Abstract 2611: Primary efficacy and safety results of BAT1308, a PD-1 inhibitor, + chemotherapy ± bevacizumab in phase 2 trial for persistent, recurrent, or metastatic cervical cancer

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Background

- BAT1308 is a fully humanized and high-affinity anti-PD-1 IgG4κ antibody. Previous phase 1 study demonstrated BAT1308 has a promising safety and efficacy profile in patients with advanced solid tumors.
- A total of 59 participants were enrolled in that phase 1 study. After “3+3” dose escalation of 100mg, 300mg, and 600mg, IV, Q3W of BAT1308, 300mg Q3W dose was expanded. The results demonstrated BAT1308 had low immunogenicity and exhibited long-lasting, high affinity to PD-1 receptor. No DLT events were observed. Common TRAEs included decreased white blood cell count, anemia, and hypothyroidism. The most common irAE were thyroid dysfunction. The ORR is 41.7% (5 of 12 patients) in NSCLC, 16.7% (2 of 12 patients) in cervical cancer, and 14.3% (2/14) in HCC.
- Here we present the primary safety and efficacy results in phase 2 study for BAT1308 combined with platinum-based chemotherapy ± bevacizumab as first-line therapy for PD-L1–positive persistent, recurrent, or metastatic cervical cancer.

Objective

To investigate the safety and efficacy of BAT1308 + chemotherapy ± bevacizumab for patients with persistent, recurrent, or metastatic cervical cancer.

Methods

- This is a multicenter, single-arm, open-labeled, phase 2 study.
- Eligible patients received BAT1308 (300 mg Q3W for up to 24 months) plus platinum -based chemotherapy (paclitaxel 175 mg /m^2 + cisplatin 50 mg /m^2 or carboplatin AUC 5) and, per investigator discretion, with or without bevacizumab (15 mg /kg) for up to 6 cycles. The treatment will continue until disease progression, intolerable toxicity, the investigator determines that the participant is no longer benefiting from the treatment, the participant withdraws informed consent, or the treatment duration reaches 2 years.

Eligiblility

- ≥18 to ≤75 years of age;
- PD-L1 CPS ≥1;
- Have persistent, recurrent, or metastatic squamous cell carcinoma, adenosquamous carcinoma, adenocarcinoma, or clear cell carcinoma of the cervix which has not been treated with systemic chemotherapy and is not amenable to curative treatment (such as with surgery and/or radiation);
- Patients who have received concurrent chemotherapy with radiation therapy or carboplatin/paclitaxel as neoadjuvant or adjuvant therapy are eligible, if the interval between the last treatment and the subsequent recurrence is at least 6 months;
- Patients with radiographically stable brain metastases may participate.

Patients

As of April 28, 2025, a total of 29 patients were enrolled, with a median age of 53 years (range 32-69), 20 (69.0%) patients had ECOG performance status of 1, 15 (50.7%) patients with PD-L1 CPS ≥ 10, 24 (82.8%) patients had squamous-cell carcinoma, 17 (58.6%) patients received previous neoadjuvant or adjuvant chemotherapy or chemoradiotherapy with a paclitaxel + platinum regimen, 7 (24.1%) patients had previous untreated metastatic disease at trial entry. Bevacizumab was used by 23 (79.3%) patients in this phase II study. All 29 subjects received combination therapy.

Baseline characteristics of Subjects

Characteristic	Subjects (n=29)
Median Age (range), years	53 (32-69)
ECOG performance status score, n (%)	
0	9 (31)
1	20 (69)
Stage at initial diagnosis, n (%)	
I	3 (10.3)
II	4 (13.8)
III	14 (48.3)
IVA	1 (3.4)
IVB	7 (24.1)
Disease status at study entry, n (%)	
Metastatic	7 (24.1)
Persistent or recurrent with distant metastases	18 (62.1)
Persistent or recurrent without distant metastases	4 (13.8)
Histology, No. (%)	
Squamous cell carcinoma	24 (82.8)
Adenocarcinoma	4 (13.8)
Adenosquamous	1 (3.4)
PD-L1 combined positive score, n (%)	
≥1 to <10	14 (49.3)
≥10	15 (50.7)
Previous neoadjuvant/adjuvant or chemoradiotherapy with a paclitaxel plus platinum regimen, n (%)	
Yes	17 (58.6)
No	12 (41.4)
Bevacizumab used during the study, n (%)	
Yes	23 (79.3)
No	6 (20.7)

Safety

The most common adverse events were anemia (82.8%), white blood cell decreased (51.7%), alopecia (51.7%), thrombocytopenia (48.3%), and neutropenia (44.8%). Grade 3 and above adverse events occurred in 72.4% of 29 patients, and ≥ Grade 3 irAEs observed in 3 (10.3%) patients. Serious adverse events occurred in 44.8% of the patients.

