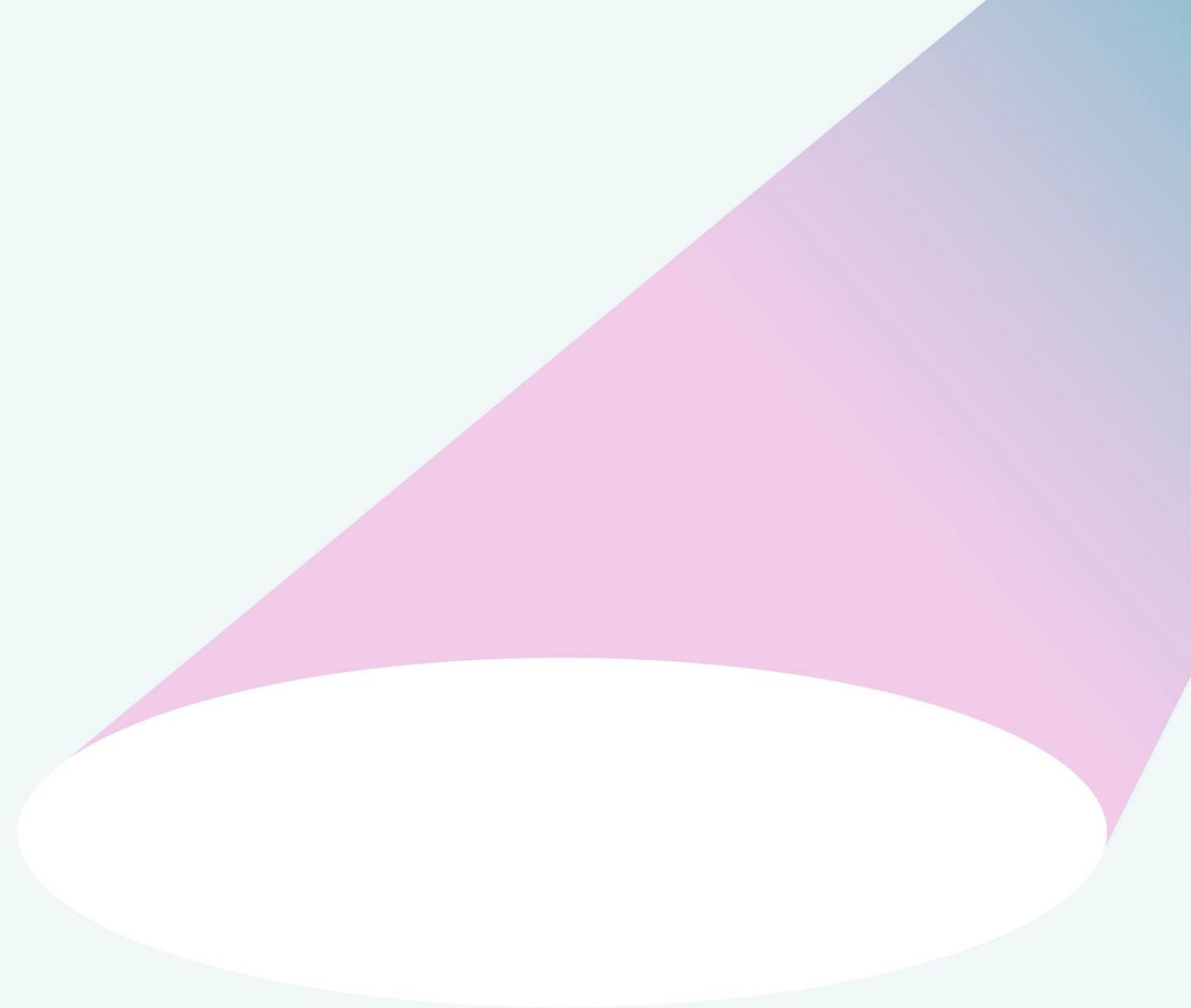


29 MAYO-2 JUNIO | CHICAGO

2026 **ASCO**[®]
ANNUAL MEETING

SPOT LIGHTS 2026

FARMACIA HOSPITALARIA AL DÍA EN ONCOLOGÍA



Una iniciativa científica de:

