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KEY TAKEAWAY

These results highlight the potential for PAS as a first-in-class KLK2xCD3 T-cell engager therapy for mCRPC and support inclusion of Asian patients in ongoing global phase 3 trials

NAVIGATION

KEY TAKEAWAY
CONCLUSIONS
INTRODUCTION
METHODS
FIGURE 1
Study design
RESULTS
Table 1: Baseline characteristics
FIGURE 2
Maximum PSA reduction from baseline
TABLE 2
Pharmacokinetics (PAS dose 1)
FIGURE 3
PAS serum concentrations
FIGURE 4
Interferon gamma (IFNγ) levels
TABLE 3
Safety
APPENDIX

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CONCLUSIONS

- The safety, efficacy, pharmacokinetic, and pharmacodynamic profile of PAS in patients with mCRPC in APAC is broadly consistent with its profile previously reported in the global mCRPC population
- Similar to the global (US and EU) study population, the APAC cohort had <10% CRS (all Grade 1) at the RP2D of PAS with a Q6W schedule

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NAVIGATION

KEY TAKEAWAY
CONCLUSIONS
INTRODUCTION
METHODS
FIGURE 1
Study design
RESULTS
Table 1: Baseline characteristics
FIGURE 2
Maximum PSA reduction from baseline
TABLE 2
Pharmacokinetics (PAS dose 1)
FIGURE 3
PAS serum concentrations
FIGURE 4
Interferon gamma (IFNγ) levels
TABLE 3
Safety
APPENDIX

Phase 1 safety, efficacy, pharmacokinetics (PK) and pharmacodynamics (PD) of pasritamig in Asian population with metastatic castration-resistant prostate cancer (mCRPC)

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INTRODUCTION

- Human kallikrein2 (encoded by the *KLK2* gene and hereafter referred to as KLK2) is a novel target expressed on prostate cancer cells and has limited expression in normal tissues[1]
- Pasritamig (PAS) is a first-in-class bispecific T-cell engager that simultaneously binds KLK2 on prostate cancer cells and CD3 receptor complexes on T cells, leading to T-cell–directed killing of KLK2-expressing prostate cancer cells
- A tolerable safety profile and promising anti-tumor activity for PAS was reported for US and EU patients with metastatic castration-resistant prostate cancer (mCRPC)[2,3]
- We report results for the Asia Pacific (APAC) population from the first-in-human study (NCT04898634) evaluating PAS in patients with mCRPC

NAVIGATION

KEY TAKEAWAY
CONCLUSIONS
INTRODUCTION
METHODS
FIGURE 1
Study design
RESULTS
Table 1: Baseline characteristics
FIGURE 2
Maximum PSA reduction from baseline
TABLE 2
Pharmacokinetics (PAS dose 1)
FIGURE 3
PAS serum concentrations
FIGURE 4
Interferon gamma (IFNγ) levels
TABLE 3
Safety
APPENDIX

Presented by N Liu at ASCO GU 2026; February 26-28, 2026; San Francisco, CA, USA

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METHODS

- The primary study objective was safety
- Secondary study objectives included preliminary antitumor activity, PK, and PD
- Two cohorts were evaluated in APAC (**Figure 1**):
  - Cohort 2A: mCRPC metastatic to bone, lymph node, or both without evidence of metastasis to visceral organs
  - Cohort 2C: mCRPC with lesions in visceral tissue with or without bone or lymph node metastases
- PAS was administered outpatient at a target dose of 300 mg intravenous (IV) every 6 weeks with two step-up doses of 3.5 mg IV on cycle 1 day 1 and 18 mg IV on cycle 1 day 8
  - Premedication with acetaminophen, diphenhydramine and dexamethasone (16 mg) were implemented for step-up and first treatment doses

NAVIGATION

KEY TAKEAWAY
CONCLUSIONS
INTRODUCTION
METHODS
FIGURE 1 Study design
RESULTS Table 1: Baseline characteristics
FIGURE 2 Maximum PSA reduction from baseline
TABLE 2 Pharmacokinetics (PAS dose 1)
FIGURE 3 PAS serum concentrations
FIGURE 4 Interferon gamma (IFNγ) levels
TABLE 3 Safety
APPENDIX

