# TRADEMARK ASSIGNMENT COVER SHEET

Electronic Version v1.1
Stylesheet Version v1.2

ETAS ID: TM530766

| | |
|---|---|
| **SUBMISSION TYPE:** | NEW ASSIGNMENT |
| **NATURE OF CONVEYANCE:** | ASSIGNMENT OF THE ENTIRE INTEREST AND THE GOODWILL |

**CONVEYING PARTY DATA**

| Name | Formerly | Execution Date | Entity Type |
|---|---|---|---|
| Sanofi Biotechnology | | 07/01/2019 | Corporation: FRANCE |

**RECEIVING PARTY DATA**

| | |
|---|---|
| **Name:** | Regeneron Pharmaceuticals, Inc. |
| **Street Address:** | 777 Old Saw Mill River Road |
| **City:** | Tarrytown |
| **State/Country:** | NEW YORK |
| **Postal Code:** | 06901 |
| **Entity Type:** | Corporation: NEW YORK |

**PROPERTY NUMBERS Total: 1**

| Property Type | Number | Word Mark |
|---|---|---|
| **Registration Number:** | 5643567 | LIBTAYO SURROUND |

**CORRESPONDENCE DATA**

**Fax Number:** 2033276401

***Correspondence will be sent to the e-mail address first; if that is unsuccessful, it will be sent using a fax number, if provided; if that is unsuccessful, it will be sent via US Mail.***

**Phone:** 2033274500
**Email:** jscepanski@ogrp.com
**Correspondent Name:** Jeffrey J. Scepanski
**Address Line 1:** Ohlandt, Greeley, Ruggiero & Perle, LLP
**Address Line 2:** 1 Landmark Square, 10th Floor
**Address Line 4:** Stamford, CONNECTICUT 06901

CH $40.00 5643567

| | |
|---|---|
| **ATTORNEY DOCKET NUMBER:** | 554.1626UST1(554.0725USG) |
| **NAME OF SUBMITTER:** | Jeffrey J. Scepanski |
| **SIGNATURE:** | /Jeffrey J. Scepanski/ |
| **DATE SIGNED:** | 07/08/2019 |

**Total Attachments: 7**
source=LIBTAYO SURROUND_Assignment#page1.tif
source=LIBTAYO SURROUND_Assignment#page2.tif
source=LIBTAYO SURROUND_Assignment#page3.tif
source=LIBTAYO SURROUND_Assignment#page4.tif

source=LIBTAYO SURROUND_Assignment#page5.tif
source=LIBTAYO SURROUND_Assignment#page6.tif
source=LIBTAYO SURROUND_Assignment#page7.tif

# TRADEMARK ASSIGNMENT AGREEMENT

This Trademark Assignment Agreement (the "Agreement") is effective as of July 1st, 2019 (the "Effective date"), by and between SANOFI BIOTECHNOLOGY with its principal place of business located at 54, rue La Boétie, 75008 Paris, France (the "Assignor") and REGENERON PHARMACEUTICALS, INC. (the "Assignee") with its principal place of business located at 777 Old Saw Mill River Road, Tarrytown, NY 10591, USA.

The Assignor and the Assignee are individually referred to as a "Party" and collectively as the "Parties."

Unless otherwise indicated explicitly herein, all the provisions set forth in the Immuno-Oncology License and Collaboration Agreement (the "Collaboration Agreement," as defined below) shall be applicable to this Agreement. All capitalized terms used in the present Agreement and the Collaboration Agreement shall have the meaning ascribed in the Collaboration Agreement.

WITNESSETH

WHEREAS on July 1, 2015 the Assignor and the Assignee entered into an Immuno-Oncology License and Collaboration Agreement (the "Collaboration Agreement"); and

WHEREAS on September 28, 2018, the US Food and Drug Administration approved the cemiplimab-rwlc, PD-1 Licensed Product ("LIBTAYO Product") for the treatment of patients with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for curative surgery or curative radiation and Assignor and Assignee have sold the LIBTAYO Product in the USA for such treatment; and

WHEREAS Assignor and Assignee have commenced co-marketing of the LIBTAYO Product in the USA; and

WHEREAS Assignor is the owner of the trademark LIBTAYO SURROUND in the United States of America (the "Trademark") and US Trademark Registration No. 5643567 for the Trademark, registered on January 1, 2019 (the "Registration"); and

WHEREAS Assignor and Assignee have commenced using the Trademark in connection with providing medical information regarding diagnosis and treatment of metastatic cutaneous squamous cell carcinoma (CSCC), an example of which is attached to this Agreement[1]; and

