

Dave  
Actual LIBTAYO Patient

**Meaningful Stories. Meaningful Hope.**

## 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.

### 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

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

LIBTAYO is a medicine that may treat a type of skin cancer 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 problem 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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### 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 that might provide a different option: LIBTAYO<sup>®</sup> (cemiplimab-rwlc), an immunotherapy for 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 advanced CSCC patients with this therapy. When Dave heard there was 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 symptoms of the following problems or these symptoms get worse:**

- **Lung problems (pneumonitis).** Signs and symptoms of pneumonitis may include new or worsening cough, shortness of breath, and chest pain.
- **Intestinal problems (colitis) that can lead to tears or holes in your intestine.** Signs and symptoms of colitis may include diarrhea (loose stools) or more frequent bowel movements than usual; stools that are black, tarry, sticky or that have blood or mucus; and severe stomach-area (abdomen) pain or tenderness.
- **Liver problems (hepatitis).** Signs and symptoms of hepatitis may include yellowing of your skin or the whites of your eyes, severe nausea or vomiting, pain on the right side of your stomach area (abdomen), drowsiness, dark urine (tea colored), bleeding or bruising more easily than normal, and feeling less hungry than usual.

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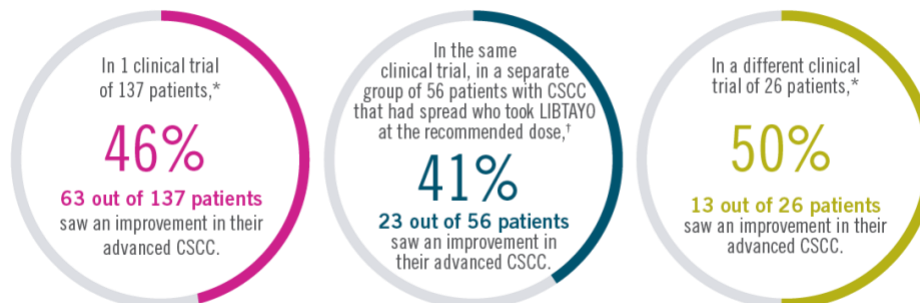
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### Seeing the Results

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 2 clinical trials of 219 patients with cutaneous squamous cell carcinoma (CSCC) that had spread or could not be cured by surgery or radiation



\*Patients were dosed by body weight.

†LIBTAYO 350 mg over a 30-minute infusion every 3 weeks.

In these trials, responses lasted between 1 month and more than 2 years (24.2+ months); plus sign (+) denotes ongoing at last assessment.

### 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):**

- **Hormone gland problems** (especially the adrenal glands, pituitary, thyroid and pancreas). Signs and symptoms that your hormone glands are not working properly may include headaches that will not go away or unusual headaches, rapid heartbeat, increased sweating, extreme tiredness, weight gain or weight loss, dizziness or fainting, feeling more hungry or thirsty than usual, hair loss, feeling cold, constipation, deeper voice, very low blood pressure, urinating more often than usual, nausea or vomiting, stomach-area (abdomen) pain, and changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness.

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In the LIBTAYO clinical trials of 219 patients with CSCC that had spread or could not be cured by surgery or radiation, the most common side effects of LIBTAYO were:



Tiredness  
74 out of 219  
patients (34%)  
experienced tiredness



Muscle or bone pain  
53 out of 219  
patients (24%)  
experienced muscle  
or bone pain



Rash  
68 out of 219  
patients (31%)  
experienced having  
a rash



Nausea  
46 out of 219  
patients (21%)  
experienced nausea



Diarrhea  
55 out of 219 patients (25%)  
experienced diarrhea

**These are not all the possible side effects of LIBTAYO.**

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 symptoms of the following problems or these symptoms get worse (continued):

- **Kidney problems**, including nephritis and kidney failure. Signs of these problems may include decrease in your amount of urine, blood in your urine, swelling in your ankles, and loss of appetite.

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## 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):**

- **Skin problems.** Signs of these problems may include rash, itching, skin blistering, and painful sores or ulcers in the mouth, nose, throat, or genital area
- **Problems in other organs.** Signs of these problems may include headache, tiredness or weakness, sleepiness, changes in heartbeat (such as beating fast, seeming to skip a beat, or a pounding sensation), confusion, fever, muscle weakness, balance problems, nausea, vomiting, stiff neck, memory problems, seizures (encephalitis), swollen lymph nodes, rash or tender lumps on skin, cough, shortness of breath, vision changes, or eye pain (sarcoidosis), seeing or hearing things that are not there (hallucinations), severe or persistent muscle pain, severe muscle weakness, low red blood cells (anemia), bruises on the skin or bleeding, and changes in eyesight.
- **Rejection of a transplanted organ.** Your doctor should tell you what signs and symptoms you should report and monitor you, depending on the type of organ transplant that you have had.
- **Infusion (IV) reactions that can sometimes be severe and life-threatening.** Signs of these problems may include chills or shaking, itching or rash, flushing, shortness of breath or wheezing, dizziness, fever, feeling of passing out, back or neck pain, and facial swelling.

**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 delay or completely stop treatment 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 had an organ transplant;
- have lung or breathing problems;
- have liver or kidney problems;
- have diabetes;
- are pregnant or plan to become pregnant; LIBTAYO can harm your unborn baby

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## 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.
- 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 tiredness, rash, diarrhea, muscle or bone pain, and nausea. 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.

## 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.

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