Presented by N Liu at ASCO GU 2026; February 26-28, 2026; San Francisco, CA, USA

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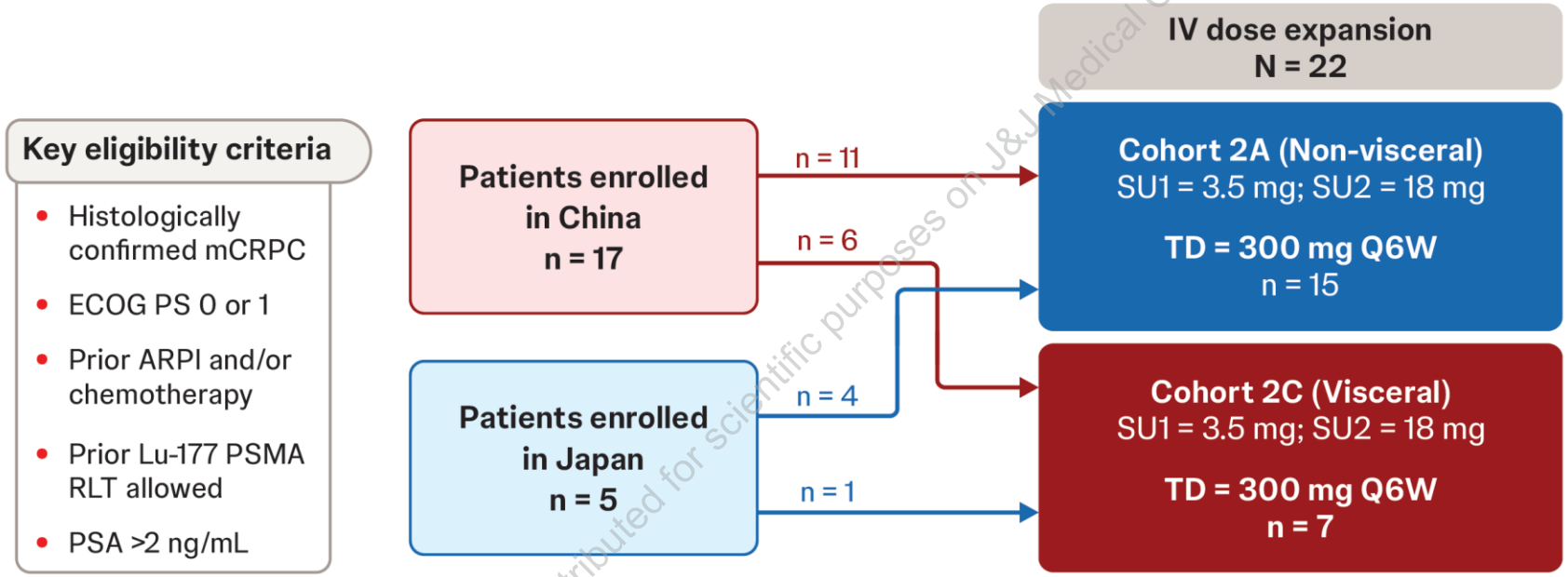
METHODS

FIGURE 1: Global, phase 1, first-in-human, dose-escalation and dose-expansion study



ARPI, androgen receptor pathway inhibitor; ECOG PS; Eastern Cooperative Oncology Group performance status; IV, intravenous; Lu-177 PSMA RLT, lutetium Lu 177 vipivotide tetraxetan prostate-specific membrane antigen radioligand therapy; PSA, prostate-specific antigen; Q6W, every 6 weeks; rPFS, radiographic progression-free survival; SU, step-up dose; TD, treatment dose.

