Cemiplimab

PD-1 monoclonal antibody

Research & Development

Cutaneous Squamous Cell Carcinoma

A Phase 2 Trial of Neoadjuvant Cemiplimab in Patients with Stage II to IV (M0) Cutaneous Squamous Cell Carcinoma

Clinical trial design

Estimated enrollment (N=76)

Patients with Stage II to IV (M0) CSCC, for which surgery would be recommended in routine clinical practice.
For stage II patients, lesion must be ≥3 cm at the longest diameter.

Cemiplimab
350 mg IV Q3W
4 doses

Response assessments† after 2 doses

Surgery

Adjuvant Radiotherapy

OR

Cemiplimab
350 mg IV Q3W
16 doses

OR

Observation only

Primary endpoint:
pCR rate (central)

Secondary endpoints:
pCR rate (local),
mCR rate (central & local),
ORR, EFS, DFS, OS, Safety

Study Sites in EU:
Germany (Dresden, Essen, Kiel, Tübingen)

† Tumour response assessed using Response Evaluation Criteria In Solid Tumors(RECIST) 1.113 or modified WHO or composite response criteria.

IV=intravenously; Q3W=every 3 weeks; pCR=pathologic complete response; mPR=major pathologic response; ORR=objective response rate; EFS=event free survival; DFS=disease free survival; OS=overall survival; CR=complete response

ClinicalTrials.gov, NCT04154943. Accessed March 2022.

NCT04154943

MAT-DE-2001478 V3 03/2022

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Cemiplimab

PD-1 monoclonal antibody

Research & Development

Cutaneous Squamous Cell Carcinoma

Clinical trial design

Selected inclusion criteria:

- Adults aged ≥18 years old
- Stage II to IV (M0) CSCC, for which surgery would be recommended in routine clinical practice
  - For stage II patients, lesion must be ≥3 cm at the longest diameter
- At least 1 lesion that is measurable by RECIST 1.1
- ECOG performance status ≤1
- Adequate organ, bone marrow, and hepatic function

Selected exclusion criteria:

- Solid malignancy within 5 years of enrollment, or hematologic malignancy at any time
- Distant metastatic disease (M1), visceral and/or distant nodal
- Prior radiation therapy for CSCC
- Corticosteroid therapy (>10 mg prednisone/day or equivalent) within 14 days of the first dose of study drug
- Autoimmune disease that has required systemic therapy within 5 years of enrollment
- History of interstitial lung disease or active, noninfectious pneumonitis that required immune-suppressive doses of glucocorticoids
- Uncontrolled HIV, HBV or HCV infection, or diagnosis of immunodeficiency
- Active tuberculosis

Other protocol-defined inclusion/exclusion criteria apply.

CSCC=cutaneous squamous cell carcinoma; ECOG=Eastern Cooperative Oncology Group; HBV=hepatitis B virus; HCV=hepatitis C virus; HIV=human immunodeficiency virus; PD-1=programmed cell death-1; RECIST=response evaluation criteria in solid tumors

ClinicalTrials.gov, NCT04154943. Accessed March 2022.

For further information visit www.clinicaltrials.gov.

CEMIPLIMAB NCT04154943

Cemiplimab is approved in the EU for the treatment of adult patients with metastatic or locally advanced cutaneous squamous cell carcinoma who are not candidates for curative surgery or curative radiation but is under investigation and has not been fully evaluated by regulatory authorities in all other cancer types.

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Cemiplimab

PD-1 monoclonal antibody

Research & Development

Cutaneous Squamous Cell Carcinoma

A Phase 2 Trial of Cemiplimab in Patients with Advanced Cutaneous Squamous Cell Carcinoma

Clinical trial design

Estimated enrollment (N=433)

Group 1 Metastatic (nodal or distant) CSCC	**Cemiplimab** 3 mg/kg IV Q2W	
Group 2 Locally advanced CSCC; not candidates for surgery or radiation	**Cemiplimab** 3 mg/kg IV Q2W	
Group 3 Metastatic (nodal or distant) CSCC	**Cemiplimab** 350 mg IV Q3W	**Primary endpoint:** ORR
Group 4 Advanced CSCC (metastatic or locally advanced)	**Cemiplimab** IV Q4W	**Key secondary endpoints:** DOR, PFS, OS, CR, PK, safety, and tolerability
Group 6 Advanced CSCC (metastatic or locally advanced)	**Cemiplimab** IV Q3W	

