C-POST (NCT03969004) PHASE 3 ENROLLING

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
(standard of care surgery followed by adjuvant radiation)

R
1:1

Arm 1
Cemiplimab (IV)
Q3W for 12 weeks
Q6W for 36 additional weeks

Arm 2
Placebo (IV)
Q3W for 12 weeks
Q6W for 36 additional weeks

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.

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C-POST (NCT03969004) **PHASE 3 ENROLLING**

CEMIPLIMAB

An Investigational, Fully Human PD-1 Monoclonal Antibody

Designed to block cancer cells from using the PD-1 pathway to suppress T-cell activation[1]

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
- 0 or 1 — 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 [+353 (0)61 533 400 or 844 REGN-MID].
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[a]Inclusion/exclusion criteria include a summary of selected criteria. Please review the complete study design on clinicaltrials.gov for complete details. [b]The 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 January 16, 2024.

1. Markham A, Duggan S. *Drugs*. 2018;78(17):1841-1846.
US-CEM-EM-24-03-0001 March 2024.

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