[1] Such example available at:
https://www.libtayohcp.com/-/media/EMS/Conditions/Oncology/Brands/LibtayoHCP/pdf/LIBTAYO%20Surround%20Patient%20Support%20Program%20overview_US-LIB-1062a.pdf?la=en

WHEREAS pursuant to the Collaboration Agreement, Assignee is the Lead Commercialization Party for all PD-1 Licensed Products in the USA and is therefore entitled pursuant to the Collaboration Agreement to own and retain all right, title and interest in and to the Trademark and the Registration; and

WHEREAS in accordance with the terms of the Collaboration Agreement, the Assignor now wishes to assign the Trademark and the Registration to the Assignee and the Assignee wishes to accept such assignment;

**NOW THEREFORE,** it is hereby agreed as follows:

Section 1/ Assignment

NOW THEREFORE, for good and valuable consideration, receipt and sufficiency of which is hereby acknowledged, the Assignor hereby expressly assigns, as of the Effective Date, to the Assignee, Assignor's entire right, title and interest in the United States of America in and to the Trademark and the Registration, including the goodwill of the business connected with the use of and symbolized by the Trademark, and the right to claim priority, in accordance with the terms and conditions set forth herein.

Section 2/ Representations and warranties

2.1 Assignor hereby represents and warrants that it is the sole and beneficial owner of the Trademark and the Registration.

2.2 Assignor makes no warranty with respect to the Trademark and the Registration other than the one relating to their material existence.

Section 3 /Enforcement of the Trademark

3.1 The Assignment shall also include all the Assignor's rights to sue for past infringements which are not barred pursuant to any applicable statute of limitation at the Effective Date.

3.2 Only the Assignee will be entitled to act against any counterfeiter or infringer of the assigned Trademark including concerning any counterfeiting or infringing acts that have occurred before the Effective Date.

Section 4/Financial provisions

The Financial provisions applicable to this Agreement are those set forth in the Collaboration Agreement.

Section 5/Management of the Trademark

The prosecution and maintenance rules of the Trademark and Registration applicable to this Agreement are those set forth in the Collaboration Agreement.

Section 6/License

Assignee hereby grants to Assignor a co-exclusive license to the Trademark under the terms set forth in the Collaboration Agreement.

**Section 7/Applicable Law and conflict Resolution**

The Governing law, Jurisdiction and Conflict Resolution applicable to this Agreement are those set forth in the Collaboration Agreement.

**Section 8/Miscellaneous**

8.1 This Trademark Assignment Agreement shall be binding upon and inure to the benefit of the Parties and their respective successors and permitted assignees. Nothing in this Agreement shall create or be deemed to create any third party beneficiary rights in any individual, corporation, partnership, association, trust or other legal entity or organization not Party to this Agreement. No assignment of this Agreement or of any rights or obligations hereunder may be made by either Party without the prior written consent of the other Party and any attempted assignment without such required consent shall be null and void.

8.2 This Trademark Assignment Agreement may only be amended, supplemented or modified and any provision hereof may only be waived, pursuant to a written instrument making specific reference to this Agreement and executed by duly authorized representatives of the Parties.

8.3 This Trademark Assignment Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, and all of which together shall constitute one and the same instrument.

**IN WITNESS WHEREOF**, the Parties have caused this Agreement to be executed by their duly authorized representatives.

**Sanofi Biotechnology**

Signature:

Printed Name: Emmanuelle RAGON

Title: Proxy Holder

Date: July 1st 2019

**Regeneron Pharmaceuticals, Inc.**

Signature:

Printed Name: Gonzalo Merino

Title: Vice President, Chief Intellectual Property Counsel

Date: 7/1/19

LIBTAYO SURROUND™

# LIBTAYO Surround™ patient access and reimbursement support program

LIBTAYO®
(cemiplimab-rwlc)
Injection 350 mg

**LIBTAYO Surround is committed to providing reimbursement and access support for your patient's medication, as well as providing financial support for your eligible patients**

## Indications and Usage

LIBTAYO is indicated for the treatment of patients with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for curative surgery or curative radiation.

## Important Safety Information

### Warnings and Precautions

#### Severe and Fatal Immune-Mediated Adverse Reactions

Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue and usually occur during treatment; however, they can also occur after discontinuation. Early identification and management are essential to ensuring safe use of PD-1–blocking antibodies. Monitor for symptoms and signs of immune-mediated adverse reactions. Evaluate clinical chemistries, including liver tests and thyroid function tests, at baseline and periodically during treatment. Institute medical management promptly to include specialty consultation as appropriate.