CR=complete response; CSCC=cutaneous squamous cell carcinoma; DOR=duration of response; IV=intravenous; N=number of patients; ORR=objective response rate; OS=overall survival; PD-1=programmed cell death-1; PFS=progression-free survival; PK=pharmacokinetics; Q2W=every 2 weeks; Q3W=every 3 weeks; Q4W=every 4 weeks

ClinicalTrials.gov, NCT02760498. Accessed March 2022; Migden MR. N Engl J Med 2018;379:341-351.

NCT02760498

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Cemiplimab

PD-1 monoclonal antibody

Research & Development

Cutaneous Squamous Cell Carcinoma

Clinical trial design

Selected inclusion criteria:

- Adults (≥18 years) with histologically confirmed diagnosis of invasive CSCC
- At least 1 measurable lesion per RECIST 1.1
- ECOG performance status ≤1
- Adequate bone marrow function, renal function, and hepatic function
- Archived or newly obtained tumor material
- Patients must consent to undergo biopsies of CSCC lesions (Groups 2, 4, and 6)
- Surgical or radiological treatment of lesions contraindicated

Selected exclusion criteria:

- Ongoing or recent (within 5 years) evidence of significant autoimmune disease that required treatment with systemic immunosuppressive treatments
- Prior treatment with a BRAF inhibitor or an agent that blocks the PD-1/PD-L1 pathway
- History of non-infectious pneumonitis within the last 5 years, solid organ transplant, untreated brain metastasis(es) that may be considered active, or any medical co-morbidity, physical examination finding, or metabolic dysfunction, or clinical laboratory abnormality that renders the patient unsuitable
- Immunosuppressive corticosteroid dose (>10 mg prednisone daily or equivalent) within 28 days prior to treatment with cemiplimab
- Prior treatment with other immune-modulating agents within 4 weeks prior to first dose of cemiplimab, or associated with immune-mediated adverse events that were ≥ grade 1 within 90 days prior to first dose of cemiplimab, or associated with toxicity that resulted in discontinuation of the immune-modulating agent
- HIV, or active HBV or HCV infection
- Allergic reactions or acute hypersensitivity reaction attributed to antibody treatments, or a known allergy to doxycycline or tetracycline

Other protocol-defined inclusion/exclusion criteria apply.

CSCC=cutaneous squamous cell carcinoma; ECOG=Eastern Cooperative Oncology Group; HBV=hepatitis B virus; HCV=hepatitis C virus; HIV=human immunodeficiency virus; PD-1=programmed cell death-1; PD-L1=programmed death ligand 1; RECIST=response evaluation criteria in solid tumors

ClinicalTrials.gov, NCT02760498. Accessed March 2022; Migden MR. N Engl J Med 2018;379:341-351.

For further information visit www.clinicaltrials.gov.

CEMIPLIMAB NCT02760498

Cemiplimab is approved in the EU for the treatment of adult patients with metastatic or locally advanced cutaneous squamous cell carcinoma who are not candidates for curative surgery or curative radiation but is under investigation and has not been fully evaluated by regulatory authorities in all other cancer types.

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Cemiplimab

PD-1 monoclonal antibody

Research & Development

Cervical Cancer

A Phase 3 Trial of Cemiplimab Versus Investigator's Choice Chemotherapy in Recurrent or Metastatic Platinum-Refractory Cervical Cancer

Clinical trial design

Estimated enrollment (N=590)

Patients with recurrent, persistent, and/or metastatic cervical cancer with squamous cell histology without curative intent option

R

1:1

Cemiplimab
350 mg IV Q3W

IC chemotherapy
- **Pemetrexed** 500 mg/m² Q3W
- **Gemcitabine** 1000 mg/m² Days 1 and 8, every 21 days
- **Topotecan** 1 mg/m² daily x 5 days, every 21 days
- **Irinotecan** 100 mg/m² weekly x 4, followed by 2 weeks rest for a 42-day (6-week) cycle
- **Vinorelbine** 30 mg/m² Days 1 and 8, every 21 days

Primary endpoint:
OS

Key secondary endpoints:
PFS, ORR, DOR
QoL, safety

DOR=duration of response; IC=investigator's choice; IV=intravenous; N=number of patients; ORR=objective response rate; OS=overall survival; PD-1=programmed cell death-1; PFS=progression-free survival; Q3W=every 3 weeks; QoL=quality of life; R=randomization

ClinicalTrials.gov, NCT03257267. Accessed March 2022; Tewari KS. TPS5600. Poster presented at the American Society of Clinical Oncology, Chicago, IL, June 1-5, 2018.

