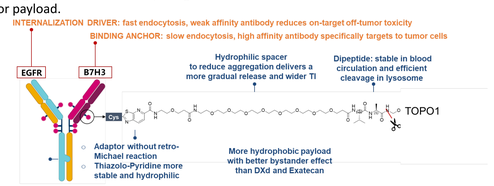
Preliminary Safety and Pharmacokinetic Results for TJ101, an EGFR × B7-H3 bispecific antibody-drug conjugate, in patients with advanced solid tumors: results from an ongoing global Phase I study

Poster # 3472

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BACKGROUND

EGFR and B7-H3 are frequently overexpressed in solid tumors, supporting a dual-targeting antibody–drug conjugate (ADC) approach. TJ101 is a bispecific ADC targeting EGFR and B7-H3, designed to enhance tumor-selective internalization and delivery of a topoisomerase I inhibitor payload.



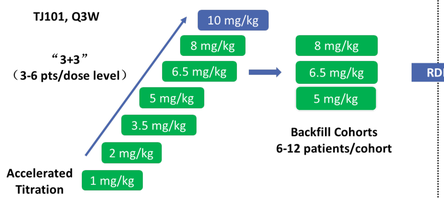
TJ101 is being evaluated in an ongoing first-in-human Phase 1a/1b study in China and the United States in patients with advanced solid tumors refractory to standard of care (SOC). We report preliminary safety, PK, and early antitumor activity from the Phase 1a dose escalation study.

STUDY DESIGN

Phase 1a Dose Escalation / Phase 1b Expansion

Dose Escalation（Phase Ia）

Primary Objectives：Safety; To determine Dose Limiting Toxicities (DLTs) and Recommended Doses for Expansion (RDEs)



RDEs

Dose Expansion（Phase Ib）

Primary Objectives: Safety and efficacy; To determine Recommended Phase 2 Dose (RP2D)

NSCLC AGA-
Urothelial Carcinoma
Prostate Cancer

RP2D

2-3 RDEs, Randomized Dose Optimization Cohorts, 40-60 patients/Cohort

PATIENT CHARACTERISTICS

As of September 28, 2026, 52 patients had been enrolled in the Phase 1a study and received TJ101 at 1–8 mg/kg via intravenous infusion (IV) once every three weeks (Q3W). Non-small cell lung cancer (NSCLC) was the most common tumor type, followed by urothelial cancer; patients had received a median of 2 prior lines of treatment.

Characteristics	Total (N=52)	Characteristics	Total (N=52)
Age		**Diagnosis**	**n (%)**
Median, years (range)	64.0 (30–78)	NSCLC	23 (44.2%)
Gender	**n (%)**	AGA Positive	6 (11.5%)
Male	32 (61.5%)	AGA Negative	17 (32.7%)
Female	20 (38.5%)	Squamous	6 (11.5%)
Race	**n (%)**	Non-squamous	11 (21.2%)
Asian	37 (71.2%)	Urothelial Carcinoma	9 (17.3%)
White	13 (25%)	Prostate Cancer	8 (15.4%)
Hispanic	1 (1.9%)	SCLC	6 (11.5%)
Not Reported	1 (1.9%)	Head and Neck Cancer	3 (5.8%)
ECOG	**n (%)**	Other	3 (5.8%)
0	12 (23.1%)	**Number of prior lines of anticancer therapy**	
1	40 (76.9%)	Median (range)	2 (1–5)

SAFETY & TOLERABILITY

TJ101 was generally well tolerated up to 8 mg/kg Q3W. Most treatment-related AEs (TRAEs) were low grade, with a low incidence of dose delays and reductions due to AEs. The most common TRAEs regardless of grade included nausea, skin hyperpigmentation, alopecia, decreased appetite, fatigue, neutropenia, and anemia; no interstitial lung disease (ILD) was reported.

Grade ≥3 TRAEs occurred predominantly at 8 mg/kg. One DLT (stomatitis) was reported at 8 mg/kg and was the only AE leading to dose reduction; no hematologic DLTs were observed. The MTD was not reached. IRRs were reported in 15.4% of patients, including one Grade 3 event. IRR premedication and prophylactic steroid mouthwash were introduced midway through the study.