Presented by N Liu at ASCO GU 2026; February 26-28, 2026; San Francisco, CA, USA

NAVIGATION

KEY TAKEAWAY
CONCLUSIONS
INTRODUCTION
METHODS
FIGURE 1 Study design
RESULTS Table 1: Baseline characteristics
FIGURE 2 Maximum PSA reduction from baseline
TABLE 2 Pharmacokinetics (PAS dose 1)
FIGURE 3 PAS serum concentrations
FIGURE 4 Interferon gamma (IFNγ) levels
TABLE 3 Safety
APPENDIX

Phase 1 safety, efficacy, pharmacokinetics (PK) and pharmacodynamics (PD) of pasritamig in Asian population with metastatic castration-resistant prostate cancer (mCRPC)

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RESULTS

- As of December 15, 2025, 22 participants in APAC (17 Chinese, 5 Japanese) received at least 1 PAS dose
- All APAC participants had prior androgen receptor pathway inhibitor (ARPI; **Table 1**)
- Baseline disease characteristics for APAC participants are generally consistent with the previously reported all-treated global population except for
  - A higher proportion of APAC participants received prior taxane (95.5% vs 78.2%) and a lower proportion received prior radioligand therapy (lutetium Lu 177 vipivotide tetraxetan 4.5% vs 17.8%) compared with the global population[3]
  - APAC participants, compared with the global population, had higher median prostate-specific antigen (PSA) at baseline (127.5 vs 74.8 ng/mL) and a higher proportion had visceral metastasis (31.8% vs 24.3%)[3]
- The median duration of therapy including step-up dosing was 5.98 [range: 0.5, 11.6] months, with 7 (31.8%) participants ongoing study treatment as of data cutoff

TABLE 1: Baseline characteristics

	China (n=17)	Japan (n=5)	APAC (N=22)
Age, years	69 [55, 85]	69 [52, 85]	69 [52, 85]
Baseline PSA, ng/mL	127.0 [6.8, 1973]	128.0 [8.8, 583]	127.5 [6.8, 1973]
Disease involvement			
Bone	14 (82.4)	5 (100)	19 (86.4)
Lymph node	9 (52.9)	0	9 (40.9)
Visceral	6 (35.3)	1 (20.0)	7 (31.8)
Liver	3 (17.6)	1 (20.0)	4 (18.2)
Number of prior therapies	3.0 [2, 5]	3.0 [2, 6]	3.0 [2, 6]
Prior therapies[a]			
ARPI	17 (100)	5 (100)	22 (100)
Taxane chemotherapy	17 (100)	4 (80)	21 (95.5)
1 regimen	12 (70.6)	3 (60.0)	15 (68.2)
>1 regimen	5 (29.4)	1 (20.0)	6 (27.3)

Data presented as n (%) or median [range].
[a]Additionally, 1 participant in China was previously treated with lutetium Lu 177 vipivotide tetraxetan prostate-specific membrane antigen radioligand therapy before the study.
APAC, Asia Pacific; ARPI, androgen receptor pathway inhibitor; PSA, prostate-specific antigen.

NAVIGATION

KEY TAKEAWAY
CONCLUSIONS
INTRODUCTION
METHODS
FIGURE 1 Study design
RESULTS Table 1: Baseline characteristics
FIGURE 2 Maximum PSA reduction from baseline
TABLE 2 Pharmacokinetics (PAS dose 1)
FIGURE 3 PAS serum concentrations
FIGURE 4 Interferon gamma (IFNγ) levels
TABLE 3 Safety
APPENDIX