NCT03257267

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Cemiplimab

PD-1 monoclonal antibody

Research & Development

Cervical Cancer

Clinical trial design

Selected inclusion criteria:

- Adults (≥18 years) with recurrent, persistent, and/or metastatic cervical cancer, for which there is not a curative intent option (surgery or radiation therapy with or without chemotherapy)
- Squamous cell histology
- Tumor progression or recurrence after treatment with platinum therapy for recurrent, persistent, or metastatic cervical cancer
- At least 1 radiographically measurable lesion as defined by RECIST 1.1
- ECOG performance status ≤1
- Adequate bone marrow function, renal function, and hepatic function
- Received prior bevacizumab therapy or had clinically documented reason why not administered
- Received prior paclitaxel therapy or had clinically documented reason why not administered

Selected exclusion criteria:

- Ongoing or recent (within 5 years) evidence of significant autoimmune disease that required treatment with systemic immunosuppressive treatments
- Prior treatment with an agent that blocks the PD-1/PD-L1 pathway
- Prior treatment with other systemic immune-modulating agents within 4 weeks prior to first dose of cemiplimab, or associated with immune-mediated adverse events of any grade within 90 days prior to first dose of cemiplimab, or associated with toxicity that resulted in discontinuation of the immune-modulating agent
- Untreated brain metastasis that may be considered active
- Immunosuppressive corticosteroid therapy (>10 mg prednisone/day or equivalent) within 4 weeks prior to first dose of cemiplimab

Other protocol-defined inclusion/exclusion criteria apply.

ECOG=Eastern Cooperative Oncology Group; PD-1=programmed cell death-1; PD-L1=programmed death ligand 1; RECIST=response evaluation criteria in solid tumors

ClinicalTrials.gov, NCT03257267. Accessed March 2022; Tewari KS. TPS5600. Poster presented at the American Society of Clinical Oncology, Chicago, IL, June 1-5, 2018.

For information, visit www.clinicaltrials.gov or please call 844-REGN-MID.

CEMIPLIMAB NCT03257267

Cemiplimab is approved in the EU for the treatment of adult patients with metastatic or locally advanced cutaneous squamous cell carcinoma who are not candidates for curative surgery or curative radiation but is under investigation and has not been fully evaluated by regulatory authorities in all other cancer types.

MAT-DE-2001478 V3 03/2022

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Cemiplimab

PD-1 monoclonal antibody

Research & Development

Non-small Cell Lung Cancer

A Phase 3 Trial of Cemiplimab in Combination with Platinum-Based Chemotherapy in Patients with Advanced or Metastatic Non-Small Cell Lung Cancer

Clinical trial design

Estimated enrollment (N=774)

Patients with systemic treatment-naïve stage IIIB, IIIC, or stage IV squamous or non-squamous NSCLC

Part 1

R

- **Cemiplimab** 350 mg IV Q3W + **Platinum-based chemotherapy** Q3W for 4 cycles
- **Cemiplimab** 350 mg IV Q3W + **Platinum-based chemotherapy** Q3W for 2 cycles + **Ipilimumab** 50 mg Q6W x 4
- **Placebo** + **Platinum-based chemotherapy** Q3W for 4 cycles

Part 2

R

- **Cemiplimab** 350 mg IV Q3W + **Platinum-based chemotherapy** Q3W for 4 cycles
- **Placebo** + **Platinum-based chemotherapy** Q3W for 4 cycles

Primary endpoints: OS

Key secondary endpoints: PFS, ORR

IV=intravenous; N=number of patients; NSCLC=non-small cell lung cancer; ORR=objective response rate; OS=overall survival; PD-1=programmed cell death-1; PFS=progression-free survival; Q3W=every 3 weeks; Q6W=every 6 weeks; R=randomization
ClinicalTrials.gov, NCT03409614. Accessed March 2022; Rizvi N et al. J Thorac Oncol 2018 (suppl; abstr. P3. 04-25) (poster presentation).

