

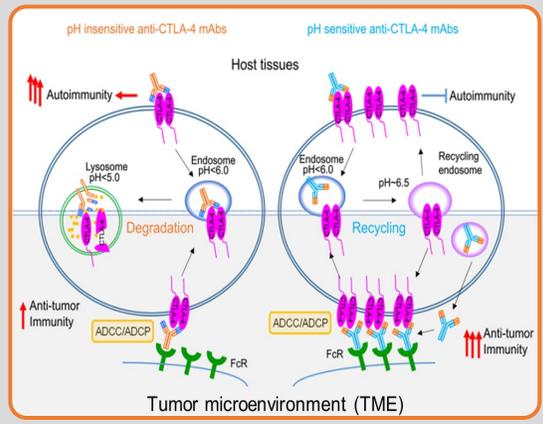
PHASE 2, RANDOMIZED, OPEN-LABEL, MULTICENTER STUDY OF GOTISTOBART + PEMBROLIZUMAB IN PLATINUM-RESISTANT OVARIAN CANCER (PROC)



OBJECTIVES

- **Gotistobart** is a pH-sensitive CTLA-4-preserving antibody.
- PRESERVE-004 aims to assess **safety and efficacy of gotistobart + pembrolizumab in PROC**.

METHODS



HGS PROC randomized 1:1

gotistobart 1 mg/kg + pembrolizumab 200 mg IV Q3W (N = 33)	gotistobart 2 mg/kg + pembrolizumab 200 mg IV Q3W (N = 29)
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Primary endpoint

- ORR by investigator per RECIST 1.1
- Safety per TRAEs, TRSAEs, and irAEs

Secondary endpoints

- DoR, DCR, BOR, PFS, OS

Exploratory endpoints

- PK and E-R, TRAE-related study discontinuation

CONCLUSIONS

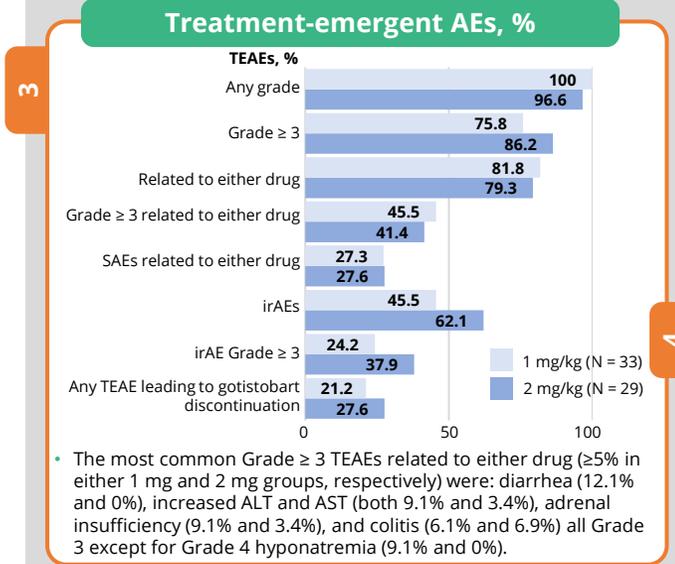
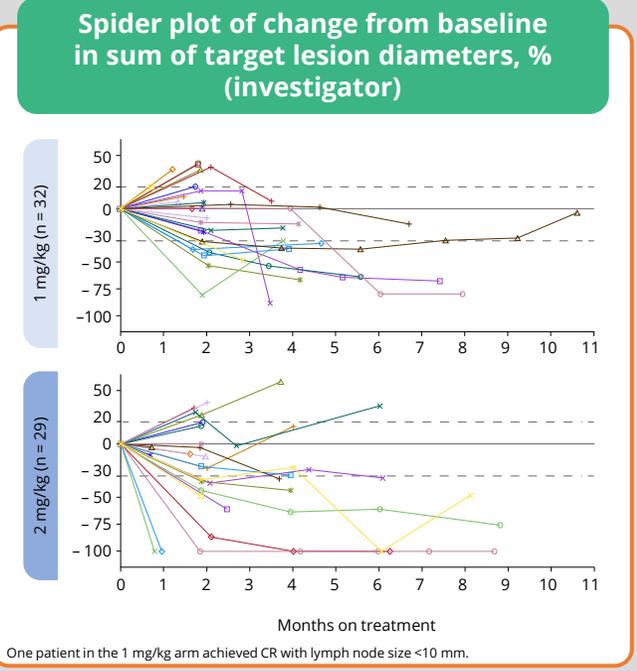
- Early results from PRESERVE-004 demonstrate that **gotistobart + pembrolizumab in PROC has a manageable tolerability profile** at both dose levels, with no new safety signals.
- Preliminary results for **efficacy are encouraging** at both dose levels.
- Preliminary exposure-response supports potential recommended phase 2 dose selection of gotistobart at lower doses (1-2 mg/kg) + pembrolizumab 200 mg Q3W for patients with PROC.

RESULTS

Best overall response per RECIST v1.1

	gotistobart + pembrolizumab 200 mg	
	1 mg/kg	2 mg/kg
By investigator	n = 32	n = 29
ORR % (n)^a	25.0% (8)	27.6% (8)
95% CI	11.5–43.4	12.7–47.2
CR ^b	3.1% (1)	6.9% (2)
PR ^b	21.9% (7)	20.7% (6)
By blinded independent central review	n = 33 ^c	n = 29
ORR % (n)^d	27.3% (9)	34.5% (10)
95% CI	13.3–45.5	17.9–54.3
CR ^e	3.0% (1)	6.9% (2)
PR ^e	24.2% (8)	27.6% (8)

^aIncludes both confirmed and unconfirmed responses (3 unconfirmed responders in each treatment group); ^bOne out of 3 unconfirmed responders are still on treatment, for both treatment groups; ^cAt the time of data extraction, scans for one patient were included for BICR review while investigator response data for this patient were not entered in the electronic database collection; ^d3 and 5 unconfirmed responders in 1 mg and 2 mg groups, respectively; ^e1 unconfirmed responder is still on treatment in the 2 mg group.



- Gotistobart PK parameters and exposure-response analyses**
- Gotistobart C_{max}, C_{min}, and AUC increased proportionally with dose in combination with pembrolizumab.
 - PK characteristics were comparable with gotistobart monotherapy, indicating lack of pembrolizumab effect on PK.
 - There was a positive trend between gotistobart exposures and Grade ≥ 3 TRAE and ALT/AST elevation.
 - No trend observed for efficacy (ORR) or other safety endpoints.