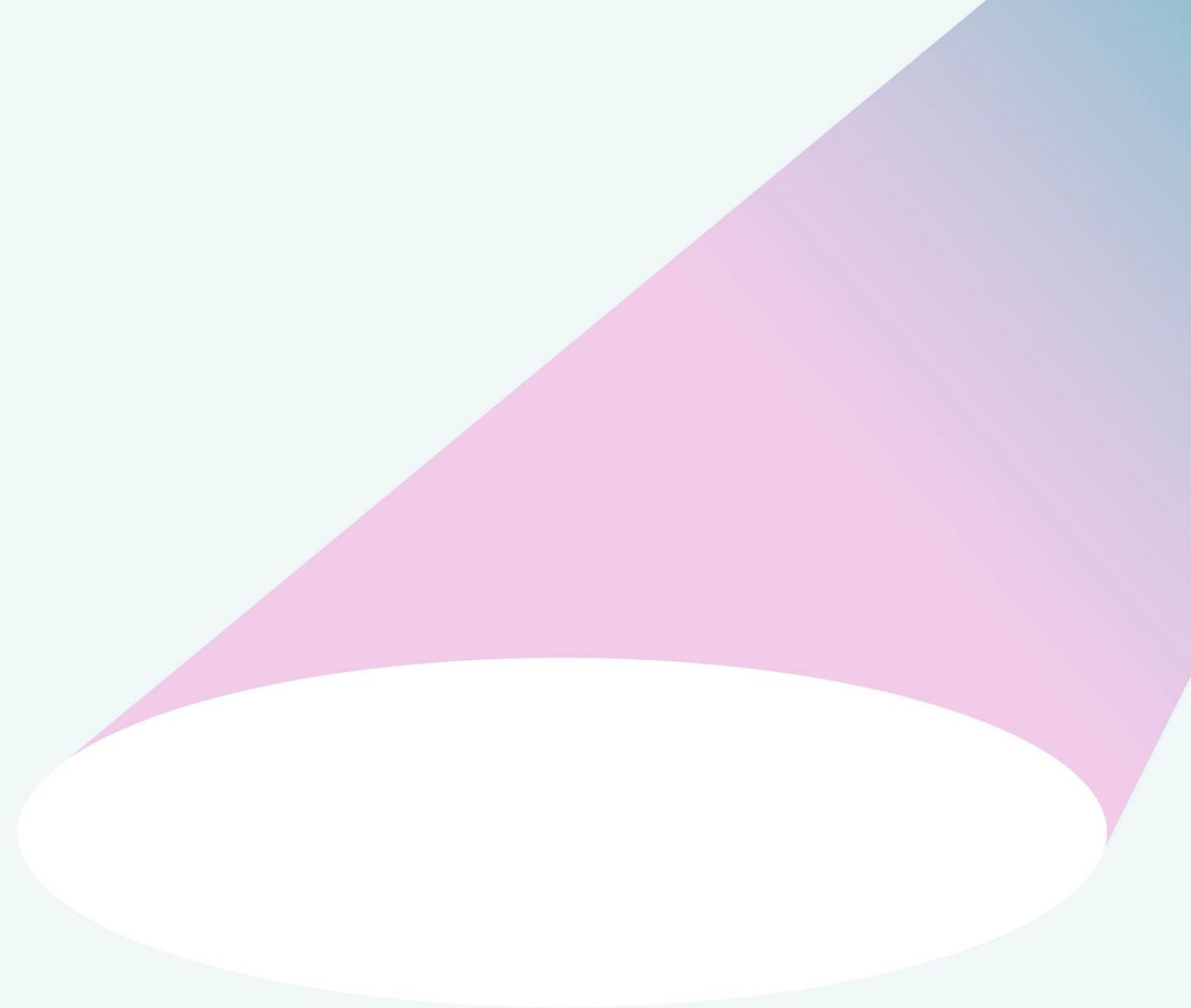


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SPOT LIGHTS 2026

FARMACIA HOSPITALARIA