NCT03409614

MAT-DE-2001478 V3 03/2022

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Cemiplimab

PD-1 monoclonal antibody

Research & Development

Non-small Cell Lung Cancer

Clinical trial design

Selected inclusion criteria:

- Adults ≥18 years with histologically or cytologically documented squamous or nonsquamous NSCLC with stage IIIB or IIIC disease who are not candidates for treatment with definitive concurrent chemoradiation or patients with stage IV disease if they have not received prior systemic treatment for recurrent or metastatic NSCLC
  - In Japan, adults ≥20 years of age
- Part 1 only: expression of PD-L1 in <50% of tumor cells by immunohistochemistry
- At least 1 radiographically measurable lesion per RECIST 1.1
- ECOG performance status ≤1
- Adequate bone marrow function, renal function, and hepatic function
- Archival or newly obtained formalin-fixed tumor tissue from a metastatic/recurrent site, which has not previously been irradiated

Selected exclusion criteria:

- Part 1 only: non-smokers, defined as ≤100 cigarettes in a lifetime
- Ongoing or recent evidence of significant autoimmune disease requiring systemic immunosuppressive treatments
- Tumors positive for EGFR gene mutations, ALK gene translocations, ROS1 fusions
- Active or untreated brain metastases or spinal cord compression
- Encephalitis, meningitis, or uncontrolled seizures within a year prior to informed consent
- Patients with a condition requiring corticosteroid therapy (>10 mg prednisone/day or equivalent) within 14 days of randomization
- History of interstitial lung disease (e.g., idiopathic pulmonary fibrosis or organizing pneumonia), or active, noninfectious pneumonitis requiring immunosuppressive doses of glucocorticoids to assist with management of pneumonitis within the last 5 years

Other protocol-defined inclusion/exclusion criteria apply.

ALK=anaplastic lymphoma kinase; ECOG=Eastern Cooperative Oncology Group; EGFR=epidermal growth factor receptor; NSCLC=non-small cell lung cancer; PD-1=programmed cell death-1; PD-L1=programmed death ligand 1; RECIST=response evaluation criteria in solid tumors; ROS1=C-ros oncogene receptor tyrosine kinase

ClinicalTrials.gov, NCT03409614. Accessed March 2022; Rizvi N et al. J Thorac Oncol 2018 (suppl; abstr. P3. 04-25) (poster presentation).

For information, visit www.clinicaltrials.gov or please call 844-REGN-MID.

CEMIPLIMAB NCT03409614

Cemiplimab is approved in the EU for the treatment of adult patients with metastatic or locally advanced cutaneous squamous cell carcinoma who are not candidates for curative surgery or curative radiation but is under investigation and has not been fully evaluated by regulatory authorities in all other cancer types.

MAT-DE-2001478 V3 03/2022

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Cemiplimab

PD-1 monoclonal antibody

Research & Development

Non-small Cell Lung Cancer

A Phase 3 trial of Cemiplimab Compared to Platinum-Based Chemotherapy in Partients With Advanced or Metastatic Non-Small Cell Lung Cancer (NSCLC)

Clinical trial design

Estimated enrollment (N=710)

Patients with squamous or non-squamous NSCLC with stage IIIB or stage IIIC disease

- not candidates for treatment with definitive concurrent chemoradiation

OR

Patients with stage IV squamous or non-squamous NSCLC

- no prior systemic treatment for recurrent or metastatic NSCLC

R

Standard-of-care platinum doublet chemotherapy (4–6 cycles)

Cemiplimab monotherapy 350mg IV Q3W

Primary endpoints: OS, PFS (assessed by IRC using RECIST criteria)

Key secondary endpoint: ORR

Treat until PD or 108 weeks*

* Patients in the cemiplimab arm who progress may receive cemiplimab combined with chemotherapy, whereas patients in the chemotherapy arm may cross over to receive cemiplimab for up to 108 weeks at the time of confirmed PD.

