

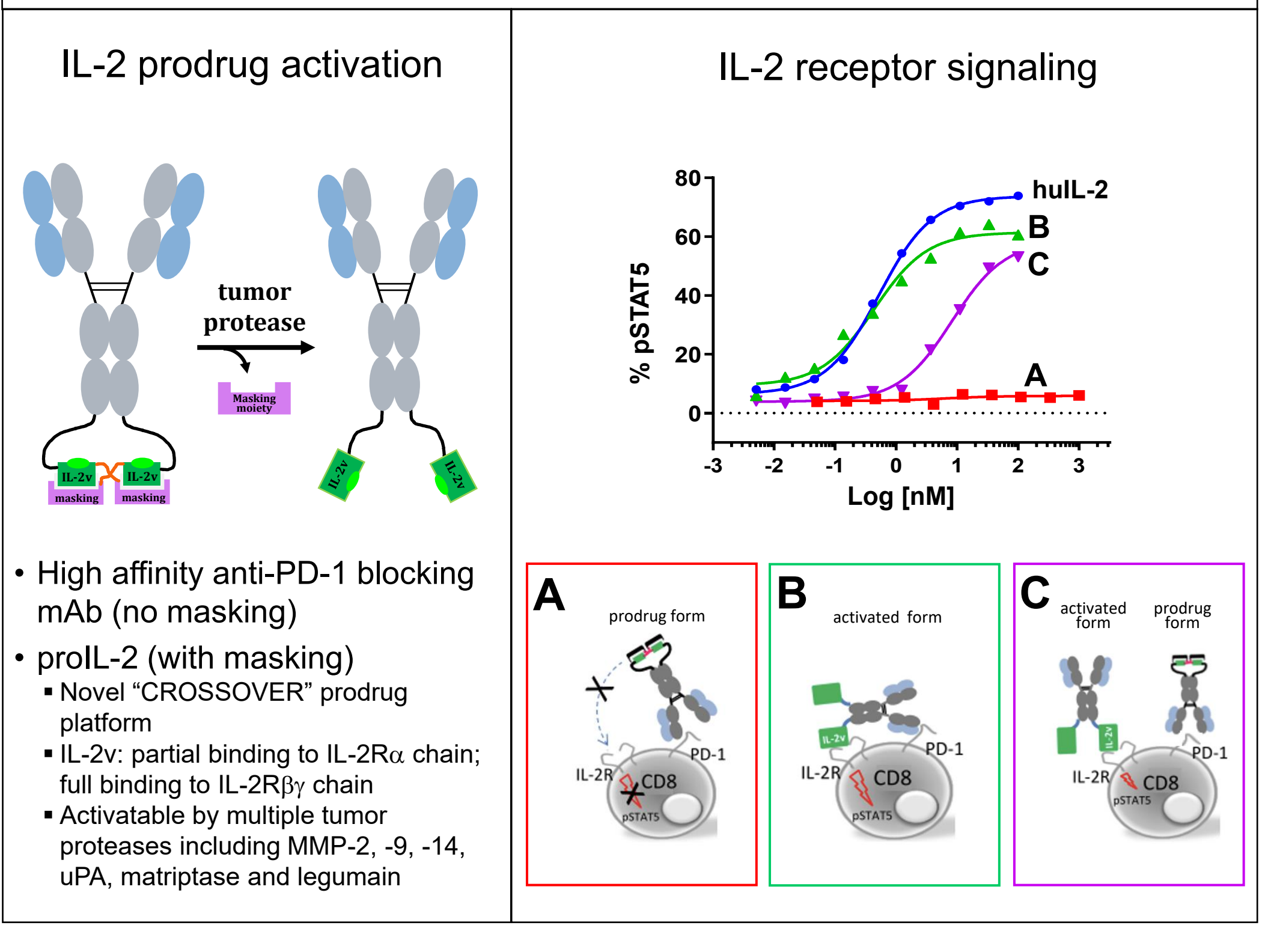
Phase Ia Study of PTX-912, an Anti–PD-1–proIL-2 Fusion Protein, in Patients with Advanced or Metastatic Solid Tumors