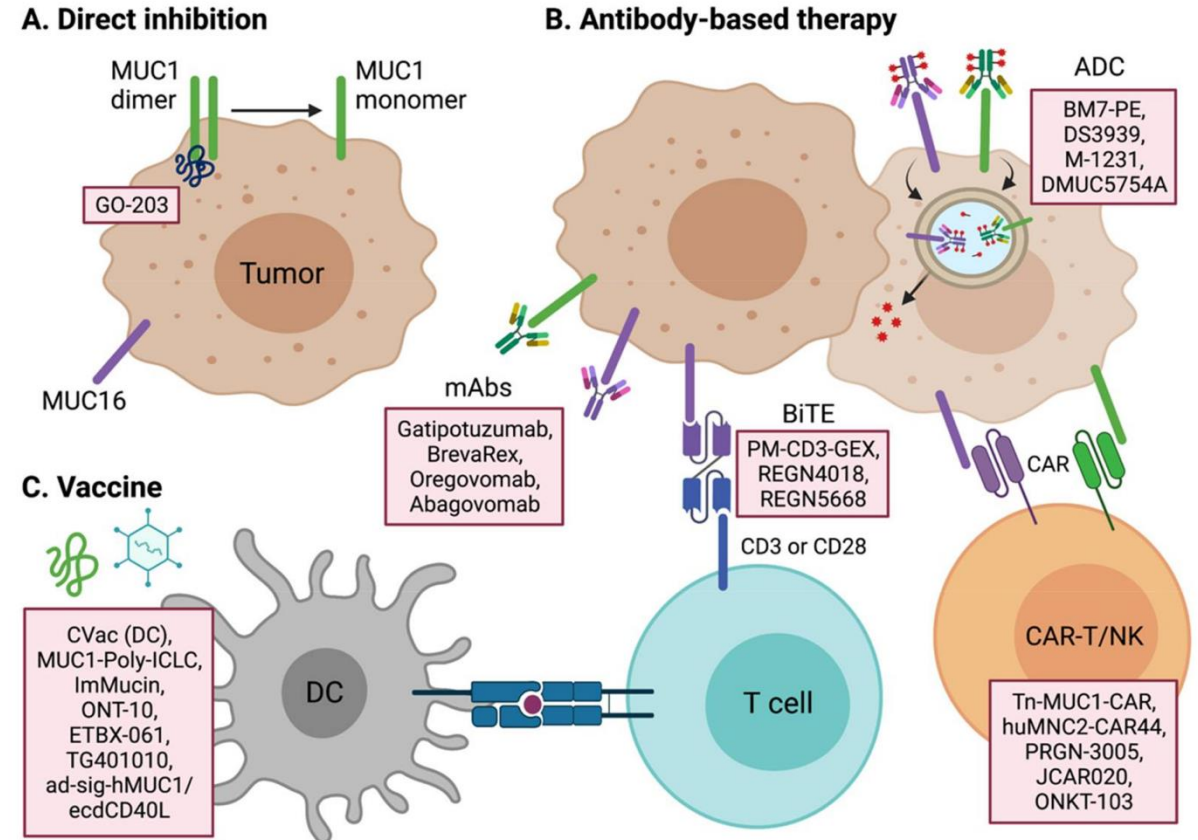


Con el patrocinio de:

REGENERON[®]