ICR=independent central review; IV=intravenous; NSCLC=non-small cell lung cancer; ORR=overall response rate; OS=overall survival; PD=progressive disease; PD-L1=programmed cell death ligand 1; PFS = progression-free survival; Q3W=every 3 weeks; RECIST=Response Evaluation Criteria in Solid Tumors
ClinicalTrials.gov, NCT03088540. Accessed March 2022; Sezer A et al. ESMO 2020 (Abstract #1158).

NCT03088540

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Cemiplimab

PD-1 monoclonal antibody

Research & Development

Non-small Cell Lung Cancer

Clinical trial design

Selected inclusion criteria:

- Patients ≥18 years with histologically or cytologically documented squamous or non-squamous NSCLC with stage IIIB or IIIC disease who are not candidates for treatment with definitive concurrent chemoradiation, or patients with stage IV disease who have not received prior systemic treatment for recurrent or metastatic NSCLC
- Archival or newly obtained formalin-fixed tumor tissue from a metastatic/recurrent site which has not been previously irradicated
- Expression of PD-L1 in ≥50% of tumor cells by immunohistochemistry
- At least 1 radiographically measurable lesion per RECIST 1.1
- ECOG performance status of ≤1
- Adequate organ and bone marrow function

Selected exclusion criteria:

- Non-smokers, defined as <100 cigarettes in a lifetime
- Tumors positive for EGFR gene mutations, ALK gene translocations, or ROS1 fusions
- Active or untreated brain metastases or spinal cord compression; adequately treated, clinically stable CNS metastases were allowed
- Uncontrolled infection with HBV, HCV or HIV or diagnosis of immunodeficiency; controlled HBV, HCV or HIV infections were allowed
- Encephalitis, meningitis, or uncontrolled seizures in the year prior to randomization
- History of interstitial lung disease, or active, noninfectious pneumonitis requiring immune-suppressive doses of glucocorticoids
- Active, known, or suspected autoimmune disease that has required systemic therapy in the past 2 years
- Patient with a condition requiring corticosteroid therapy (>10 mg prednisone/day or equivalent) within 14 days of randomization
- Prior treatment with an agent that blocks the PD- 1/PD-L1 pathway
- Treatment-related immune-mediated adverse events from immune-modulatory agents

Other protocol-defined inclusion/exclusion criteria apply.

ALK=anaplastic lymphoma kinase; ECOG=Eastern Cooperative Oncology Group; EGFR=epidermal growth factor receptor; HBV=hepatitis B virus; HCV=hepatitis C virus; HIV=human immunodeficiency virus; NSCLC=non-small cell lung cancer; PD-1=programmed cell death protein-1; PD-L1=programmed death-ligand 1; RECIST=response evaluation criteria in solid tumors; ROS1=C-ros oncogene receptor tyrosine kinase

ClinicalTrials.gov, NCT03088540. Accessed March 2022; Sezer A et al. ESMO 2020 (Abstract #1158).

For information, visit www.clinicaltrials.gov.

CEMIPLIMAB NCT03088540

Cemiplimab is approved in the EU for the treatment of adult patients with metastatic or locally advanced cutaneous squamous cell carcinoma who are not candidates for curative surgery or curative radiation but is under investigation and has not been fully evaluated by regulatory authorities in all other cancer types.