**Please see additional Important Safety Information throughout and click here for full Prescribing Information.**

LIBTAYO SURROUND™

## LIBTAYO Surround comprises 3 core components

**Patient support**

LIBTAYO Surround offers patient support that facilitates access to medication when patients need assistance with out-of-pocket costs. This includes Copay and Patient Assistance Programs for eligible patients.

**Access and reimbursement support**

LIBTAYO Surround provides assistance with access and reimbursement. This begins with a benefits investigation and continues through the approval and reimbursement process for eligible patients. Additional service offerings include prior authorization (PA) assistance, appeal support, and claims assistance for billing and reimbursement.

**Product support**

LIBTAYO Surround provides support for product ordering and returns.

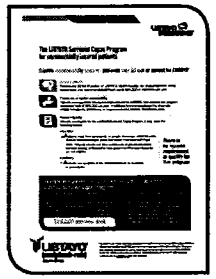
**For more information, call 1-877-LIBTAYO (1-877-542-8296) Option 1, Monday–Friday, 8 AM–8 PM Eastern time**

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

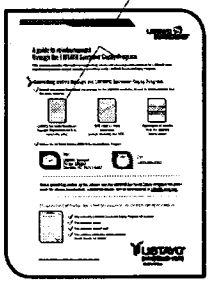
Please see additional Important Safety Information throughout and click here for full Prescribing Information.

## Patient support

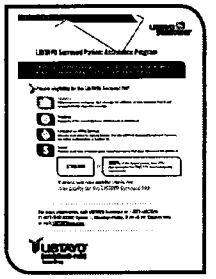
LIBTAYO Surround offers an array of support services for eligible patients who enroll to help them have access to LIBTAYO. LIBTAYO Surround provides financial support to eligible patients who need help with the cost of their medication. Information about the following programs for your patients is detailed in the handouts available at LIBTAYOhcp.com.



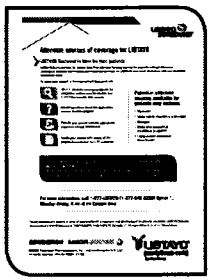
**LIBTAYO Surround Copay Program for eligible commercially insured patients**



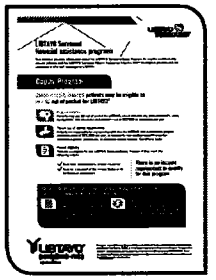
**LIBTAYO Surround Copay Program reimbursement guide and fax cover sheet**



**LIBTAYO Surround Patient Assistance Program**



**Identification of alternate sources of funding**



**LIBTAYO Surround financial assistance programs**

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

TRADEMARK
FILE: 006687 FRAME: 0852

# Access and reimbursement support

LIBTAYO Surround provides access and reimbursement support to help your patients receive their medication as quickly as possible.

## Benefits investigation

The LIBTAYO Surround Enrollment Form is the key to unlocking LIBTAYO Surround support services. Upon enrollment, a Reimbursement Specialist can provide the following assistance:

- Benefits investigation, which addresses:
  - How the medication may be covered under your patient's health plan
  - Acquisition options for your patient's medication
  - Your patient's eligibility for copay assistance
  - Any additional coverage information to facilitate your patient's access to medication

## PA, appeal, and claims assistance

Once your patient's coverage requirements have been verified, LIBTAYO Surround is available to provide ongoing support to facilitate approval of and reimbursement for LIBTAYO for eligible patients

- PA support to review and explain payer requirements
- Appeal assistance when PAs are denied
- Claims assistance to address questions as you prepare claims and to review the status of claims with the patient's health insurer

**LIBTAYO Surround Enrollment Forms are available for download at LIBTAYOhcp.com**

## Remember these important steps when filling out the LIBTAYO Surround Enrollment Form

**Step 1**
Make sure each field is complete and accurate

**Step 2**
Be sure to sign the form

**Step 3**
Fax the completed form to 1-833-853-8362

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

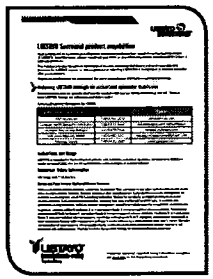
Please see additional Important Safety Information throughout and click here for full Prescribing Information.



LIBTAYO SURROUND™

# Product support

Infused medications, such as LIBTAYO, are available through numerous sources. Distribution depends on whether the product is accessed through a specialty distributor (buy and bill) or through a specialty pharmacy. A handout, available at LIBTAYOhcp.com, outlines how to order LIBTAYO through these 2 channels and how to return LIBTAYO if needed.



