.

Breathing exercise cards and pillow: Breathing exercises may be beneficial for you. Be sure to check with your doctor before you start any exercise program.

Various magazines: Read the inspirational stories of other people and learn about their personal victories and struggles.

LIBTAYO patient wallet card: [Click here](#) to download your printable wallet card and carry it with you while you are on treatment with LIBTAYO. If you see a healthcare provider who is not involved in your cancer treatment, such as a primary care provider or a doctor in the emergency room, show the care team this card to alert them that you are taking LIBTAYO. This information is important for all healthcare providers involved in your care.

Telemedicine best practice guide: An informational guide to help you prepare for telemedicine appointments with your healthcare providers

Medicare Part B guide: An overview of healthcare coverage through Medicare and how Medicare Part B may help pay for treatments that require infusions



Order your **FREE** starter kit today! Call LIBTAYO Surround at 1.877.LIBTAYO (1.877.542.8296), select option 1, Monday–Friday, 8:00 AM–8:00 PM Eastern Time.

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Additional resources

Advocacy organizations give not only information, but also encouragement. There are a number of organizations that support people with lung cancer and their caregivers. The organizations listed below provide materials and services to assist patients throughout their journeys.



CancerCare

CancerCare is the leading national organization providing free, professional support services and information to help people manage the emotional, practical, and financial challenges of cancer. Their services include case management, counseling, support groups, educational workshops, publications, and more. For more information, visit: cancercares.org



Cancer Support Community

The Cancer Support Community is the largest professionally led nonprofit network of cancer support worldwide. This global network is dedicated to helping all people impacted by cancer. In addition to producing educational resources, the Cancer Support Community conducts cutting-edge research on the psychological, financial, and emotional journey of cancer patients. For more information, For more information, visit: cancersupportcommunity.org



GO₂ Foundation for Lung Cancer

Founded by patients and survivors, GO₂ Foundation for Lung Cancer transforms survivorship as the world's leading organization dedicated to saving, extending, and improving the lives of those vulnerable, at risk, and diagnosed with lung cancer. They work to change the reality of living with lung cancer by ending stigma, increasing public and private research funding, and ensuring access to care. For more information, visit: go2foundation.org



LUNGEvity Foundation

LUNGEvity Foundation focuses on improving outcomes for people with lung cancer through research, education, support, and policy initiatives. LUNGEvity seeks to make an immediate impact on quality of life and survivorship for everyone touched by the disease—while ensuring that health equity and access to optimal care are available for all. The organization provides an active community for patients and survivors—and those who help them live longer and better lives. For more information, visit: lungevity.org

The organizations listed above are independent nonprofit organizations. Their inclusion here does not imply endorsement of LIBTAYO (cemiplimab-rwlc), Regeneron, or Sanofi Genzyme.

In a study, LIBTAYO was proven to help patients live longer versus chemotherapy

Median overall survival (OS)*

- **At 22.1 months**, half of the patients taking LIBTAYO were alive
- **At 14.3 months**, half of the patients taking chemotherapy were alive

*Median overall survival (OS) is the time in a trial—expressed in months or years—when half of the patients are still living.

- Results showed that 248 out of 356 patients (70%) taking LIBTAYO were alive, compared with 213 out of 354 patients (60%) taking chemotherapy

LIBTAYO reduced the risk of cancer spreading, growing, or getting worse by 41% compared with chemotherapy.

The most common side effects of LIBTAYO include **muscle or bone pain, tiredness, rash, and diarrhea**. These are not all the possible side effects of LIBTAYO.

Important Safety Information

What is the most important information I should know about LIBTAYO?

LIBTAYO is a medicine that may treat certain cancers by working with your immune system. LIBTAYO can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work. These problems can sometimes become severe or life-threatening and can lead to death. You can have more than one of these problems at the same time. These problems may happen anytime during treatment or even after your treatment has ended.

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