LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

Meaningful Stories. Meaningful Hope.



Dave
Actual LIBTAYO Patient

Sight Unseen

Another way of looking at management of advanced CSCC with this treatment option

Little things mean a lot to Dave. As an engineer and technology project manager for a major financial institution, precision is key. As a professional troubleshooter, Dave spends his days designing solutions. But when it came to his CSCC, the answers were not so easy.

His story began in 2008 with a small, rough patch of skin on the inner part of his left ear. Nothing to worry about, right? But a biopsy revealed cancer: cutaneous squamous cell carcinoma (CSCC). And that was just the beginning.

What is LIBTAYO?

LIBTAYO is a prescription medicine used to treat people with a type of skin cancer called cutaneous squamous cell carcinoma (CSCC) that has spread or cannot be cured by surgery or radiation.

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.

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Living with CSCC

Over the next couple of years, Dave battled CSCC as the surgeons removed patches of skin from his ear, nose, neck, wrist, forehead, face, and scalp. Medical appointments, surgeries, and post-op downtimes depleted Dave's paid time off and vacation time. The recurrence of CSCC began to wear on him emotionally as it took its toll.

In 2016, a rapidly growing CSCC appeared on his left forehead area about an inch and a half above his left eye. Using the Mohs process, his facial surgeon performed five iterations to identify and remove all of the cancerous tissue.

But the tumor had spread significantly under the skin and was much larger than it appeared. It had grown into the muscle of his left eyebrow so that entire brow and muscle had to be removed. After reconstructive surgery, he hoped this was the end of cancer on his face and head. But he was wrong.

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
- **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

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Beneath the surface

About eight months after that surgery, he began to notice a very soft, squishy bulge under his left eye. He hoped it would go away. For a time, he ignored it, not wanting to take off any more time from work. But the bulge continued to grow.
Soon, the skin on his left cheek area began to thicken and harden. It started to spread across his face toward his nose. When his cheek became numb, Dave had to concede that his CSCC was likely back.

LIBTAYO (cemiplimab-rwlc): A Different Option for Dave

In September 2018, Dave's dermatologist referred him to yet another facial surgeon. Surgery, radiation, and chemotherapy, or some combination were discussed. But there was a high probability that Dave could lose his eye in the procedure. Dave and his doctor decided at that point that surgery or radiation would not be an option as they would likely not be curative for his advanced CSCC.

Then the surgeon had another idea. He'd heard of an FDA-approved treatment: **LIBTAYO® (cemiplimab-rwlc), a prescription medicine used to treat people with a type of skin cancer called cutaneous squamous cell carcinoma (CSCC) that has spread or cannot be cured by surgery or radiation.** He referred Dave to an oncologist who had experience treating some of his appropriate advanced CSCC patients with this therapy. When Dave heard there was possibly a drug for his type of skin cancer, he was excited. He had never looked into his options before because he assumed none existed. After discussing the risks and benefits together, Dave and his doctor decided that LIBTAYO was an appropriate treatment option for Dave.

Important Safety Information (continued)

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

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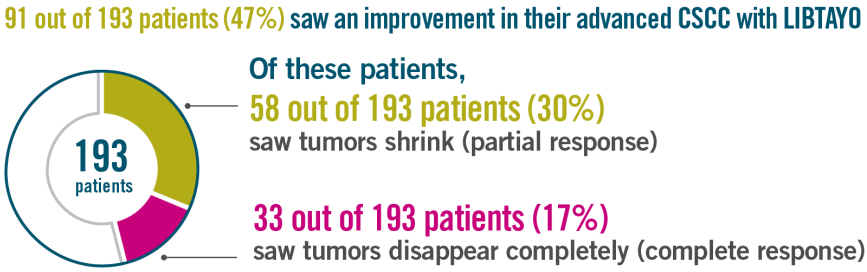
Seeing the results

After his second LIBTAYO infusion, Dave could see that the bulge under his eye was beginning to shrink. After six infusions, he saw further visible reduction.

A total-body PET scan was performed to evaluate Dave's progress. Thankfully, both he and his doctor were pleased with the results. After starting LIBTAYO, Dave experienced hives and itching in different areas of his body. Throughout his treatment, he also noticed some fatigue for a few days after receiving his infusion. **Individual results may vary, and patients should consult with their doctors to see if LIBTAYO could be right for them.**

In 1 clinical trial of 193* patients with CSCC that had spread or could not be cured by surgery or radiation treated with LIBTAYO:



*137 out of 193 patients in the trial were dosed by body weight; 56 out of 193 were given the recommended dose

LIBTAYO may not work for everyone.

Important Safety Information (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, or bruising

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- **In 84 out of 91 patients (92%)** who responded to LIBTAYO, the response lasted 6 months or longer
- **In 70 out of 91 patients (77%)** who responded to LIBTAYO, the response lasted 12 months or longer

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 or life-threatening.** Signs and symptoms of infusion reactions may include: nausea, vomiting, 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

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In the LIBTAYO clinical trial of 358 patients with advanced CSCC, the most common side effects reported were:

- 136 out of 358 patients (38%) experienced tiredness
- 122 out of 358 patients (34%) experienced having a rash
- 118 out of 358 patients (33%) experienced muscle or bone pain
- 93 out of 358 patients (26%) experienced diarrhea
- 79 out of 358 patients (22%) experienced itching
- 75 out of 358 patients (21%) experienced nausea
- 50 out of 358 patients (14%) experienced infection of the nose, throat, and/or airways
- 47 out of 358 patients (13%) experienced constipation
- 43 out of 358 patients (12%) experienced a cough
- 39 out of 358 patients (11%) experienced vomiting
- 39 out of 358 patients (11%) experienced a loss of appetite
- 39 out of 358 patients (11%) experienced a skin infection
- 36 out of 358 patients (10%) experienced scaly patches or bumps on the skin
- 36 out of 358 patients (10%) experienced headaches
- 36 out of 358 patients (10%) experienced dizziness

Today, Dave is back on the job. He is still concerned about his CSCC, but is also focusing on living his life.

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

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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.

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 received radiation treatment to your chest area
- 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 to 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.

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Important Safety Information (continued)

The most common side effects of LIBTAYO when used alone include tiredness, muscle or bone pain, rash, diarrhea, and low levels of red blood cells (anemia). The most common side effects of LIBTAYO when used in combination with platinum-containing chemotherapy include hair loss, muscle or bone pain, nausea, tiredness, numbness, pain, tingling, or burning in your hands or feet, and decreased appetite. 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 at 1-877-542-8296.

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What is LIBTAYO?

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REGENERON®

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