**LIBTAYO Surround product acquisition**

## Important Safety Information (cont'd)

### Warnings and Precautions (cont'd)

#### Severe and Fatal Immune-Mediated Adverse Reactions (cont'd)

In general, withhold LIBTAYO for Grade 3 or 4 and certain Grade 2 immune-mediated adverse reactions. Permanently discontinue LIBTAYO for Grade 4 and certain Grade 3 immune-mediated adverse reactions. For Grade 3 or 4 and certain Grade 2 immune-mediated adverse reactions, administer corticosteroids (1 to 2 mg/kg/day prednisone or equivalent) or other appropriate therapy until improvement to Grade 1 or less followed by a corticosteroid taper over 1 month. Consider administration of other systemic immunosuppressants in patients whose immune-mediated adverse reaction is not controlled with corticosteroids. Institute hormone replacement therapy for endocrinopathies as warranted.

**Immune-mediated pneumonitis:** Immune-mediated pneumonitis occurred in 2.4% of 534 patients receiving LIBTAYO, including Grade 5 (0.2%), Grade 3 (0.7%), and Grade 2 (1.3%). Pneumonitis led to permanent discontinuation of LIBTAYO in 1.3% of patients. Systemic corticosteroids were required in all patients with pneumonitis, including 85% who received prednisone ≥40 mg/day or equivalent. Pneumonitis resolved in 62% of patients. Withhold LIBTAYO for Grade 2, and permanently discontinue for Grade 3 or 4. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper.

**Immune-mediated colitis:** Immune-mediated colitis occurred in 0.9% of 534 patients receiving LIBTAYO, including Grade 3 (0.4%) and Grade 2 (0.6%). Colitis led to permanent discontinuation of LIBTAYO in 0.2% of patients. Systemic corticosteroids were required in all patients with colitis, including 60% who received prednisone ≥40 mg/day or equivalent. Colitis resolved in 80% of patients. Withhold LIBTAYO for Grade 2 or 3, and permanently discontinue for Grade 4. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper.

Please see additional Important Safety Information throughout and click here for full Prescribing Information.

## Important Safety Information (cont'd)

### Warnings and Precautions (cont'd)

#### Severe and Fatal Immune-Mediated Adverse Reactions (cont'd)

**Immune-mediated hepatitis:** Immune-mediated hepatitis occurred in 2.1% of 534 patients receiving LIBTAYO, including Grade 5 (0.2%), Grade 4 (0.2%), and Grade 3 (1.7%). Hepatitis led to permanent discontinuation of LIBTAYO in 0.9% of patients. Systemic corticosteroids were required in all patients with hepatitis, including 91% who received prednisone ≥40 mg/day or equivalent. Hepatitis resolved in 64% of patients. Withhold LIBTAYO if AST or ALT increases to more than 3 and up to 10 times the upper limit of normal (ULN) or if total bilirubin increases up to 3 times the ULN. Permanently discontinue LIBTAYO if AST or ALT increases to more than 10 times the ULN or total bilirubin increases to more than 3 times the ULN. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper.

**Immune-mediated endocrinopathies:** Withhold LIBTAYO if clinically necessary for Grade 2, 3, or 4.

- **Adrenal insufficiency:** Adrenal insufficiency occurred in 0.4% of 534 patients receiving LIBTAYO, including Grade 3 (0.2%) and Grade 2 (0.2%)
- **Hypophysitis:** Hypophysitis, which can result in hypopituitarism, occurred in 0.2% of 534 patients receiving LIBTAYO, which consisted of 1 patient with Grade 3 hypophysitis
- **Hypothyroidism:** Hypothyroidism occurred in 6% of 534 patients receiving LIBTAYO, including Grade 3 (0.2%) and Grade 2 (5.6%); no patients discontinued hormone replacement therapy
- **Hyperthyroidism:** Hyperthyroidism occurred in 1.5% of 534 patients receiving LIBTAYO, including Grade 3 (0.2%) and Grade 2 (0.4%); hyperthyroidism resolved in 38% of patients
- **Type 1 diabetes mellitus:** Type 1 diabetes mellitus, which can present with diabetic ketoacidosis, occurred in 0.7% of 534 patients, including Grade 4 (0.4%) and Grade 3 (0.4%); type 1 diabetes mellitus led to permanent discontinuation of LIBTAYO in 0.2% of patients

**Immune-mediated nephritis with renal dysfunction:** Immune-mediated nephritis occurred in 0.6% of 534 patients receiving LIBTAYO, including Grade 3 (0.4%) and Grade 2 (0.2%). Nephritis led to permanent discontinuation of LIBTAYO in 0.2% of patients. Systemic corticosteroids were required in all patients with nephritis, including 67% who received prednisone ≥40 mg/day or equivalent. Nephritis resolved in all patients. Withhold LIBTAYO for Grade 3, and permanently discontinue for Grade 4. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper.

