# Study of REGN2810 in Patients With Advanced Cutaneous Squamous Cell Carcinoma

**This study is currently recruiting participants.** (see Contacts and Locations)

*Verified December 2016* by Regeneron Pharmaceuticals

**Sponsor:**
Regeneron Pharmaceuticals

**Information provided by (Responsible Party):**
Regeneron Pharmaceuticals

**ClinicalTrials.gov Identifier:**
NCT02760498

First received: April 8, 2016
Last updated: December 1, 2016
Last verified: December 2016
History of Changes



## Purpose

To estimate the clinical benefit of REGN2810 monotherapy for patients with metastatic (nodal or distant) cutaneous squamous cell carcinoma (CSCC) (Group 1) or with unresectable locally advanced CSCC (Group 2), as measured by overall response rate (ORR), according to central review.

| Condition | Intervention | Phase |
|---|---|---|
| Advanced Cutaneous Squamous Cell Carcinoma | Drug: REGN2810 | Phase 2 |

Study Type: Interventional
Study Design: Allocation: Non-Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: A Phase 2 Study of REGN2810, a Fully Human Monoclonal Antibody to Programmed Death-1 (PD-1), in Patients With Advanced Cutaneous Squamous Cell Carcinoma

**Further study details as provided by Regeneron Pharmaceuticals:**

Primary Outcome Measures:

- Overall Response Rate [ Time Frame: During the 12 treatment cycles (96 weeks) ] [ Designated as safety issue: No ]

  Overall Response Rate as determined by RECIST 1.1 for Group 1 and/or assessed per composite response criteria (Group 2)

Secondary Outcome Measures:

- Duration of response [ Time Frame: From date of treatment until date of first documented progression or date of death, assessed up to 30 months ] [ Designated as safety issue: No ]
- PFS (progression-free survival) [ Time Frame: From date of treatment until date of death, assessed up to 30 months ] [ Designated as safety issue: No ]
- Overall Survival [ Time Frame: From date of treatment until date of death, assessed up to 30 months ] [ Designated as safety issue: No ]
- Change in scores of patient reported outcomes on EORTC QLQ-C30 [ Time Frame: From date of treatment until date of first documented progression or date of death, assessed up to 24 months ] [ Designated as safety issue: No ]

Estimated Enrollment: 129
Study Start Date: March 2016
Estimated Study Completion Date: May 2019
Estimated Primary Completion Date: May 2019 (Final data collection date for primary outcome measure)

| Arms | Assigned Interventions |
|---|---|
| Experimental: Group 1<br>Patients with metastatic CSCC: to distant sites or lymph nodes | Drug: REGN2810 |
| Experimental: Group 2<br>Patients with unresectable locally advanced CSCC | Drug: REGN2810 |

## Eligibility

Ages Eligible for Study: 18 Years and older (Adult, Senior)
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

**Criteria**

Key Inclusion Criteria:

- At least 1 measurable lesion
- Eastern Cooperative Oncology Group (ECOG) performance status ≤1
- Adequate bone marrow function
- Adequate renal function
- Adequate hepatic function
- Archived or newly obtained tumor material
- Patients must consent to undergo biopsies of externally visible CSCC lesions (Group 2 only)
- Surgical or radiological treatment of lesions contraindicated

Key Exclusion Criteria:

- Ongoing or recent (within 5 years) evidence of significant autoimmune disease that required treatment with systemic immunosuppressive treatments, which may suggest risk for immune-related adverse events
- Prior treatment with an agent that blocks the PD-1/PD-L1pathway
- Prior treatment with a BRAF inhibitor
- Prior treatment with other immune modulating agents within fewer than 4 weeks prior to the first dose of REGN2810. Examples of immune modulating include therapeutic vaccines, cytokine treatments, or agents that target cytotoxic T-lymphocyte antigen 4 (CTLA-4), 4-1BB (CD137), or OX-40.
- Untreated brain metastasis(es) that may be considered active
- Immunosuppressive corticosteroid doses (>10 mg prednisone daily or equivalent) within 4 weeks prior to the first dose of REGN2810
- Infection with human immunodeficiency virus (HIV) and/or chronic/active infection with hepatitis B virus or hepatitis C virus
- History of pneumonitis within the last 5 years
- Allergic reactions or acute hypersensitivity reaction attributed to antibody treatments
- Known allergy to doxycycline or tetracycline
- Patients with a history of solid organ transplant
- Any medical co-morbidity, physical examination finding, or metabolic dysfunction, or clinical laboratory abnormality that renders the patient unsuitable

Other protocol-defined inclusion/exclusion criteria may apply

## Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT02760498

**Contacts**

Contact: Clinical Trials Administrator clinicaltrials@regeneron.com

**Show 26 Study Locations**

**Sponsors and Collaborators**

Regeneron Pharmaceuticals

**Investigators**

Study Director: Clinical Trial Management Regeneron Pharmaceuticals

## More Information

| | |
|---|---|
| Responsible Party: | Regeneron Pharmaceuticals |
| ClinicalTrials.gov Identifier: | NCT02760498 History of Changes |
| Other Study ID Numbers: | **R2810-ONC-1540** |
| Study First Received: | April 8, 2016 |
| Last Updated: | December 1, 2016 |
| Health Authority: | United States: Institutional Review Board |

Additional relevant MeSH terms:

| | |
|---|---|
| Carcinoma | Neoplasms by Histologic Type |
| Carcinoma, Squamous Cell | Neoplasms |
| Neoplasms, Glandular and Epithelial | Neoplasms, Squamous Cell |

ClinicalTrials.gov processed this record on December 30, 2016