AL DÍA EN ONCOLOGÍA



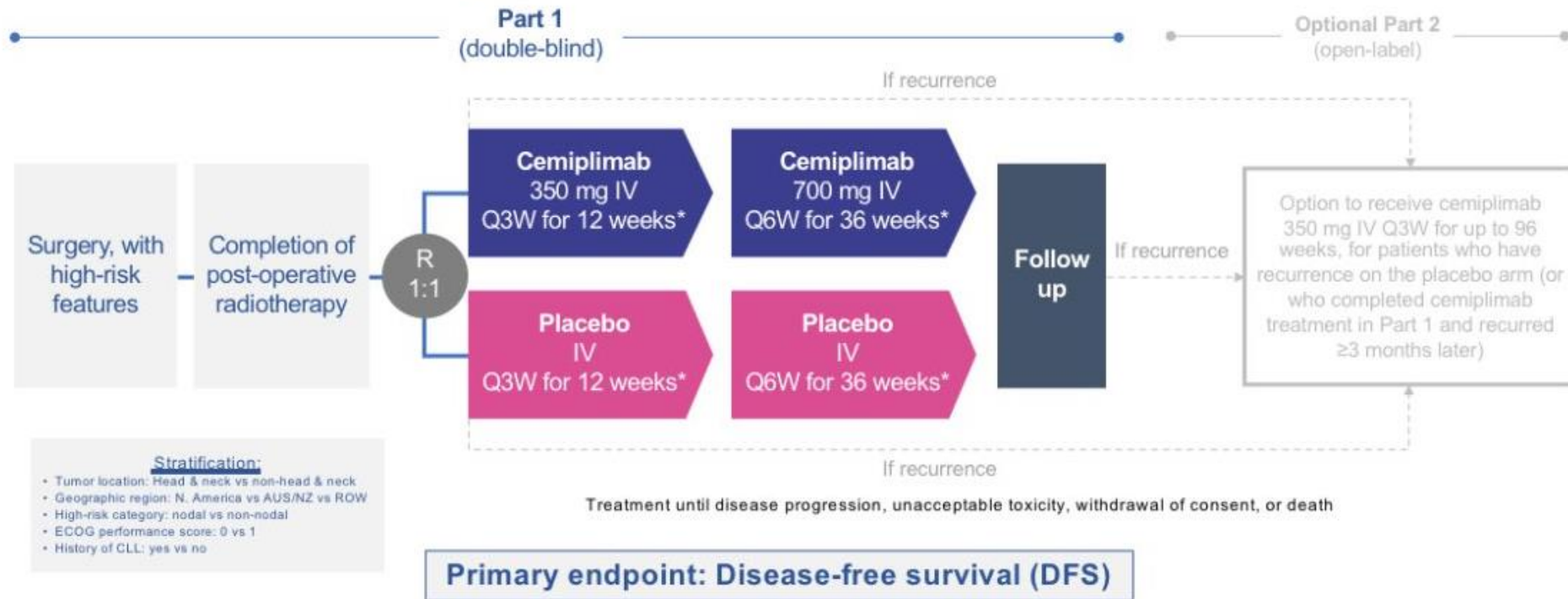
Una iniciativa científica de:



Con el patrocinio de:

REGENERON[®]