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INTRODUCTION

- PD-(L)1 checkpoint blockade-based regimens are widely adopted as standard first-line treatment for multiple solid tumors; however, effective subsequent therapeutic options remain limited upon the development of drug resistance
- IL-2 induces durable antitumor responses as a single agent and acts synergistically with PD-1 blockade. Nevertheless, severe systemic toxicity limits the clinical use of conventional IL-2 therapy
- PTX-912 is a first-in-class anti-PD-1 and tumor-activatable IL-2 prodrug fusion protein. Preclinically, it enhances T-cell proliferation and reinvigoration selectively in the TME to overcome PD-1 resistance, with minimal peripheral immune activation and improved safety
- This poster reports the phase 1 dose-escalation study of PTX-912 in patients with advanced solid tumors

Figure 1. Mechanism of Action of PTX-912



METHODS

- Key Inclusion Criteria:
 - ≥ 18 years
 - Histologically or cytologically confirmed advanced or metastatic solid tumors
 - At least one measurable tumor lesion per RESIST 1.1
- Treatment: PTX-912 at doses of 1, 2, 3, 4, 6, or 8 mg/kg, administered via intravenous infusion over 60 minutes, every 2 weeks
- Study objectives:
 - Primary endpoints were safety, tolerability, and determination of the recommended dose for expansion
 - Secondary endpoints included objective response rate (ORR), disease control rate (DCR), PK, and anti-drug antibody (ADA) incidence

RESULTS

A total of 38 previously treated patients were enrolled as of April 30, 2026, of whom 33 had NSCLC and 5 had other solid tumor malignancies and were treated across six dose cohorts.

Safety: All 38 patients were safety-evaluable. Treatment-emergent adverse events (TEAEs) occurred in all patients and were predominantly Grade 1-2; Grade ≥ 3 treatment-related adverse events (TRAEs) were reported in 31.6% (n=12) of patients. One DLT (liver injury) was reported in a TSCC patient in the 6 mg/kg cohort. Inflammatory cytokine release was minimal and no VLS observed. The MTD was not reached.

Efficacy: Thirty-seven (37) patients were efficacy-evaluable, 94.6% of whom had prior ICI treatment failure. The ORR was 32.4% (12/37) and the DCR was 81.1% (30/37) (Table 3). In prior IO subgroup (n=35), PR rates were 50% (4/8), 33.3% (3/9), and 44.4% (4/9) for the 2 mg/kg, 3 mg/kg, and 4 mg/kg cohorts, respectively, demonstrating antitumor activity in an ICI-resistant setting. Within the squamous NSCLC subgroup with prior IO treatment (n=23), 91.3% (21/23) of patients achieved target tumor regression, with ORR and DCR of 39.1% (9/23) and 87.0% (20/23).

Immunogenicity (ADA): ADA was detectable, with marked inter-patient variability in titers; ADA levels gradually declined with repeated drug dosing.

Table 1: Baseline Characteristics

Baseline	Total (N=38)
Age (range), years	66.5 (46-78)
Gender, n (%)	
Male	35 (92.1)
Female	3 (7.9)
ECOG PS, n (%)	
0	0 (0)
1	38 (100)
Tumor histology, n (%)	
sq-NSCLC	24 (63.2)
ad-NSCLC	9 (23.7)
Lung NOS	1 (2.6)
ES-SCLC	1 (2.6)
TSCC, GEJ, NEC	3 (7.9)
Disease stage	
III	7 (18.4)
IV	31 (81.6)
Metastatic site, n (%)	
Lung	21 (55.3)
Bone	10 (26.3)
Liver	5 (13.2)
Previous lines of therapy	
1	13 (34.2)
2	11 (28.9)
≥ 3	14 (36.8)
Prior IO	36 (94.7)

Table 2: Overview of treatment emergent adverse events by dose groups

N (%)	1 mg/kg (N=1)	2 mg/kg (N=9)	3.0 mg/kg (N=9)	4 mg/kg (N=10)	6 mg/kg (N=7)	8 mg/kg (N=2)	Total (N=38)
TEAEs	1 (100)	9 (100)	9 (100.0)	10 (100)	7 (100)	2 (100)	38 (100.0)
Grade ≥ 3 TEAEs	0	3 (33.3)	1 (11.1)	7 (70.0)	7 (100)	2 (100)	20 (52.6)
TRAEs	1 (100)	9 (100)	8 (88.9)	10 (100)	7 (100)	2 (100)	37 (97.4)
Grade ≥ 3 TRAEs	0	3 (33.3)	0	4 (40.0)	4 (57.1)	1 (50)	12 (31.6)
TRSAE	0	1 (11.1)	1 (11.1)	4 (40.0)	2 (28.6)	1 (50.0)	9 (23.7)
TRAEs leading to Tx DC	0	0	0	0	2 (28.6)	0	2 (5.3)