Presented by N Liu at ASCO GU 2026; February 26-28, 2026; San Francisco, CA, USA

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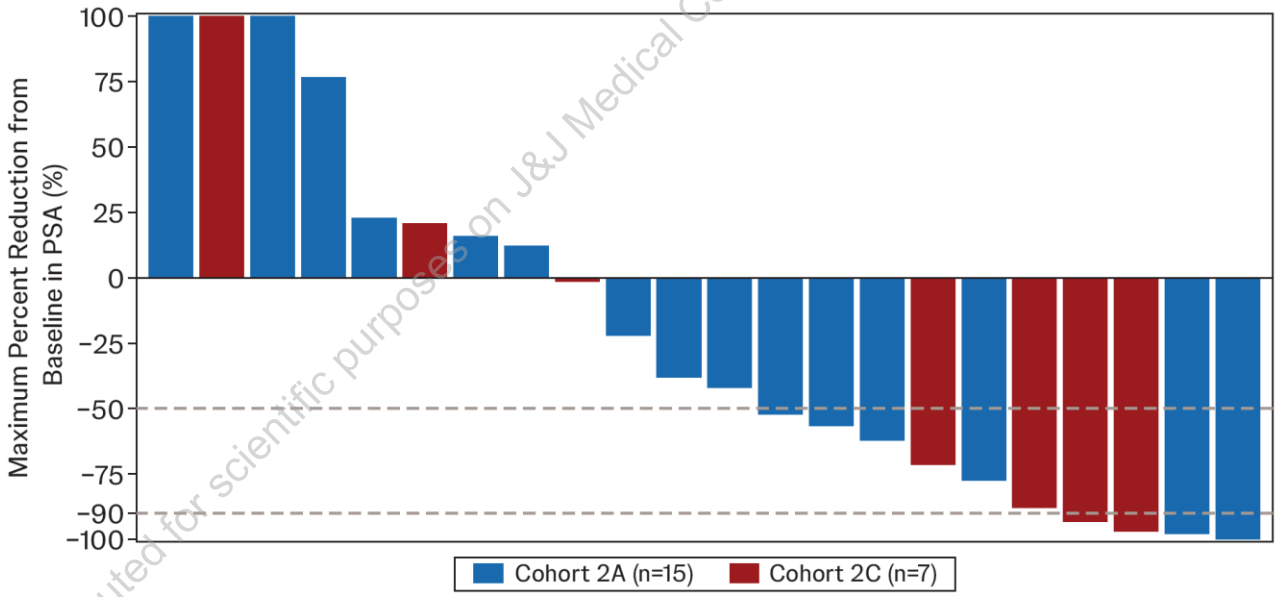
RESULTS

- Unconfirmed PSA50 response at any time was 45.5% (10/22), and the confirmed PSA50 was 31.8% (7/22), including 4 confirmed responders with visceral metastasis (**Figure 2**)
- With a median follow-up of 7.8 months in APAC, median overall radiographic progression-free survival (rPFS) was 8.31 (95% CI: 3.75, not estimable [NE]) months with 68.2% (15/22) of participants still being followed
  - Median rPFS was 8.31 (95% CI: 3.75, NE) months in Cohort 2A and 4.83 (95% CI: 1.18, NE) months in Cohort 2C

FIGURE 2: Maximum percent reduction from baseline of PSA



Reference lines represent 50% and 90% decrease. Increase >100% is set to 100%.
PSA, prostate-specific antigen.

NAVIGATION

KEY TAKEAWAY
CONCLUSIONS
INTRODUCTION
METHODS
FIGURE 1 Study design
RESULTS Table 1: Baseline characteristics
FIGURE 2 Maximum PSA reduction from baseline
TABLE 2 Pharmacokinetics (PAS dose 1)
FIGURE 3 PAS serum concentrations
FIGURE 4 Interferon gamma (IFNγ) levels
TABLE 3 Safety
APPENDIX

Presented by N Liu at ASCO GU 2026; February 26-28, 2026; San Francisco, CA, USA

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RESULTS

- PAS PK in APAC participants were linear, with a mean half-life of 14 days and was generally consistent with the global population (**Table 2** and **Figure 3**)
- PAS PD were similar between APAC participants and the global population
  - Increases in interferon gamma (IFNγ) serum levels were observed following PAS treatment, indicating peripheral T cell activation (**Figure 4**)

Table 2: Pharmacokinetics (PAS dose 1)

	C_{max} (µg/mL)	T_{max} (h)	AUC_{42days} (h*µg/mL)	C_{trough} (µg/mL)	$T_{1/2}$ (days)
APAC (N=22)	106 (17.7)	2 [2, 8]	23790 (5011)[a]	7.16 (3.04)[a]	13.8 (4.3)
Global (N=33)	74.7 (15.7)	2 [2, 168]	17717 (4131)[b]	6.34 (2.77)[b]	16.5 (5.9)[c]

Data shown as mean (SD) for all parameters, except for T_{max} shown as median [range].
[a]n=16. [b]n=27. [c]n=31. AUC, area under the curve; C_{max}, maximum concentration; C_{trough}, trough concentration; $T_{1/2}$, half-life; T_{max}, time to peak plasma concentration.