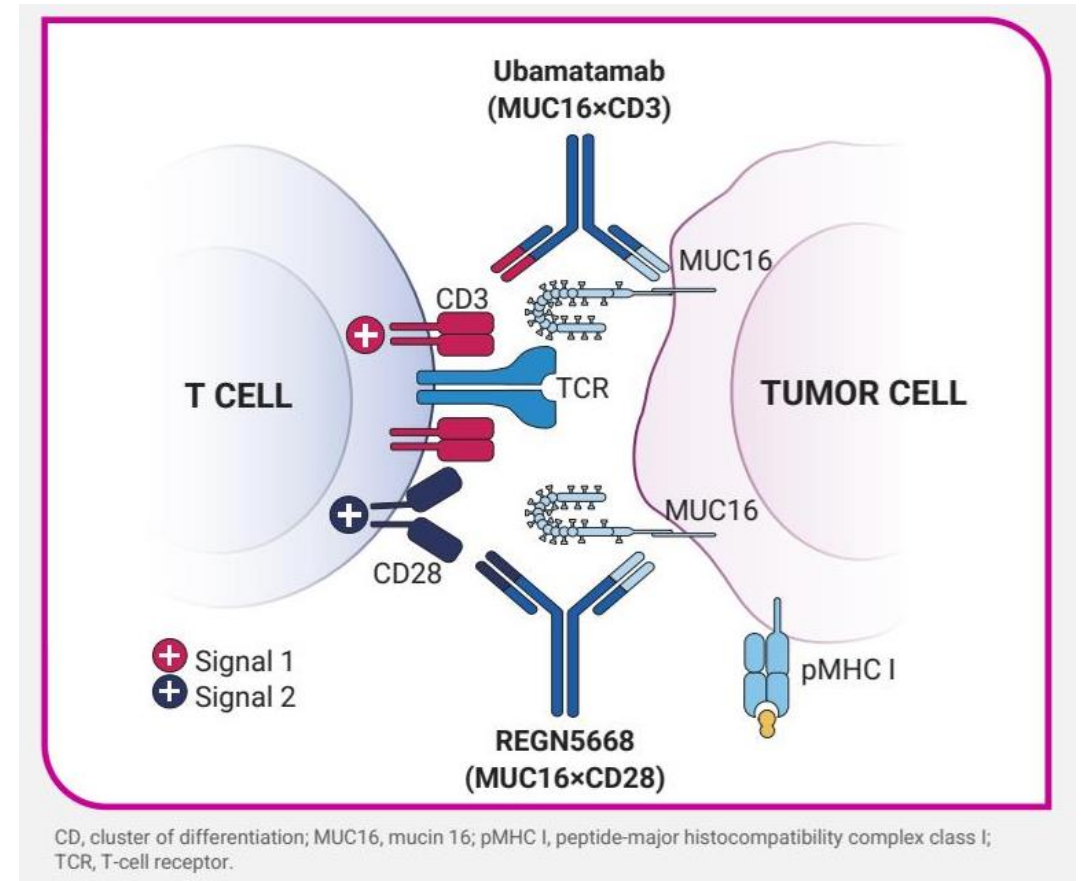
Introducción

- MUCIN 16, también conocida como MUC16 o CA-125, es una glicoproteína de gran tamaño perteneciente a la familia de las mucinas. Estas proteínas se caracterizan por estar altamente glicosiladas y formar parte de la superficie de células epiteliales, donde contribuyen a la protección, lubricación y mantenimiento de las barreras mucosas.
- MUC16 se expresa principalmente en tejidos epiteliales, como el aparato reproductor femenino, el tracto respiratorio y algunas superficies serosas. Su fragmento soluble, CA-125, es especialmente conocido por su uso clínico como marcador tumoral, sobre todo en el seguimiento del cáncer de ovario epitelial.



Introducción

- El cáncer de ovario resistente al platino y el cáncer de endometrio que recurre tras tratamiento anti-PD-1 se asocian con mal pronóstico, lo que representa una necesidad no cubierta de nuevas terapias que puedan mejorar los resultados a largo plazo de las pacientes.
- REGN5668 y ubamatamab son anticuerpos biespecíficos basados en inmunoglobulina G4 que conectan las células tumorales positivas para MUC16 con linfocitos T que expresan el grupo de diferenciación CD28 y CD3, respectivamente, con el objetivo de estimular la citotoxicidad mediada por linfocitos T.
- Los resultados de escalada de dosis de este estudio demostraron actividad clínica temprana y un perfil de seguridad aceptable de REGN5668 en pacientes con cáncer de ovario recurrente resistente al platino.