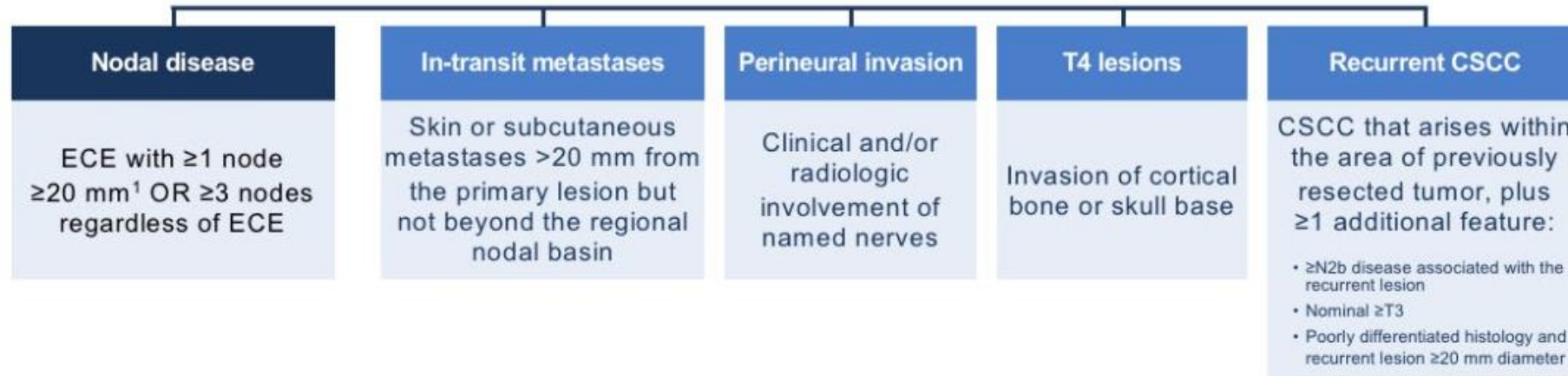
Methods: C-POST phase 3 trial



*Original regimen was Q3W only. Starting with protocol amendment 2 (Jun 2021), the regimen was Q3W start / Q6W switch, as shown in the diagram.

Methods: High-risk criteria

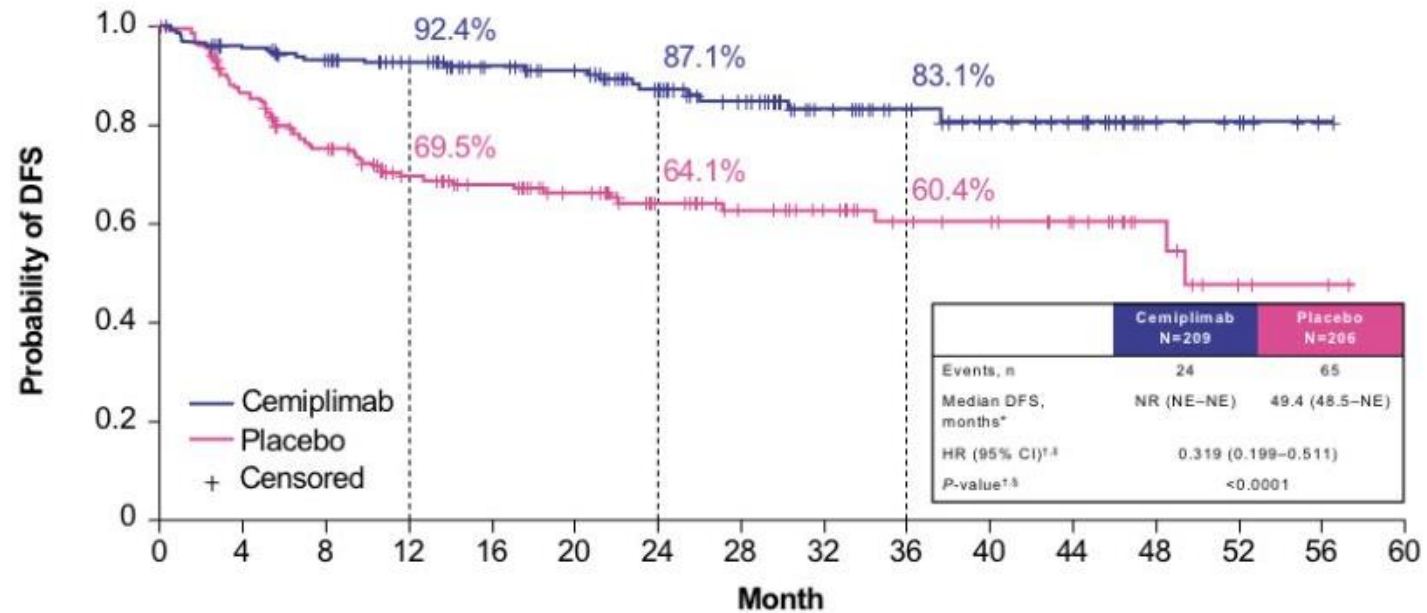
Nodal and non-nodal high-risk criteria*



*High-risk CSCC with both nodal and non-nodal features was categorized as high-risk nodal disease.

ECE, extracapsular extension.
1. Connolly et al. Proc ESTRO 2025. E25-1045.