Presented by N Liu at ASCO GU 2026; February 26-28, 2026; San Francisco, CA, USA

NAVIGATION

KEY TAKEAWAY
CONCLUSIONS
INTRODUCTION
METHODS
FIGURE 1 Study design
RESULTS Table 1: Baseline characteristics
FIGURE 2 Maximum PSA reduction from baseline
TABLE 2 Pharmacokinetics (PAS dose 1)
FIGURE 3 PAS serum concentrations
FIGURE 4 Interferon gamma (IFNγ) levels
TABLE 3 Safety
APPENDIX

Phase 1 safety, efficacy, pharmacokinetics (PK) and pharmacodynamics (PD) of pasritamig in Asian population with metastatic castration-resistant prostate cancer (mCRPC)

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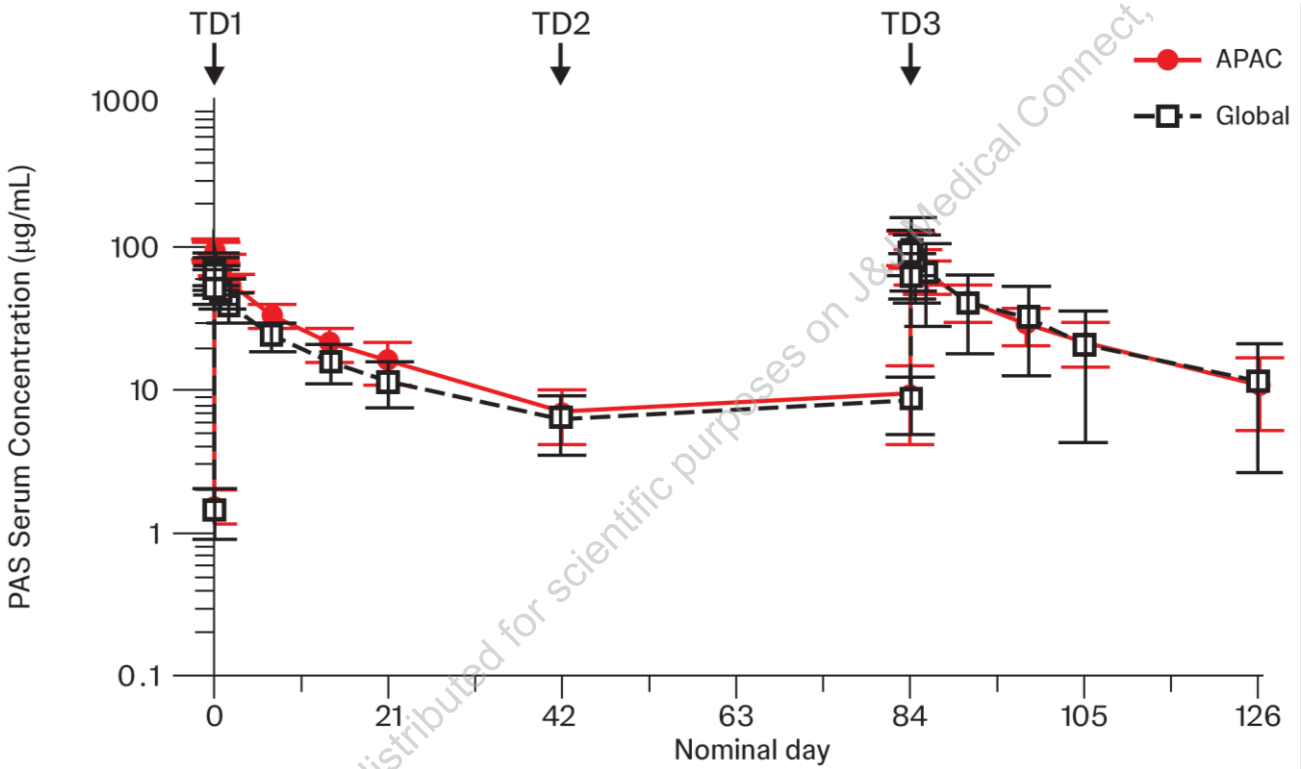
RESULTS

FIGURE 3: PAS serum concentrations[a]



[a]Profile of mean observed PAS serum concentrations (plot with standard deviation error bars; semilogarithmic plots).
APAC, Asia Pacific; PAS, pasritamig; TD, target dose.

