Cemiplimab

Targets (1)

IDENTIFICATION

Name	Cemiplimab
Accession Number	DB14707
Type	Biotech
Groups	Approved, Investigational
Biologic Classification	Protein Based Therapies Monoclonal antibody (mAb)
Description	The U.S. Food and Drug Administration (FDA) approved Cemiplimab (*Libtayo*), manufactured by Regeneron Pharmaceuticals, on September 28, 2018. This is the first FDA approval of a drug specifically for the treatment of advanced cutaneous squamous cell carcinoma (CSCC) [1,4].
Protein chemical formula	Not Available
Protein average weight	146000.0 Da
Sequences	Not Available
Synonyms	Cemiplimab-rwlc
External IDs	REGN-2810 / REGN2810

Prescription Products

Show 10 entries Search

NAME	DOSAGE	STRENGTH	ROUTE	LABELLER	MARKETING START	MARKETING END	
Libtayo	Injection	50 mg/1mL	Intravenous	Regeneron Pharmaceuticals, Inc.	2018-09-28	Not applicable	
Libtayo	Solution	350 mg	Intravenous	Sanofi Aventis	Not applicable	Not applicable	
Libtayo	Solution	250 mg	Intravenous	Sanofi Aventis	Not applicable	Not applicable	

Showing 1 to 3 of 3 entries ‹ 1 ›

Categories	Amino Acids, Peptides, and Proteins	Antineoplastic Agents, Immunological	Immunoglobulins
	Antibodies	Blood Proteins	Immunoproteins
	Antineoplastic Agents	Globulins	Proteins
			Serum Globulins
UNII	6QVL057INT		
CAS number	1801342-60-8		

PHARMACOLOGY

Drugs

of patients with metastatic cutaneous squamous cell carcinoma (CSCC) or locally advanced CSCC who are not candidates for curative surgery or curative radiation [Label,1].

Associated Conditions

Metastatic cutaneous squamous cell carcinoma

Locally advanced cutaneous squamous cell carcinoma, and not a candidate for curative surgery or curative radiation

Pharmacodynamics

Cemiplimab inhibits tumor growth by an immune-mediated mechanism, specifically by the inhibition of the programmed death receptor 1 (PD-1), treating cutaneous squamous cell carcinoma [Label, 1, 3].

Mechanism of action

Binding of the programmed death receptor (PD) ligands PD-L1 and PD-L2, to the PD-1 receptor, which is found on T cells, inhibits T-cell proliferation and cytokine production. The upregulation of PD-1 ligands occurs in some tumors and signaling through this pathway may contribute to the inhibition of active T-cell immune surveillance of tumors. Cemiplimab is a recombinant human immunoglobulin G4 (IgG4) monoclonal antibody that binds to the PD-1 receptor and blocks its interaction with PD-L1 and PD-L2 ligands, causing PD-1 pathway-mediated inhibition of the immune response, including the anti-tumor immune response. In mouse tumor models, blocking PD-1 activity resulted in decreased rates of tumor growth [Label].

TARGET	ACTIONS	ORGANISM
(A) Programmed cell death protein 1	inhibitor	Humans

Absorption

After a dose of 350 mg cemiplimab administered intravenously every 3 weeks, median steady-state concentrations (CV%) of cemiplimab ranged between a maximum concentration (Cmax,ss) of 166 mcg/mL (28%) and a minimum concentration (Cmin,ss) of 59 mcg/mL (48%). Steady-state exposure was achieved after approximately 4 months [Label].

Volume of distribution

The volume of distribution of cemiplimab at steady state is 5.3 L (25%) [Label].

Protein binding

Not Available

Metabolism

Not Available

Route of elimination

Not Available

Half life	The elimination half-life (CV%) at steady state is 19 days (30%) [Label].
Toxicity	The most common adverse reactions (incidence ≥ 20%) were fatigue, rash, and diarrhea in clinical studies [Label]. Severe and fatal immune-mediated adverse reactions may occur in any organ system or tissue, including the following: immune-mediated pneumonitis, immune-mediated colitis, immune-mediated hepatitis, immune-mediated endocrinopathies, immune-mediated dermatologic adverse reactions, and immune-mediated nephritis and renal dysfunction. Monitor for symptoms and signs of immune-mediated adverse reactions. Regularly perform chemistry panels, including liver and thyroid function, at baseline and periodically during treatment. Withhold or permanently discontinue this drug and administer corticosteroids based on the severity of the reaction. Infusion-related reactions may also occur. Interrupt, decrease the rate of infusion or permanently discontinue based on the severity of the reaction. **A note on fetal toxicity:** This drug can cause fetal harm. Advise females of reproductive potential of the potential risk to a fetus and use of effective contraception [Label].
Affected organisms	Humans and other mammals
Pathways	Not Available
Pharmacogenomic Effects/ADRs	Not Available

INTERACTIONS

Drug Interactions

ALL DRUGS | APPROVED | VET APPROVED | NUTRACEUTICAL | ILLICIT | WITHDRAWN | INVESTIGATIONAL | EXPERIMENTAL

Show 10 entries Search

DRUG	INTERACTION
Abciximab	The risk or severity of adverse effects can be increased when Abciximab is combined with Cemiplimab.
Abituzumab	The risk or severity of adverse effects can be increased when Abituzumab is combined with Cemiplimab.
Abrilumab	The risk or severity of adverse effects can be increased when Cemiplimab is combined with Abrilumab.
Adalimumab	The risk or severity of adverse effects can be increased when Adalimumab is combined with Cemiplimab.
Adecatumumab	The risk or severity of adverse effects can be increased when Adecatumumab is combined with Cemiplimab.
Aducanumab	The risk or severity of adverse effects can be increased when Aducanumab is combined with Cemiplimab.
Afelimomab	The risk or severity of adverse effects can be increased when Afelimomab is combined with Cemiplimab.
Alefacept	The risk or severity of adverse effects can be increased when Alefacept is combined with Cemiplimab.
Alemtuzumab	The risk or severity of adverse effects can be increased when Alemtuzumab is combined with Cemiplimab.
Alirocumab	The risk or severity of adverse effects can be increased when Alirocumab is combined with Cemiplimab.