Disease-free survival



No. of patients at risk:

	0	4	8	12	16	20	24	28	32	36	40	44	48	52	56	60
Cemiplimab	209	172	157	132	116	104	83	66	47	33	27	22	9	6	1	0
Placebo	206	161	130	94	82	69	53	42	36	26	24	18	10	4	2	0

NE, not evaluable; NR, not reached.

*Based on Kaplan-Meier method. [†]Stratified by anatomic region of resected high-risk tumor & geographical region. [‡]Based on stratified proportional hazards model. [§]Two-sided P-value. Significance threshold set to 0.00455 using the O'Brien Fleming alpha spending function.

C-POST study of adjuvant cemiplimab for high-risk cutaneous squamous cell carcinoma (CSCC): Disease-free survival (DFS) analyses per high-risk criteria and per start time after radiotherapy.

BACKGROUND

- Patients with CSCC who are at high risk of disease recurrence after surgery and adjuvant RT need effective adjuvant systemic treatment options¹
- Cemiplimab is approved in many countries for use across multiple solid tumor types, including in adult patients with locally advanced or metastatic CSCC who are not candidates for curative surgery or RT; cemiplimab is also approved in multiple countries for the adjuvant treatment of adult patients with CSCC at high risk of recurrence after surgery and RT^{2,3}
- The C-POST trial (NCT03969004) evaluated cemiplimab as an adjuvant therapy for the treatment of patients at high risk of CSCC recurrence after surgery and RT⁴
 - At primary analysis, DFS was superior with adjuvant cemiplimab vs placebo (HR, 0.32; $P < 0.0001$); safety profile was consistent with the known safety of cemiplimab in advanced solid malignancies⁵
 - Results from the study supported the approval of adjuvant cemiplimab in this patient population^{2,3}
- Additional analyses were conducted to evaluate the effect of each high-risk criterion and the interval between completion of adjuvant RT and study randomization on clinical outcomes

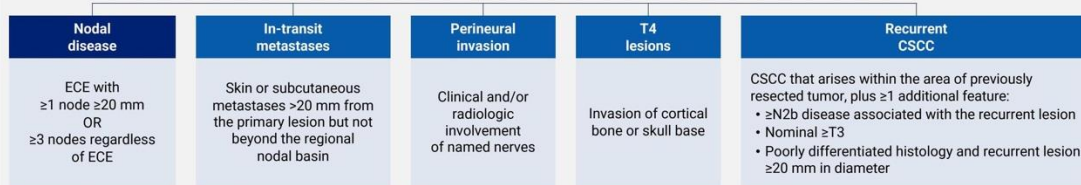
OBJECTIVE

- With approximately 6 months of additional follow-up (data cutoff: April 7, 2025) in C-POST, we present the exploratory analyses of DFS based on the following factors:
 - High-risk criteria
 - Interval between completion of adjuvant RT and study randomization

METHODS

- Patients were randomized 1:1 (N=415) to adjuvant cemiplimab or placebo
 - Patients received cemiplimab 350 mg or placebo Q3W for approximately 12 weeks, followed by cemiplimab 700 mg or placebo Q6W for 36 weeks for a total planned treatment duration of 48 weeks (4 cycles; cycle length = 12 weeks)
- All patients had high-risk CSCC defined by nodal and/or non-nodal features (Figure 1)

Figure 1. Nodal and non-nodal high-risk criteria



- Tumors had to meet ≥ 1 high-risk criteria
- Study randomization occurred within 2-11 weeks after completion of adjuvant RT
- DFS exploratory analyses were performed based on the following factors:
 - High-risk criteria presented in Figure 1
 - Interval between completion of adjuvant RT and study randomization (2-6 weeks vs > 6 weeks)
- The treatment effect on DFS was assessed in a stratified Cox proportional hazard model as the interaction between each criterion and treatment

RESULTS

- As of April 7, 2025, median duration of follow-up was 30 months
- Among 415 patients (cemiplimab, n=209; placebo, n=206) randomized, the DFS HR was 0.35 (95% CI, 0.23-0.55)

DFS per high-risk criteria

- The most common high-risk criterion was nodal disease with ECE, present in 48.4% of patients
- DFS was improved with cemiplimab vs placebo across all high-risk categories, including both nodal and non-nodal criteria (Figure 2)