Figure 1: Common TRAEs ($\geq 10\%$ in any group)

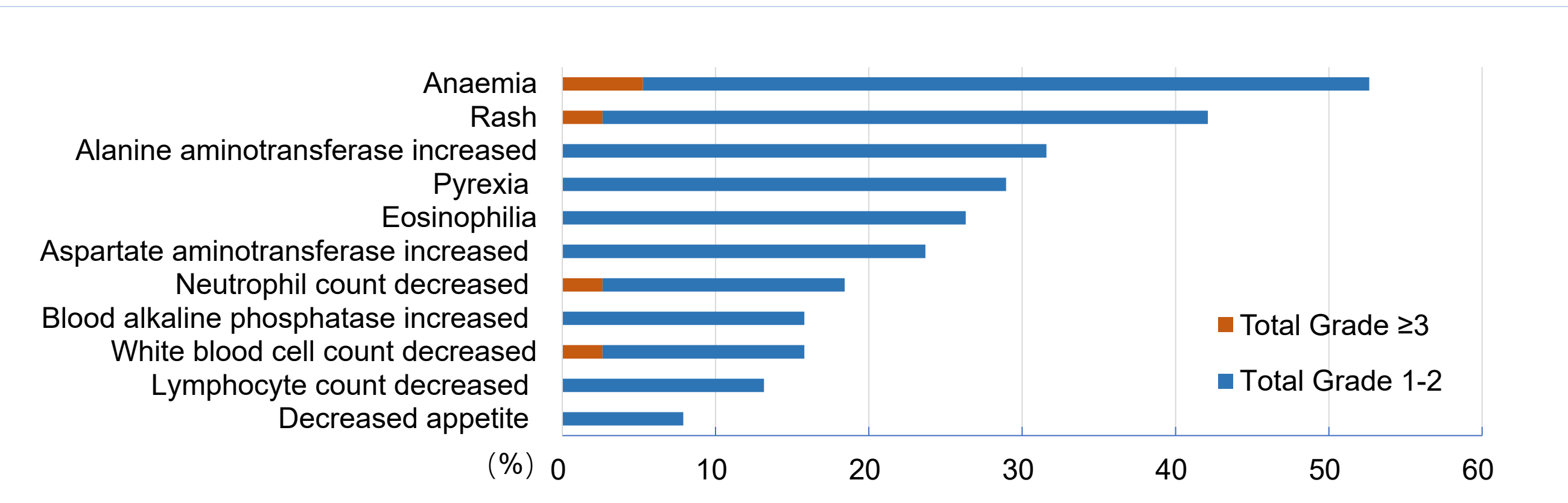


Table 3: Summary of antitumor response by dose group

BOR, n (%)	1 mg/kg (N=1)	2 mg/kg (N=9*)	3 mg/kg (N=9)	4 mg/kg (N=9)	6 mg/kg (N=7*)	8 mg/kg (N=2)	Total (N=37) (95%CI)
CR	0	0	0	0	0	0	0
PR	0	4 (44.4)	3 (33.3)	4 (44.4)	0	1 (50)	12 (32.4)**
SD	0	5 (55.6)	4 (44.4)	3 (33.3)	5 (71.4)***	1 (50)	18 (48.7)
PD	1	0	2 (22.2)	2 (22.2)	2 (28.6)	0	7 (18.9)
ORR	0	4 (44.4)	3 (33.3)	4 (44.4)	0	1 (50)	12 (32.4, 18.0-49.8)
DCR	0	9 (100.0)	7 (77.8)	7 (77.8)	5 (71.4)***	2 (100)	30 (81.1, 61.8-90.2)

* one (1) patient in 2 mg/kg and another one (1) in 6 mg/kg were IO treatment naïve.

