



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](#).

# LIBTAYO may be used as your first treatment in advanced NSCLC



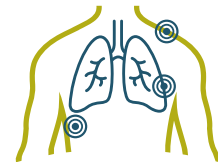
LIBTAYO may be right for people with advanced NSCLC who have tumors that test positive for high PD-L1 and the tumor does not have an abnormal EGFR, ALK, or ROS1 gene, and whose NSCLC:



AND



OR



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

Cannot have surgery or  
chemotherapy with radiation

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.

## What is biomarker testing and how does it relate to your PD-L1 status?

Biomarker testing is an important part of understanding your unique advanced NSCLC diagnosis. It is used in the 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. PD-L1, or programmed death ligand 1, is a protein that helps keep immune cells from attacking healthy cells in the body. Some cancer cells can have high amounts of PD-L1, allowing the cancer cells to hide from the immune system and avoid being attacked. Your PD-L1 levels can be checked with a biomarker test. Biomarker testing may allow for more personalized treatment options. Biomarker testing is required before using 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

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

# LIBTAYO works with your immune system to help treat advanced NSCLC



## How does LIBTAYO work?

Your immune system defends your body against disease. 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, which is involved in normal T-cell function.

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.**

**LIBTAYO is a treatment that works by blocking PD-1**, to stop 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.**



Talk to your doctor if you think LIBTAYO may be right for you. For more information, visit [LIBTAYO.com](https://www.libtayo.com).

## 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
- **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
- **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, or bruising
- **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
- **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

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

# 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 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)

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

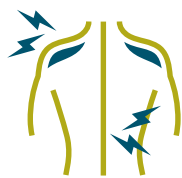
- Complications, including graft-versus-host disease (GVHD), in people who have received a bone marrow (stem cell) transplant that uses donor stem cells (allogeneic). These complications can be serious and can lead to death. These complications may happen if you underwent transplantation either before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

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

# Most common side effects of LIBTAYO

- LIBTAYO can cause serious side effects, including those described in the **Important Safety Information** throughout and [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)



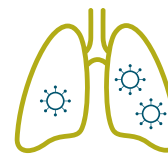
Tiredness

50 out of 355 patients (14%) experienced tiredness



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

Call your doctor for medical advice about side effects.

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

# 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?



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.

## LIBTAYO Surround<sup>®</sup> Patient Support Program



LIBTAYO Surround may be able to provide you with resources and support throughout your treatment with LIBTAYO. LIBTAYO Surround offers information on financial assistance programs and nurse support.

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](http://LIBTAYO.com).

## 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.

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

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

**Females who are able to become pregnant:**

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

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

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 [click here for full Prescribing Information](#), including [Medication Guide](#).