Presented by N Liu at ASCO GU 2026; February 26-28, 2026; San Francisco, CA, USA

NAVIGATION

KEY TAKEAWAY
CONCLUSIONS
INTRODUCTION
METHODS
FIGURE 1
Study design
RESULTS
Table 1: Baseline characteristics
FIGURE 2
Maximum PSA reduction from baseline
TABLE 2
Pharmacokinetics (PAS dose 1)
FIGURE 3
PAS serum concentrations
FIGURE 4
Interferon gamma (IFNγ) levels
TABLE 3
Safety
APPENDIX

Phase 1 safety, efficacy, pharmacokinetics (PK) and pharmacodynamics (PD) of pasritamig in Asian population with metastatic castration-resistant prostate cancer (mCRPC)

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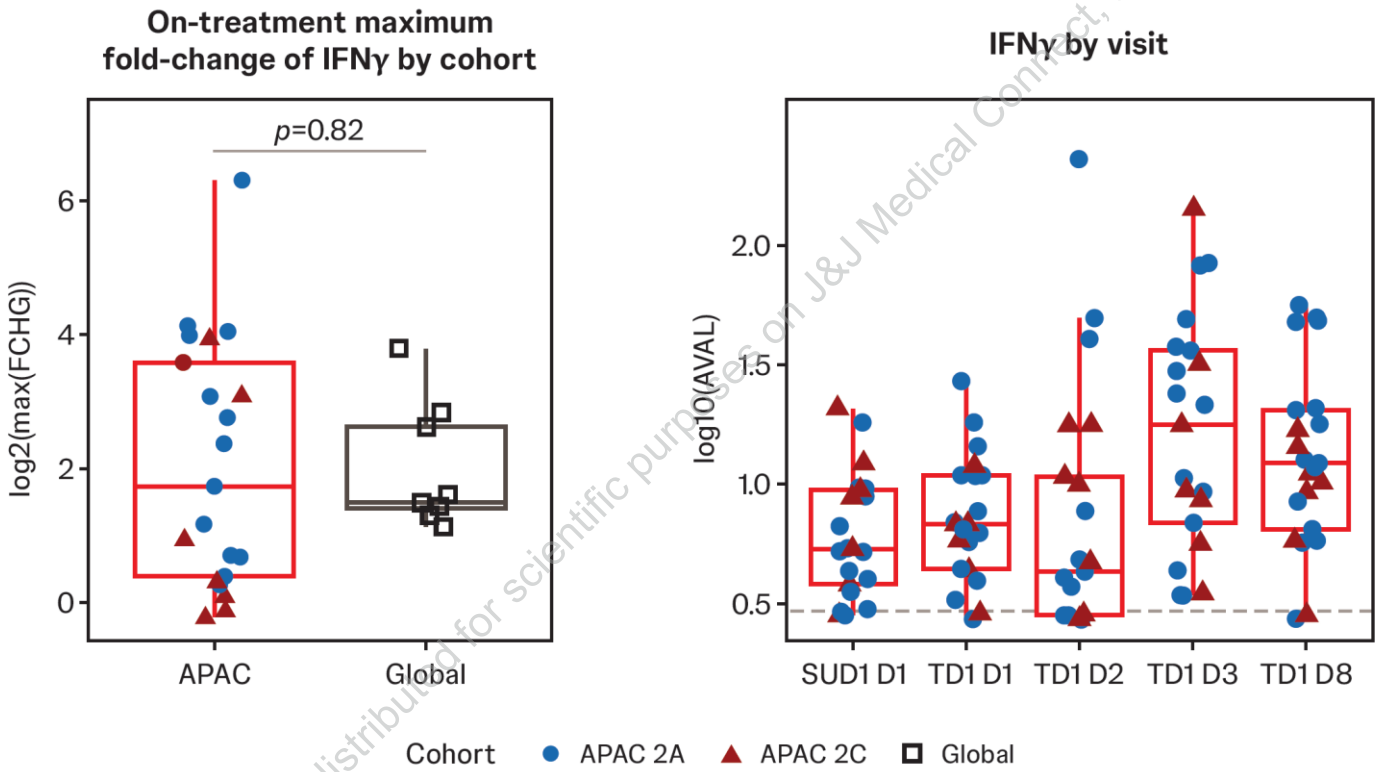
RESULTS

FIGURE 4: Interferon gamma (IFNγ) levels



IFNγ was quantified using the Meso Scale Discovery V-PLEX Proinflammatory panel. Serum samples were collected at baseline (pre-SU1); pre-TD1; and at 2, 3, and 8 days post-TD1 (TD1 D2, TD1 D3, TD1 D8).
APAC, Asia Pacific; AVAL, analysis value (concentration); D, day; FCHG, fold change over baseline; SUD, step-up dose; TD, target dose.