**As of Apr. 30, 2026, among 12 PR patients, 7 achieved confirmed PR, and the other 5 were still on-treatment with PR confirmation pending the next assessment.

***One patient had SD at the first tumor assessment (≤ 6 weeks) and subsequently withdrew from the study.

Figure 2: Swimming plot showing Individual-patient antitumor responses

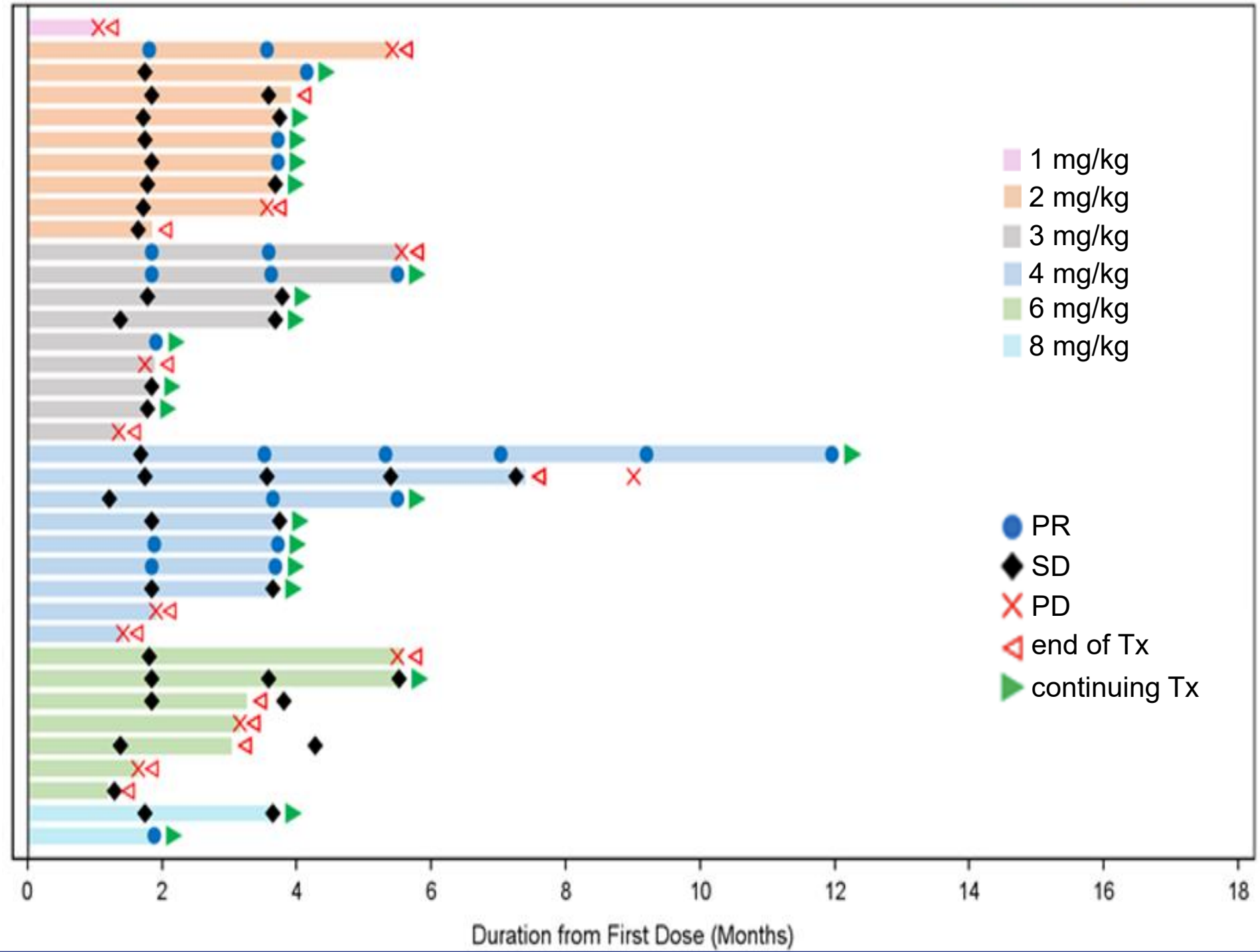


Figure 3A-B: Waterfall plot showing maximum target-lesion change and best overall response