Table 1: Safety Overview

	1 mg/kg N=1 n (%)	2 mg/kg N=3 n (%)	3.5 mg/kg N=3 n (%)	5 mg/kg N=12 n (%)	6.5 mg/kg N=16 n (%)	8 mg/kg N=17 n (%)	Total N=52 n (%)
TEAEs	1 (100.0)	3 (100.0)	3 (100.0)	12 (100.0)	16 (100.0)	17 (100.0)	52 (100.0)
--Related to TJ101	1 (100.0)	3 (100.0)	3 (100.0)	12 (100.0)	16 (100.0)	17 (100.0)	52 (100.0)
≥Grade 3 TEAEs	0	0	1 (33.3)	6 (50.0)	3 (18.8)	7 (41.2)	17 (32.7)
--Related to TJ101	0	0	0	2 (16.7)	1 (6.2)	7 (41.2)	10 (19.2)
SAEs	0	0	1 (33.3)	4 (33.3)	3 (18.8)	3 (17.6)	11 (21.2)
--Related to TJ101	0	0	0	1 (8.3)	0	3 (17.6)	4 (7.7)
TEAEs leading to dose reduction	0	0	0	0	0	1 (5.9)	1 (1.9)
--Related to TJ101	0	0	0	0	0	1 (5.9)	1 (1.9)
TEAEs leading to dose delay	0	1 (33.3)	0	3 (25.0)	3 (18.8)	4 (23.5)	11 (21.2)
--Related to TJ101	0	1 (33.3)	0	1 (8.3)	1 (6.2)	4 (23.5)	7 (13.5)
TEAEs leading to permanent discontinuation	0	0	0	1 (8.3)	0	1 (5.9)	2 (3.8)
--Related to TJ101	0	0	0	1 (8.3)	0	1 (5.9)	2 (3.8)

n(%): number of patients (%); TEAE: treatment-emergent adverse event; SAE: serious adverse event.

Table 2: Most Common Treatment-Related AEs (≥10%）

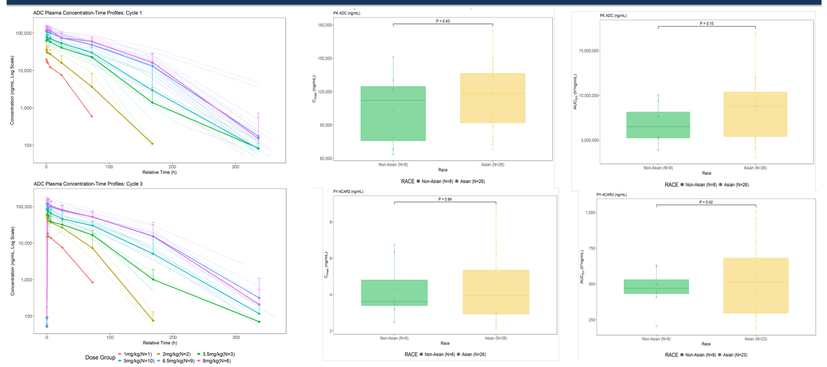
Preferred Term (MedDRA v25.0)	1 mg/kg N=1 n (%)	2 mg/kg N=3 n (%)	3.5 mg/kg N=3 n (%)	5 mg/kg N=12 n (%)	6.5 mg/kg N=16 n (%)	8 mg/kg N=17 n (%)	Total N=52 n (%)
Nausea	1 (100.0)	2 (66.7)	0	7 (58.3)	5 (31.2)	4 (23.5)	19 (36.5)
Skin hyperpigmentation	0	2 (66.7)	0	5 (41.7)	8 (50.0)	4 (23.5)	19 (36.5)
Alopecia	0	2 (66.7)	0	2 (16.7)	10 (62.5)	2 (11.8)	16 (30.8)
Decreased appetite	0	2 (66.7)	0	5 (41.7)	2 (12.5)	5 (29.4)	14 (26.9)
Fatigue	0	2 (66.7)	0	4 (33.3)	3 (18.8)	3 (17.6)	12 (23.1)
Neutrophil count decreased	0	0	1 (33.3)	2 (16.7)	3 (18.8)	4 (23.5)	10 (19.2)
Anaemia	0	2 (66.7)	1 (33.3)	1 (8.3)	3 (18.8)	3 (17.6)	10 (19.2)
Pruritus	0	1 (33.3)	0	2 (16.7)	3 (18.8)	2 (11.8)	8 (15.4)
Rash	1 (100.0)	2 (66.7)	0	2 (16.7)	1 (6.2)	2 (11.8)	8 (15.4)
Hyponatraemia	0	0	0	3 (25.0)	3 (18.8)	2 (11.8)	8 (15.4)
Hypophosphataemia	0	0	0	2 (16.7)	2 (12.5)	4 (23.5)	8 (15.4)
White blood cell count decreased	0	0	0	1 (8.3)	3 (18.8)	4 (23.5)	8 (15.4)
Infusion related reaction	0	1 (33.3)	1 (33.3)	2 (16.7)	1 (6.2)	3 (17.6)	8 (15.4)
Vomiting	0	2 (66.7)	0	3 (25.0)	1 (6.2)	1 (5.9)	7 (13.5)
Lymphocyte count decreased	0	0	0	3 (25.0)	1 (6.2)	3 (17.6)	7 (13.5)
Pyrexia	0	0	1 (33.3)	3 (25.0)	2 (12.5)	1 (5.9)	7 (13.5)
Constipation	0	0	0	0	3 (18.8)	3 (17.6)	6 (11.5)
Stomatitis	0	0	0	0	2 (12.5)	4 (23.5)	6 (11.5)
Weight decreased	0	1 (33.3)	1 (33.3)	1 (8.3)	1 (6.2)	2 (11.8)	6 (11.5)