Presented by N Liu at ASCO GU 2026; February 26-28, 2026; San Francisco, CA, USA

NAVIGATION

KEY TAKEAWAY
CONCLUSIONS
INTRODUCTION
METHODS
FIGURE 1 Study design
RESULTS Table 1: Baseline characteristics
FIGURE 2 Maximum PSA reduction from baseline
TABLE 2 Pharmacokinetics (PAS dose 1)
FIGURE 3 PAS serum concentrations
FIGURE 4 Interferon gamma (IFNγ) levels
TABLE 3 Safety
APPENDIX

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Junyong Dai,[1] Nan Liu,[1] Yonghong Li,[2] Zhixian Yu,[3] Shudong Zhang,[4] Takashi Kawahara,[5] Hiroji Uemura,[5] Chihiro Kondoh,[6] Daria Gaut,[7] Regina Brown,[8] Leanne Cartee,[8] Yanmei Liu,[9] Junya Aoyama,[10] Haocheng Ma,[9] Ei Fujikawa,[10] Debopriya Ghosh,[11] Kristin Shotts,[8] Ruchi Chaudhary,[8] Siew Kee Low,[12] Nobuaki Matsubara[6]

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RESULTS

- No dose-limiting toxicities, treatment-related deaths, or treatment-related adverse events (TRAEs) leading to treatment discontinuation were reported in the APAC cohort
- 8 of 9 reported Grade ≥3 TRAEs were cytopenias (6 lymphopenia and 2 anemia in 7 APAC participants), most (5/7) of these participants had Grade 2 cytopenia at screening or baseline (**Table 3**). The other Grade 3 TRAE was dermatitis, which recovered in 22 days with steroid treatment
- 3 treatment-related serious AEs were reported in the APAC cohort: 2 Grade 1 cytokine release syndrome (CRS, 9.1% [vs 8.9% previously reported in the global safety RP2D population[3]]) and 1 Grade 3 dermatitis; both CRS events resolved within ≤5 days (1 with tocilizumab after not responding to acetaminophen)
- No infusion-related reactions or immune effector cell-associated neurotoxicity syndrome (ICANS) were observed in APAC participants

TABLE 3: Safety

Participants with	APAC (N=22)
≥1 TRAE	16 (72.7)
CRS	2 (9.1)[a]
Grade ≥3 TRAE	8 (36.4)
Most common Grade ≥3 TRAEs (≥5%)	
Lymphopenia	6 (27.3)
Anemia	2 (9.1)
Dermatitis	1 (4.5)
TRAE leading to discontinuation	0
TRSAE	3 (13.6)

Data presented as n (%).
[a]Both events were Grade 1, and no Grade ≥2 CRS were reported.
APAC, Asia Pacific; CRS, cytokine release syndrome; TRAE, treatment-related adverse event; TRSAE, treatment-related serious adverse event.

NAVIGATION

KEY TAKEAWAY
CONCLUSIONS
INTRODUCTION
METHODS
FIGURE 1 Study design
RESULTS Table 1: Baseline characteristics
FIGURE 2 Maximum PSA reduction from baseline
TABLE 2 Pharmacokinetics (PAS dose 1)
FIGURE 3 PAS serum concentrations
FIGURE 4 Interferon gamma (IFNγ) levels
TABLE 3 Safety
APPENDIX

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APPENDIX

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NAVIGATION

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INTRODUCTION
METHODS
FIGURE 1
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RESULTS
Table 1: Baseline characteristics
FIGURE 2
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TABLE 2
Pharmacokinetics (PAS dose 1)
FIGURE 3
PAS serum concentrations
FIGURE 4
Interferon gamma (IFNγ) levels
TABLE 3
Safety
APPENDIX