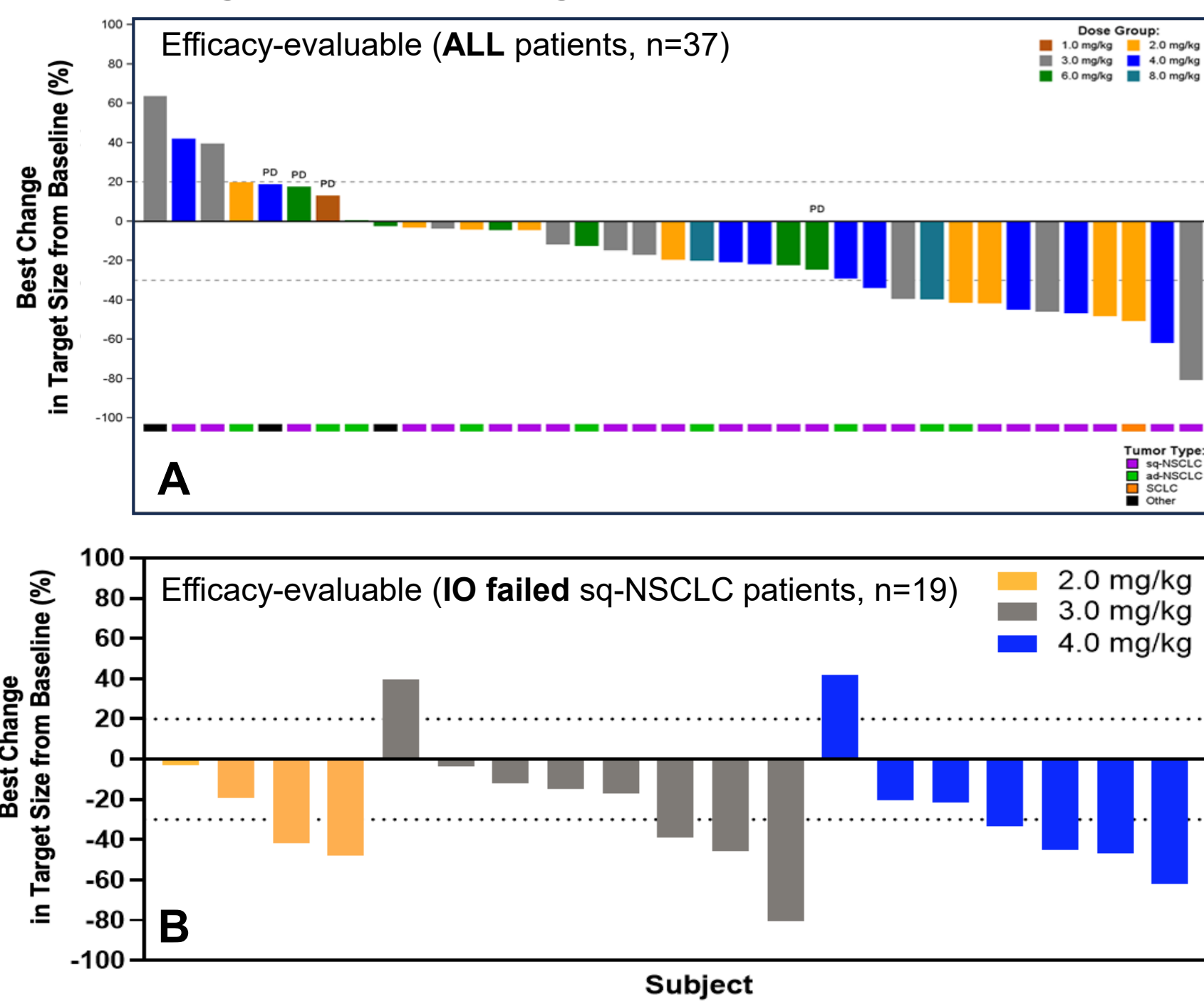
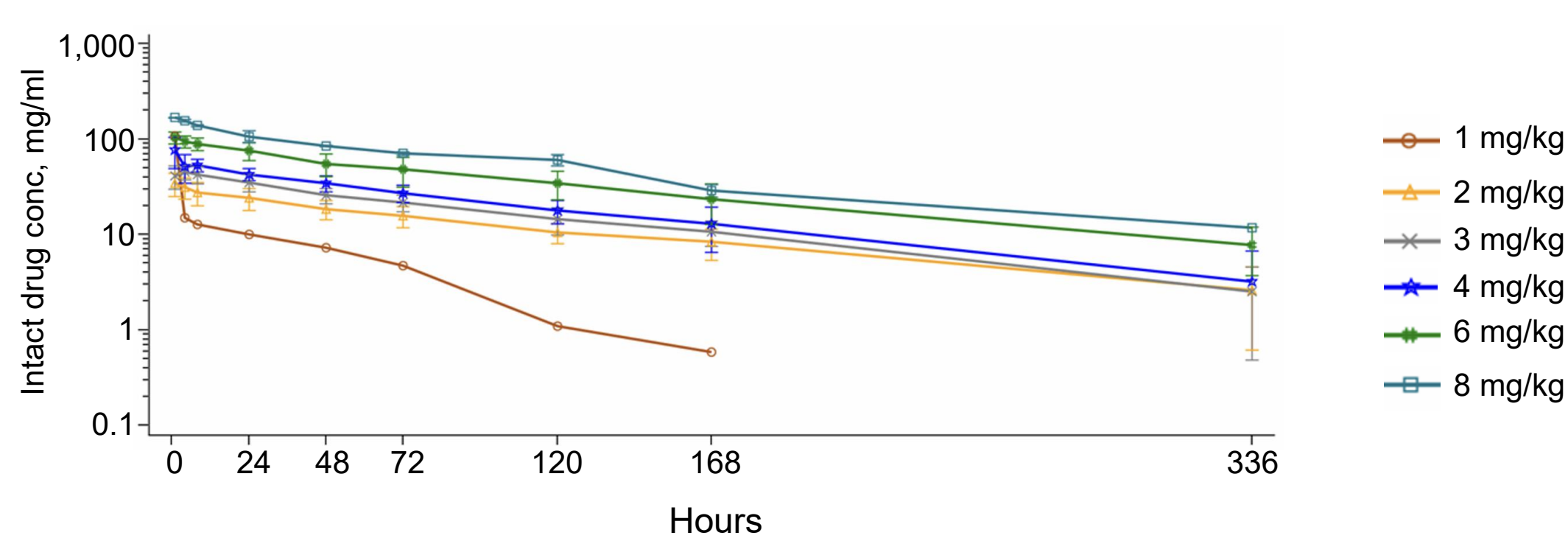


