

Study of investigational adjuvant cemiplimab in patients with high-risk cutaneous squamous cell carcinoma



Primary Objective: disease-free survival of patients with high-risk CSCC treated with cemiplimab or placebo, after surgery and radiation therapy



PATIENTS WITH HIGH-RISK CSCC (N≈412)

INTERVENTION

R
1:1

Arm 1

Cemiplimab (IV)
Q3W

Arm 2

Placebo (IV)
Q3W

Primary Endpoint

Disease-free survival

Secondary Endpoints

Overall survival

Freedom from locoregional recurrence

Freedom from distant recurrence

Incidence of second primary tumors

Safety and tolerability

Immunogenicity



FIND OUT MORE

Scan here to find out more about this study at <https://clinicaltrials.gov/ct2/show/NCT03969004>

This information is intended for investigators interested in open clinical trials.

The use of cemiplimab herein is investigational and has not been fully evaluated by any regulatory authority.

Please see full prescribing information in your country for cemiplimab.

CSCC, cutaneous squamous cell carcinoma; IV, intravenous; N, number of patients; Q3W, administered every three weeks; R, randomized.

CEMIPLIMAB

An Investigational, Fully Human PD-1 Monoclonal Antibody

Designed to block cancer cells from using the PD-1 pathway to suppress T-cell activation¹

SELECTED INCLUSION CRITERIA^a



Pathologically confirmed high-risk CSCC, with macroscopic gross resection of all diseased area



High-risk CSCC



Completion of curative intent post-operative radiation therapy within 2 to 10 weeks of randomization



ECOG PS 0 or 1



Adequate hepatic, renal, and bone marrow function

SELECTED EXCLUSION CRITERIA^a



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, but not excluding patients with CLL if they have not required systemic therapy for CLL within 6-months of enrollment



Ongoing or recent (within 5 years) evidence of significant autoimmune disease that required treatment with systemic immunosuppressive treatments^b



Prior systemic anti-cancer immunotherapy for CSCC



For more information, visit www.clinicaltrials.gov or please call 844 REGN-MID.
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^aInclusion/exclusion criteria include a summary of selected criteria. Please review the complete study design on clinicaltrials.gov for complete details. ^bThe following are not exclusionary: vitiligo, childhood asthma that has resolved, type 1 diabetes, residual hypothyroidism that required only hormone replacement, or psoriasis that does not require systemic treatment.

CLL, chronic lymphocytic leukemia; CSCC, cutaneous squamous cell carcinoma; ECOG PS, Eastern Cooperative Oncology Group performance status; PD-1, programmed cell death protein-1.

Current per clinicaltrials.gov as of August 9, 2023.

1. Markham A, Duggan S. *Drugs*. 2018;78(17):1841-1846.

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