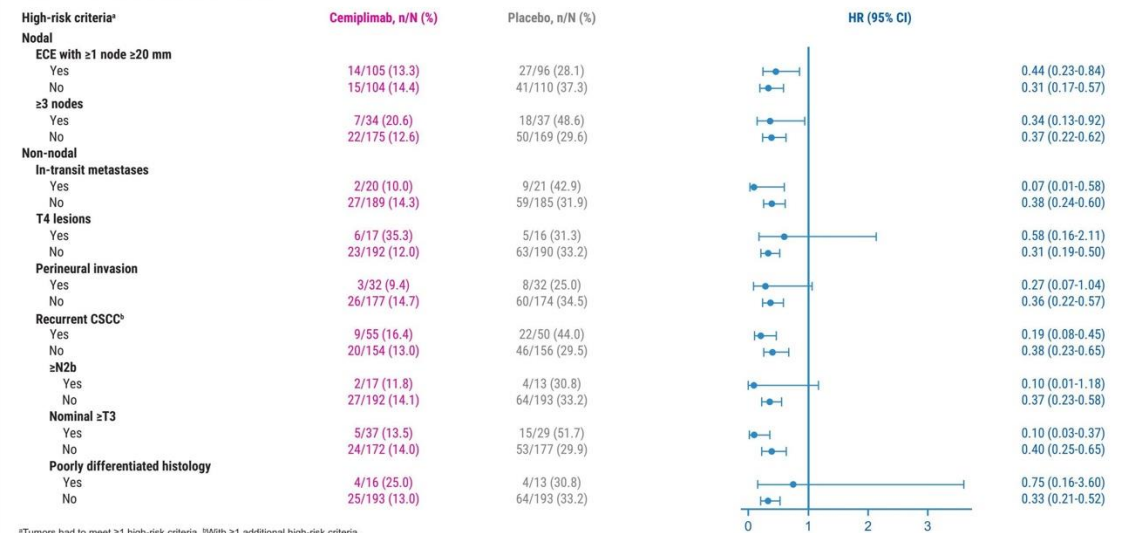
DFS per the interval between completion of adjuvant RT and study randomization

- The median time from completion of adjuvant RT to study randomization was 5.65 weeks
- The interval between adjuvant RT completion and study randomization did not impact the DFS benefit of cemiplimab vs placebo (Table 1)

Safety

- At 30-month follow-up, the overall incidence of any-grade TEAEs was comparable in the cemiplimab and placebo arms, consistent with the results from primary analysis (Supplementary Table 1)

Figure 2. DFS per high-risk criteria



*Tumors had to meet ≥ 1 high-risk criteria. ^bWith ≥ 1 additional high-risk criteria.

Table 1. DFS per start time after adjuvant RT

Parameter	Cemiplimab, n/N (%)	Placebo, n/N (%)	HR (95% CI)
Interval between prior RT and study randomization			
2-6 weeks	17/117 (14.5)	37/112 (33.0)	0.39 (0.22-0.70)
> 6 weeks	12/91 (13.2)	31/93 (33.3)	0.36 (0.19-0.71)

ABBREVIATIONS

CI, confidence interval; CSCC, cutaneous squamous cell carcinoma; DFS, disease-free survival; ECE, extracapsular extension; HR, hazard ratio; Q3W, every 3 weeks; Q6W, every 6 weeks; RT, radiotherapy; T3, tumor stage 3; T4, tumor stage 4; TEAE, treatment-emergent adverse event.

FUNDING

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Supplementary data, references, author disclosures, and acknowledgments are available in the Supplementary Information.



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Poster

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Presenting author: Danny Rischin

POSTER 6083

CONCLUSIONS

- Long-term follow-up (median, 30 months) of the phase 3 C-POST study showed continued DFS benefit with adjuvant cemiplimab vs placebo (HR, 0.35) in patients with high-risk CSCC
- In the exploratory analyses, adjuvant cemiplimab demonstrated a DFS benefit vs placebo across all high-risk categories
- A consistent benefit of cemiplimab was observed regardless of whether the interval between adjuvant RT completion and randomization was 2-6 weeks or >6 weeks