Figure 4: Mean PK profiles by dose group



DISCUSSION & CONCLUSIONS

- PTX-912 is a first-in-class PD-1-proIL-2 bispecific designed to improve safety and efficacy
 - Dual functionality:* inhibits PD-1 and activates IL-2 receptor
 - Tumor-selective activation:* restricts IL-2 activity to the TME
 - PD-1 cis-targeting:* enhances IL-2 signaling in PD-1⁺ T cells
- Consistent with its fully-masked proIL-2 design, PTX-912
 - can be safely administered via iv infusion without premedication
 - was well tolerated with low rate of grade ≥ 3 TRAEs
 - did not cause vascular leak syndrome (VLS)**
- The TSCC patient who experienced a DLT exhibited baseline of a markedly skewed CD4/CD8 T-cell ratio, suggestive of an elevated propensity for immune activation
- PTX-912 demonstrated encouraging antitumor activity
 - 32.4% ORR across all patients
 - 91.3% had tumor regression in sq-NSCLC patients
 - 47.4% ORR in sq-NSCLC with prior IO in 2, 3, and 4 mg/kg cohorts
 - Further deepening of tumor response is possible
- PTX-912 had an estimated $t_{1/2}$ of ~ 4 days, with no significant ADA-mediated impact on safety or efficacy. These findings support Q2W dosing and further evaluation of a Q3W schedule
- Study findings support further clinical investigation across multiple tumor types, including NSCLC, SCLC, RCC, MEL, CRC

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AI Disclosure: No AI tools were used to generate or analyze the data or derive conclusions in this presentation. All content was reviewed and verified by the authors, who accept full responsibility.