Table 3: Grade ≥ 3 Treatment-Related AEs

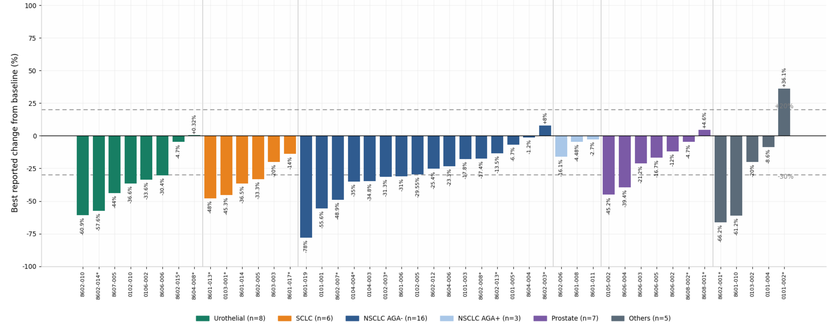
Preferred Term (MedDRA v25.0)	1 mg/kg N=1 n (%)	2 mg/kg N=3 n (%)	3.5 mg/kg N=3 n (%)	5 mg/kg N=12 n (%)	6.5 mg/kg N=16 n (%)	8 mg/kg N=17 n (%)	Total N=52 n (%)
Neutrophil count decreased	0	0	0	0	0	4 (23.5)	4 (7.7)
Lymphocyte count decreased	0	0	0	1 (8.3)	1 (6.2)	2 (11.8)	4 (7.7)
Stomatitis	0	0	0	0	0	1 (5.9)	1 (1.9)
White blood cell count decreased	0	0	0	0	0	1 (5.9)	1 (1.9)
GGT increased	0	0	0	1 (8.3)	0	0	1 (1.9)
Anaemia	0	0	0	0	0	1 (5.9)	1 (1.9)
IRR*	0	0	0	0	0	1 (5.9)	1 (1.9)

*Symptoms included rigors, nausea, chills and fever (39.4°C). The IRR resolved on the same day.

Pharmacokinetics



PRELIMINARY ANTITUMOR ACTIVITY



One bar per patient: best (minimum) numeric percentage change in target lesion size across all reported assessments, including assessments before escalation to ≥5 mg/kg.
* Overall PD recorded at or after the selected assessment; shrinkage alone does not establish response. Dashed lines are numeric references only.
SCLC includes one case converted from NSCLC. NSCLC AGA- combines adenocarcinoma and squamous histologies.
Others: ESCC, NPC, HNSCC (salivary gland), parotid basal cell carcinoma, and vulvar cancer.

CONCLUSIONS

- TJ101 was generally well tolerated through 8 mg/kg Q3W, with most treatment-related adverse events low grade and no interstitial lung disease reported.
- Grade ≥3 treatment-related adverse events occurred predominantly at 8 mg/kg. One **Grade 3 stomatitis dose-limiting toxicity** resolved and resulted in the only dose reduction. Four patients had Grade ≥3 neutrophil-count decreases, including two Grade 4 and two Grade 3 events; no hematologic dose-limiting toxicities were observed. **The MTD was not reached**.
- Following introduction of IRR premedication, including steroid-based measures, and prophylactic steroid mouthwash, lower observed frequencies of infusion-related reactions, nausea, and vomiting were seen in subsequent patients, as summarized in the table. These mitigation measures supported continued dosing and dose optimization.
- TJ101 showed dose-dependent pharmacokinetics, with no evidence of accumulation. No significant PK difference was observed between Asian and Non-Asian patients.
- Preliminary antitumor activity across **urothelial carcinoma, SCLC, AGA-negative NSCLC, and prostate cancer** supports continued evaluation of TJ101, including alternative schedules and dose optimization.

Disclaimer: The results presented are preliminary and based on data from an ongoing Phase I clinical trial (data cutoff: September 28, 2026). Data are subject to change with additional follow-up.

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