# 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

Cemiplimab (IV) Q3W

Arm 1

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.

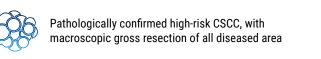
CSCC, cutaneous squamous cell carcinoma; IV, intravenous; N, number of patients; Q3W, administered every three weeks; R, randomized.



# **CEMIPLIMAB**

An Investigational, Fully Human PD-1 Monoclonal Antibody
Designed to block cancer cells from using the PD-1 pathway to suppress T-cell activation<sup>1</sup>

#### **SELECTED INCLUSION CRITERIA**<sup>a</sup>





High-risk CSCC



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

Concurrent malignancy other than localized CSCC

and/or history of malignancy other than localized CSCC within 3 years of date of randomization

SELECTED EXCLUSION CRITERIA<sup>a</sup>

Squamous cell carcinomas arising in

non-cutaneous sites



ECOG PS 0 or 1



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



Adequate hepatic, renal, and bone marrow function



Prior systemic anti-cancer immunotherapy for CSCC



For more information, visit <u>www.clinicaltrials.gov</u> or please call 844 REGN-MID. NCT03969004

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alnclusion/exclusion criteria include a summary of selected criteria. Please review the complete study design on clinicaltrials. ov for complete details. 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 August 9, 2023.

1. Markham A, Duggan S. *Drugs*. 2018;78(17):1841-1846. CEM-EM-0030 October 2023. ©2023 Regeneron Pharmaceuticals, Inc. All rights reserved