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Cemiplimab

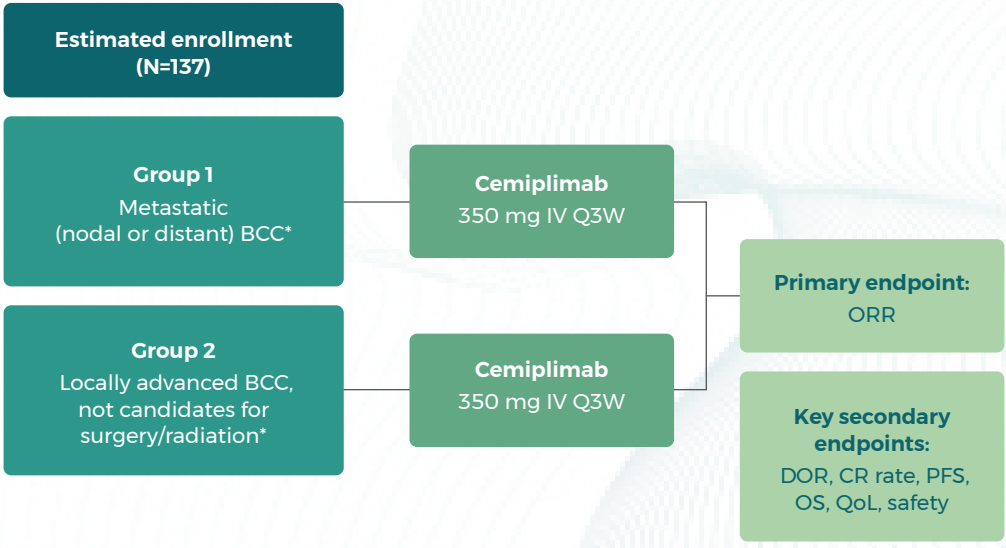
PD-1 monoclonal antibody

Research & Development

Basal Cell Carcinoma

A Phase 2 Trial of Cemiplimab in Patients with Advanced Basal Cell Carcinoma

Clinical trial design



*Patients experienced progression of disease following hedgehog inhibitor (HHI) therapy or were intolerant of prior HHI therapy.

BCC=basal cell carcinoma; CR=complete response; DOR=duration of response; IV=intravenous; N=number of patients; ORR=objective response rate; OS=overall survival; PD-1=programmed cell death-1; PFS=progression-free survival; QoL=quality of life; Q3W=every 3 weeks

ClinicalTrials.gov, NCT03132636. Accessed March 2022; Lewis KD et al. Ann Oncol 2018. 29 (suppl; 5 abstr.1240TIP) (poster presentation).

NCT03132636

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Cemiplimab

PD-1 monoclonal antibody

Research & Development

Basal Cell Carcinoma

Clinical trial design

Selected inclusion criteria:

- Adults (≥18 years) with histologically confirmed diagnosis of invasive BCC
- Progression of disease on HHI therapy or intolerance of prior HHI therapy
- ECOG performance status ≤1
- Adequate bone marrow function, renal function, and hepatic function
- At least 1 measurable lesion
- ***Group 2 only:*** must not be a candidate for radiation therapy or surgery

Selected exclusion criteria:

- Ongoing or recent (within 5 years) evidence of significant autoimmune disease that requires treatment with systemic immunosuppressive treatments
- Prior treatment with an agent that blocks the PD-1/PD-L1 pathway
- Untreated brain metastasis that may be considered active
- History of solid organ transplant
- Prior treatment with systemic immune-modulating agents within 28 days before treatment with cemiplimab
- Immunosuppressive corticosteroid doses (>10 mg prednisone daily or equivalent) within 28 days prior to treatment with cemiplimab

Other protocol-defined inclusion/exclusion criteria apply.

BCC=basal cell carcinoma; ECOG=Eastern Cooperative Oncology Group; HHI=hedgehog inhibitor; PD-1=programmed cell death-1; PD-L1=programmed death ligand 1

ClinicalTrials.gov, NCT03132636. Accessed March 2022; Lewis KD et al. Ann Oncol 2018. 29 (suppl; 5 abstr.1240TIP) (poster presentation).

For further information visit www.clinicaltrials.gov.

CEMIPLIMAB NCT03132636

Cemiplimab is approved in the EU for the treatment of adult patients with metastatic or locally advanced cutaneous squamous cell carcinoma who are not candidates for curative surgery or curative radiation but is under investigation and has not been fully evaluated by regulatory authorities in all other cancer types.

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Cemiplimab

PD-1 monoclonal antibody

Research & Development

Cutaneous Squamous Cell Carcinoma

A Phase 3 Trial of Adjuvant Cemiplimab Versus Placebo After Surgery and Radiation in Patients with High-Risk Cutaneous Squamous Cell Carcinoma: C-POST Trial

Clinical trial design

Estimated enrollment (N=412)

Patients with high-risk CSCC who have had surgery and have also had radiation therapy within 2 to 6 weeks of randomization

R

Arm A
Cemiplimab 350 mg IV Q3W for up to 48 weeks

Arm B
Placebo (IV)

Primary endpoint:
Disease-free survival

Key secondary endpoints:
OS, FFLRR, FFDR, safety

CSCC=cutaneous squamous cell carcinoma; FFDR=freedom from distant recurrence; FFLRR=freedom from locoregional recurrence; IV=intravenous; N=number of patients; OS=overall survival; PD-1=programmed cell death-1; R=randomization

ClinicalTrials.gov, NCT03969004. Accessed March 2022.