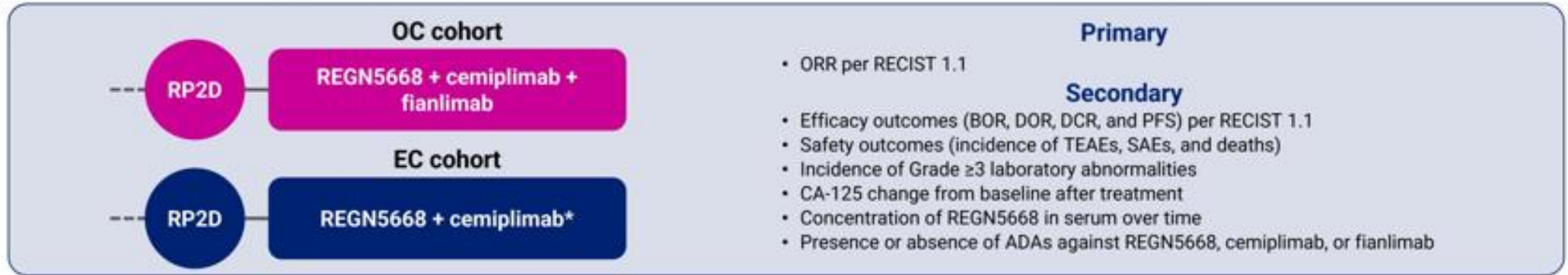


This first-in-human, Phase 1/2 study (NCT04590326) will assess the safety, tolerability, pharmacokinetics, and antitumor activity of REGN5668 + cemiplimab + fianlimab (Module 1) or REGN5668 + ubamatamab (Module 2) in patients with platinum-resistant recurrent OC or EC

STUDY DESIGN

ENDPOINTS

Module 1
(Dose expansion)



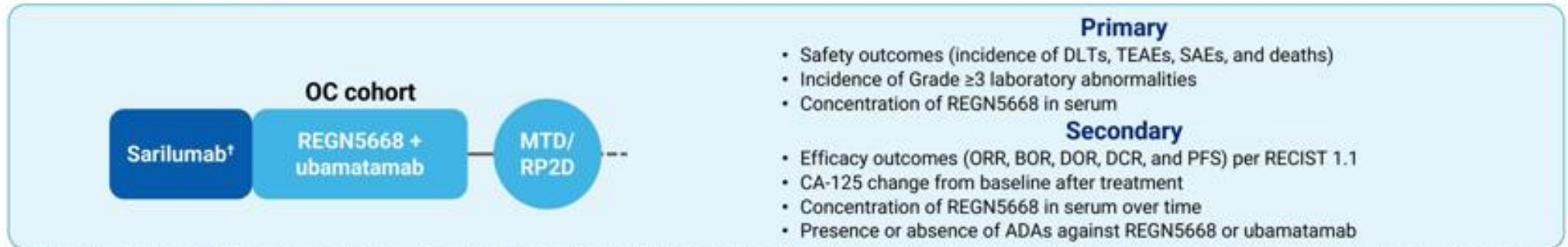
Primary

- ORR per RECIST 1.1

Secondary

- Efficacy outcomes (BOR, DOR, DCR, and PFS) per RECIST 1.1
- Safety outcomes (incidence of TEAEs, SAEs, and deaths)
- Incidence of Grade ≥3 laboratory abnormalities
- CA-125 change from baseline after treatment
- Concentration of REGN5668 in serum over time
- Presence or absence of ADAs against REGN5668, cemiplimab, or fianlimab

Module 2
(Dose escalation)



Primary

- Safety outcomes (incidence of DLTs, TEAEs, SAEs, and deaths)
- Incidence of Grade ≥3 laboratory abnormalities
- Concentration of REGN5668 in serum

Secondary

- Efficacy outcomes (ORR, BOR, DOR, DCR, and PFS) per RECIST 1.1
- CA-125 change from baseline after treatment
- Concentration of REGN5668 in serum over time
- Presence or absence of ADAs against REGN5668 or ubamatamab

*No additional expansion cohort to evaluate REGN5668 + cemiplimab + fianlimab in patients with EC may be initiated, following the safety lead-in for this combination in patients with OC and contingent on the tolerability observed in patients with EC treated with REGN5668 + cemiplimab; Sarilumab is an anti-IL-6Rα monoclonal antibody that is being evaluated as prophylaxis for ubamatamab-induced cytokine release syndrome. † ADA, anti-drug antibody; BOR, best overall response; CA-125, cancer antigen-125; DCR, disease control rate; DLT, dose-limiting toxicity; DOR, duration of response; EC, endometrial cancer; IL-6R, interleukin-6 receptor; MTD, maximum tolerated dose; OC, ovarian cancer; ORR, objective response rate; PFS, progression-free survival; RECIST 1.1, Response Evaluation Criteria in Solid Tumors version 1.1; RP2D, recommended Phase 2 dose; SAE, serious adverse event; TEAE, treatment-emergent adverse event.