Adverse Events of Any Grade with an Incidence ≥15% in all Subjects

TEAE Events	BAT1308+Chemo±Bevacizumab (n=29)	
	Any Grade,n(%）	≥Grade 3,n(%）
Anemia	24 (82.8)	11 (37.9%)
White blood cell decreased	15 (51.7)	9 (31.0%)
Alopecia	15 (51.7)	0
Thrombocytopenia	14 (48.3)	3 (10.3%)
Neutropenia	13 (44.8)	9 (31.0)
Urinary Tract Infection	8 (27.6)	0
Lymphopenia	7 (24.1)	4 (13.8%)
Hypoproteinemia	6 (20.7)	0
Fatigue	6 (20.7)	0
Nause	6 (20.7)	0
Diarrhea	6 (20.7)	0
Hyperuricemia	6 (20.7)	0
Vomiting	5 (17.2)	0
Hyperthyroidism	5 (17.2)	0
Upper respiratory tract infection	5 (17.2)	0

Summary of Adverse Events (n = 29)

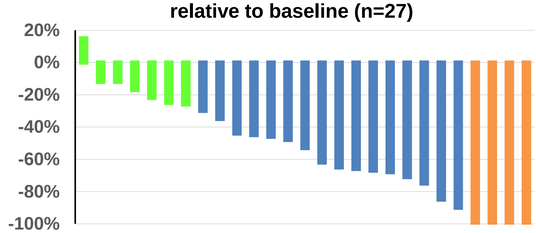
TEAE Events	Subjects No. (%)
Grade 3-5 AEs	21 (72.4)
SAEs	13 (44.8)
AEs Leading to Discontinuation	2 (6.9)
Deaths*	1 (3.4)
irAEs	13 (44.8)
Grade 3-5 irAEs	3 (10.3)
Infusion Reactions	5 (17.2)

*This discontinuation and death event is due to acute gastrointestinal hemorrhage, whose causality, as assessed by the investigator is probably related to bevacizumab.

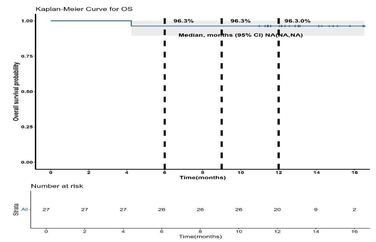
Efficacy

- As of April 28, 2025, 27 subjects completed at least one efficacy assessment. The ORR was 74.1%, with a confirmed ORR of 70.4%. The complete response rate was 11.1%, and the disease control rate was 100%.
- Currently, 13 subjects remain on treatment. Among those who discontinued the study, 8 withdrew informed consent, 7 experienced disease progression, and 1 died.
- The 6-month, 9-month, and 12 -month PFS rates were 88.9%, 81.5% , and 81.5% respectively. The 12-month OS rate is 96.3%. The median PFS and median OS have not yet been reached.

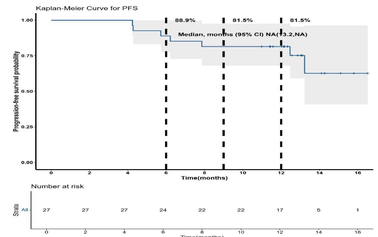
The best percentage of reduction in target lesions relative to baseline (n=27)



Kaplan-Meier Curve for OS



Kaplan-Meier Curve for PFS



Conclusion

BAT1308 combined with platinum-based chemotherapy ± Bevacizumab as first-line therapy showed durable anti-tumor activity and manageable safety profile for PD-L1-positive (CPS ≥ 1) persistent, recurrent or metastatic cervical cancer. These data are consistent with the earlier results and provide support for further studies. Phase 3 study is ongoing.

Ongoing Combination Studies

BAT1308 is currently combined with ADCs to explore novel cancer immunotherapy. The related ongoing trials are as follows:

- Oral Presentation 5517: BAT1308 + BAT8006, a FRα ADC in PROC;
- Poster 3024: BAT1308 + BAT8008, a TROP-2 ADC in advanced solid tumors.

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