NCT03969004

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Cemiplimab

PD-1 monoclonal antibody

Research & Development

Cutaneous Squamous Cell Carcinoma

Clinical trial design

Selected inclusion criteria:

- Adults ≥18 years of age with pathologically confirmed high-risk CSCC, with macroscopic gross resection of all disease
  - In Japan, adults ≥21 years of age
- Completion of curative intent post-operative radiation therapy within 2 to 6 weeks of randomization
- ECOG performance status of ≤1
- Adequate hepatic, renal, and bone marrow function

Selected exclusion criteria:

- Squamous cell carcinomas arising in non-cutaneous sites
- Concurrent malignancy other than localized CSCC and/or history of malignancy other than localized CSCC within 3 years of date of randomization
- Patients with hematologic malignancies
- Patients with history of distantly metastatic CSCC, unless the disease-free interval is at least 3 years
- Ongoing or recent (within 5 years of randomization date) evidence of significant autoimmune disease that required treatment with systemic immunosuppressive treatments
- Prior systemic anti-cancer immunotherapy for CSCC

Other protocol-defined inclusion/exclusion criteria apply.

CSCC=cutaneous squamous cell carcinoma; ECOG=Eastern Cooperative Oncology Group; PD-1= programmed cell death-1

ClinicalTrials.gov, NCT03969004. Accessed March 2022.

For further information visit www.clinicaltrials.gov.

CEMIPLIMAB NCT03969004

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Cemiplimab

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Research & Development

Cutaneous Squamous Cell Carcinoma

Cemiplimab Survivorship Epidemiology (CASE)

Observational study design

Estimated enrollment (N=350)

Patients with CSCC who are receiving or plan to receive treatment with cemiplimab-rwlc in a real-world setting per standard of care

Cemiplimab
350 mg IV Q3W

Primary outcome measures:
OS, disease recurrence rate, disease response rate, DCR, QoL, pain

CASE=CemiplimAb Survivorship Epidemiology; CSCC=cutaneous squamous cell carcinoma; DCR=disease control rate; IV=intravenous; N=number of patients; OS=overall survival; PD-1=programmed cell death-1; QoL=quality of life; Q3W=every 3 weeks

ClinicalTrials.gov, NCT03836105. Accessed March 2022; Migden MR. Future Oncol 2020;16(4):11-19.

NCT03836105

MAT-DE-2001478 V3 03/2022

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Cemiplimab

PD-1 monoclonal antibody

Research & Development

Cutaneous Squamous Cell Carcinoma

Observational study design

Selected inclusion criteria:

- Adults aged ≥18 years old who have recently initiated, or plan to initiate treatment with commercially available cemiplimab for CSCC

Other protocol-defined inclusion/exclusion criteria apply.

Selected exclusion criteria:

- Any condition that, in the opinion of the investigator, may interfere with patient's ability to participate in the study
- Concurrent participation in any study including those that involve administration of investigational therapy (including cemiplimab) or procedure (including survival follow-up)

Selected study goals are to describe, in a real-world clinical setting:

- Effectiveness and safety of cemiplimab-rwlc in patients with advanced CSCC
- Characteristics that could potentially be associated with health-related outcomes for patients with advanced CSCC undergoing treatment with cemiplimab
- Patient experience, including QoL and functional status, for patients with advanced CSCC

CSCC=cutaneous squamous cell carcinoma; PD-1=programmed cell death-1; QoL=quality of life

ClinicalTrials.gov, NCT03836105. Accessed March 2022; Migden MR. Future Oncol 2020;16(4):11-19.

For further information visit www.clinicaltrials.gov.

CEMIPLIMAB NCT03836105

Cemiplimab is approved in the EU for the treatment of adult patients with metastatic or locally advanced cutaneous squamous cell carcinoma who are not candidates for curative surgery or curative radiation but is under investigation and has not been fully evaluated by regulatory authorities in all other cancer types.

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