A phase 1/2 study of REGN5668, a MUC16×CD28 costimulatory bispecific antibody, in combination with other targeted therapies, in patients with recurrent ovarian or endometrial cancer: Trial in progress update

ELIGIBILITY CRITERIA

Table 1. Key inclusion criteria

OC cohort	EC cohort
Histologically or cytologically confirmed advanced epithelial OC (except carcinosarcoma), primary peritoneal or fallopian tube cancer	Histologically confirmed EC
Relapse or disease progression on or after most recent line of therapy	Disease progression or recurrence after anti-PD-1 therapy and platinum-based chemotherapy
Treated with ≥1 prior line of platinum-based systemic therapy	≥25% MUC16-positive tumor cells
Serum CA-125 level ≥2× ULN	≤4 prior lines of systemic therapy*
Expansion cohorts only: ≥1 lesion that is measurable by RECIST 1.1	
ECOG PS 0 or 1	
Life expectancy ≥3 months	

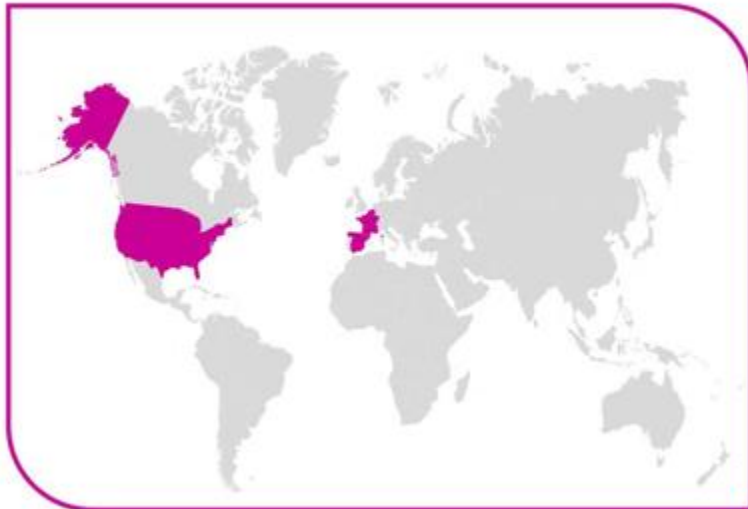
*Does not include systemic adjuvant therapy administered >12 months before first treatment in the recurrent setting or hormonal therapy as a line.
CA-125, cancer antigen-125; EC, endometrial cancer; ECOG PS, Eastern Cooperative Oncology Group performance status; MUC16, mucin 16; OC, ovarian cancer; PD-1, programmed cell death-1; RECIST 1.1, Response Evaluation Criteria in Solid Tumors version 1.1; ULN, upper limit of normal.

Table 2. Key exclusion criteria

All cohorts
Current or recent treatment with an investigational agent, systemic biologic therapy, or anticancer immunotherapy
Another malignancy within the past 5 years that is progressing, requires active treatment, or has a high likelihood of recurrence
Prior treatment with a MUC16-targeted therapy
Untreated or active CNS malignancies or metastases
Any condition requiring continuous corticosteroid therapy within 1 week prior to first study drug dose
Ongoing or recent (≤5 years) evidence of significant autoimmune disease that requires/required treatment with systemic immunosuppressive treatments
History of clinically significant cardiovascular disease
OC expansion cohort only: >5 prior lines of systemic therapy

CNS, central nervous system; MUC16, mucin 16; OC, ovarian cancer.

FIGURE 2. Enrollment sites



CONCLUSIONS

TPS5639

- This study will evaluate REGN5668 + cemiplimab + fianlimab or REGN5668 + ubamatamab in patients with recurrent OC or EC
- As of May 6, 2026, in 22 sites across 4 countries (Figure 2), Module 1 (dose expansion) has enrolled 14 patients (10 OC, 4 EC) with Module 2 (dose escalation) having progressed through multiple dose levels