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ADDITIONAL DATA AVAILABLE

Food Interactions Not Available

General References

1. Migden MR, Rischin D, Schmults CD, Guminski A, Hauschild A, Lewis KD, Chung CH, Hernandez-Aya L, Lim AM, Chang ALS, Rabinowits G, Thai AA, Dunn LA, Hughes BGM, Khushalani NI, Modi B, Schadendorf D, Gao B, Seebach F, Li S, Li J, Mathias M, Booth J, Mohan K, Stankevich E, Babiker HM, Brana I, Gil-Martin M, Homsi J, Johnson ML, Moreno V, Niu J, Owonikoko TK, Papadopoulos KP, Yancopoulos GD, Lowy I, Fury MG: PD-1 Blockade with Cemiplimab in Advanced Cutaneous Squamous-Cell Carcinoma. N Engl J Med. 2018 Jul 26;379(4):341-351. doi: 10.1056/NEJMoa1805131. Epub 2018 Jun 4. [PubMed:29863979]
2. Authors unspecified: Drug and Device News. P T. 2017 Nov;42(11):665-691. [PubMed:29089720]
3. Sidaway P: Cemiplimab effective in cutaneous SCC. Nat Rev Clin Oncol. 2018 Aug;15(8):472. doi: 10.1038/s41571-018-0056-5. [PubMed:29921845]
4. FDA Approves Libtayo [Link]
5. Libtayo, Regeneron [Link]

External Links Wikipedia Cemiplimab

FDA label Download (239 KB)

CLINICAL TRIALS

Clinical Trials

Show 10 entries Search

PHASE	STATUS	PURPOSE	CONDITIONS	COUNT
1	Active Not Recruiting	Treatment	Advanced Malignancies / Cancer, Advanced	1
1	Active Not Recruiting	Treatment	Melanoma	1
1	Active Not Recruiting	Treatment	Metastatic Squamous Cell Carcinoma Neck / Metastatic Squamous Cell Carcinoma of Head / Recurrent Squamous Cell Carcinoma of Head / Recurrent Squamous Cell Carcinoma of Neck	1
1	Recruiting	Treatment	Acute Lymphoblastic Leukaemias (ALL) / Malignant Lymphomas	1
1	Recruiting	Treatment	Advanced Malignancies	1
1	Recruiting	Treatment	Cutaneous Squamous Cell Carcinoma	1
1	Recruiting	Treatment	Lung Cancer Non-Small Cell Cancer (NSCLC)	1
1	Recruiting	Treatment	Malignancies	1
1	Recruiting	Treatment	Renal Cell Adenocarcinoma	1
1	Withdrawn	Treatment	Advanced Malignancies	1

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PHARMACOECONOMICS

Manufacturers Not Available

Packagers Not Available

Dosage forms

Show 10 entries Search

FORM	ROUTE	STRENGTH
Injection	Intravenous	50 mg/1mL
Solution	Intravenous	250 mg
Solution	Intravenous	350 mg

Showing 1 to 3 of 3 entries ‹ 1 ›

Prices Not Available

Prices	Not Available
Patents	Not Available

PROPERTIES

State	Not Available
Experimental Properties	Not Available

TAXONOMY

Description	Not Available
Kingdom	Organic Compounds
Super Class	Organic Acids
Class	Carboxylic Acids and Derivatives
Sub Class	Amino Acids, Peptides, and Analogues
Direct Parent	Peptides
Alternative Parents	Not Available
Substituents	Not Available
Molecular Framework	Not Available
External Descriptors	Not Available

TARGETS

1. Programmed cell death protein 1

Details

Kind	Protein
Organism	Humans
Pharmacological action	Yes
Actions	Inhibitor
General Function	Signal transducer activity
Specific Function	Inhibitory cell surface receptor involved in the regulation of T-cell function during immunity and tolerance. Upon ligand binding, inhibits T-cell effector functions in an antigen-specific manner. ...
Gene Name	PDCD1
Uniprot ID	Q15116
Uniprot Name	Programmed cell death protein 1
Molecular Weight	31646.635 Da

References

1. Migden MR, Rischin D, Schmults CD, Guminski A, Hauschild A, Lewis KD, Chung CH, Hernandez-Aya L, Lim AM, Chang ALS, Rabinowits

G, Thai AA, Dunn LA, Hughes BGM, Khushalani NI, Modi B, Schadendorf D, Gao B, Seebach F, Li S, Li J, Mathias M, Booth J, Mohan K, Stankevich E, Babiker HM, Brana I, Gil-Martin M, Homsi J, Johnson ML, Moreno V, Niu J, Owonikoko TK, Papadopoulos KP, Yancopoulos

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