**Immune-mediated dermatologic adverse reactions:** Immune-mediated dermatologic reactions, including erythema multiforme and pemphigoid, occurred in 1.7% of 534 patients receiving LIBTAYO, including Grade 3 (1.1%) and Grade 2 (0.6%). In addition, SJS and TEN have been observed with LIBTAYO and with other products in this class. Systemic corticosteroids were required in all patients with dermatologic reactions, including 89% who received prednisone ≥40 mg/day or equivalent. Dermatologic reactions resolved in 33% of patients. Approximately 22% of patients had recurrence of dermatologic reactions after re-initiation of LIBTAYO. Withhold LIBTAYO for Grade 3, and permanently discontinue for Grade 4. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper.

**Other immune-mediated adverse reactions:** The following clinically significant immune-mediated adverse reactions occurred at an incidence of <1% in 534 patients who received LIBTAYO or were reported with the use of other PD-1–blocking and PD-L1–blocking antibodies. Severe or fatal cases have been reported for some of these adverse reactions. Withhold LIBTAYO for Grade 3, and permanently discontinue for Grade 4. Resume in patients with complete or partial resolution (Grade 0 to 1) after corticosteroid taper.

- **Neurological:** Meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia gravis, Guillain-Barré syndrome, nerve paresis, and autoimmune neuropathy

LIBTAYO® (cemiplimab-rwlc) Injection 350 mg

**Please see additional Important Safety Information throughout and click here for full Prescribing Information.**

LIBTAYO SURROUND™

## Important Safety Information (cont'd)

### Warnings and Precautions (cont'd)

#### Severe and Fatal Immune-Mediated Adverse Reactions (cont'd)

**Other immune-mediated adverse reactions (cont'd)**

- **Cardiovascular:** Myocarditis, pericarditis, and vasculitides
- **Ocular:** Uveitis, iritis, and other ocular inflammatory toxicities. Some cases can be associated with retinal detachment. Various Grades of visual impairment to include blindness can occur. If uveitis occurs in combination with other immune-mediated adverse reactions, consider a Vogt-Koyanagi-Harada–like syndrome, as this may require treatment with systemic corticosteroids to reduce the risk of permanent vision loss
- **Gastrointestinal:** Pancreatitis to include increases in serum amylase and lipase levels, gastritis, and duodenitis
- **Musculoskeletal and connective tissue:** Myositis, rhabdomyolysis, and associated sequelae, including renal failure, arthritis, and polymyalgia rheumatica
- **Hematological and immunological:** Hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenic purpura, and solid organ transplant rejection

#### Infusion-related reactions

Severe infusion-related reactions (Grade 3) occurred in 0.2% of patients receiving LIBTAYO. Monitor patients for signs and symptoms of infusion-related reactions. Interrupt or slow the rate of infusion for Grade 1 or 2, and permanently discontinue for Grade 3 or 4.

#### Embryo-fetal toxicity

LIBTAYO can cause fetal harm when administered to a pregnant woman due to an increased risk of immune-mediated rejection of the developing fetus resulting in fetal death. Advise women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with LIBTAYO and for at least 4 months after the last dose.

### Adverse reactions

- Serious adverse reactions occurred in 28% of patients. Serious adverse reactions that occurred in ≥2% of patients were cellulitis, sepsis, pneumonia, pneumonitis, and urinary tract infection. The most common Grade 3-4 adverse reactions (≥2%) were cellulitis, sepsis, hypertension, pneumonia, musculoskeletal pain, skin infection, urinary tract infection, and fatigue
- LIBTAYO was permanently discontinued due to adverse reactions in 5% of patients; adverse reactions resulting in permanent discontinuation were pneumonitis, autoimmune myocarditis, hepatitis, aseptic meningitis, complex regional pain syndrome, cough, and muscular weakness
- The most common adverse reactions (incidence ≥20%) were fatigue, rash, and diarrhea

### Use in specific populations

- **Lactation:** Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment and for at least 4 months after the last dose of LIBTAYO
- **Females and males of reproductive potential:** Verify pregnancy status in females of reproductive potential prior to initiating LIBTAYO

**Please click here for full Prescribing Information.**

For any questions or concerns, or to report side effects with a Regeneron and Sanofi product for patients enrolled in LIBTAYO Surround, please contact LIBTAYO Surround at **1-877-LIBTAYO** (1-877-542-8296) **Option 1**, Monday–Friday, 8 AM–8 PM Eastern time.

REGENERON SANOFI GENZYME



LIBTAYO® (cemiplimab-rwlc) Injection 350 mg