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# Precentbart tocentecan (M9140), an anti-CEACAM5 ADC with exatecan payload, in patients with metastatic colorectal cancer: updated clinical data from the Phase 1 PROCEADE-CRC-01 study



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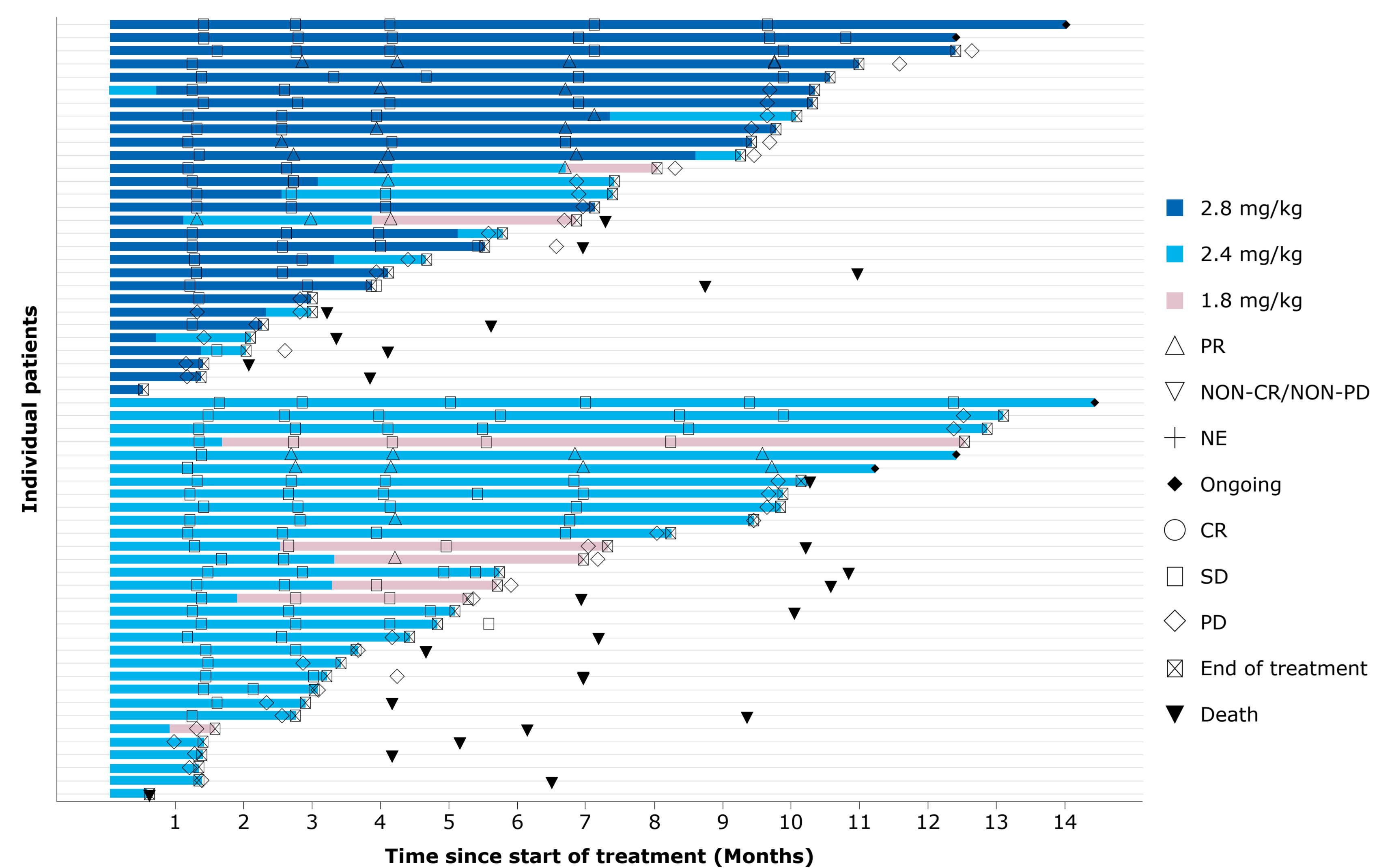
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## SUPPLEMENTARY DATA

**Table S1. Baseline and demographic characteristics**

Characteristics, n (%)	2.8 mg/kg Q3W n=29	2.4 mg/kg Q3W n=31	Total N=60
<b>Age</b>			
Median (range), years	60.0 (41.0–80.0)	61.0 (29.0–77.0)	60.0 (29.0–80.0)
<b>Age categories</b>			
<65 years	18 (62.1)	20 (64.5)	38 (63.3)
≥65 years	11 (37.9)	11 (35.5)	22 (36.7)
<b>Sex</b>			
Male	15 (51.7)	16 (51.6)	31 (51.7)
Female	14 (48.3)	15 (48.4)	29 (48.3)
<b>Race</b>			
Asian	9 (31.0)	13 (41.9)	22 (36.7)
White	17 (58.6)	17 (54.8)	34 (56.7)
Other	3 (10.3)	1 (3.2)	4 (6.7)
<b>ECOG performance status</b>			
0	21 (72.4)	23 (74.2)	44 (73.3)
1	8 (27.6)	8 (25.8)	16 (26.7)
<b>Site of primary tumor</b>			
Colon, left	10 (34.5)	5 (16.1)	15 (25.0)
Colon, right	9 (31.0)	14 (45.2)	23 (38.3)
Rectum	6 (20.7)	9 (29.0)	15 (25.0)
<b>Time since initial cancer diagnosis</b>			
Median (min–max), years	2.0 (0.8–7.6)	2.3 (0.2–8.6)	2.1 (0.2–8.6)
<b>Time since metastatic disease diagnosis</b>			
Median (min–max), years	1.6 (0.3–5.1)	1.6 (0.2–8.6)	1.6 (0.2–8.6)
<b>Previous exposure to irinotecan</b>	29 (100.0)	31 (100.0)	60 (100.0)

**Figure S1. Treatment duration and response over time**

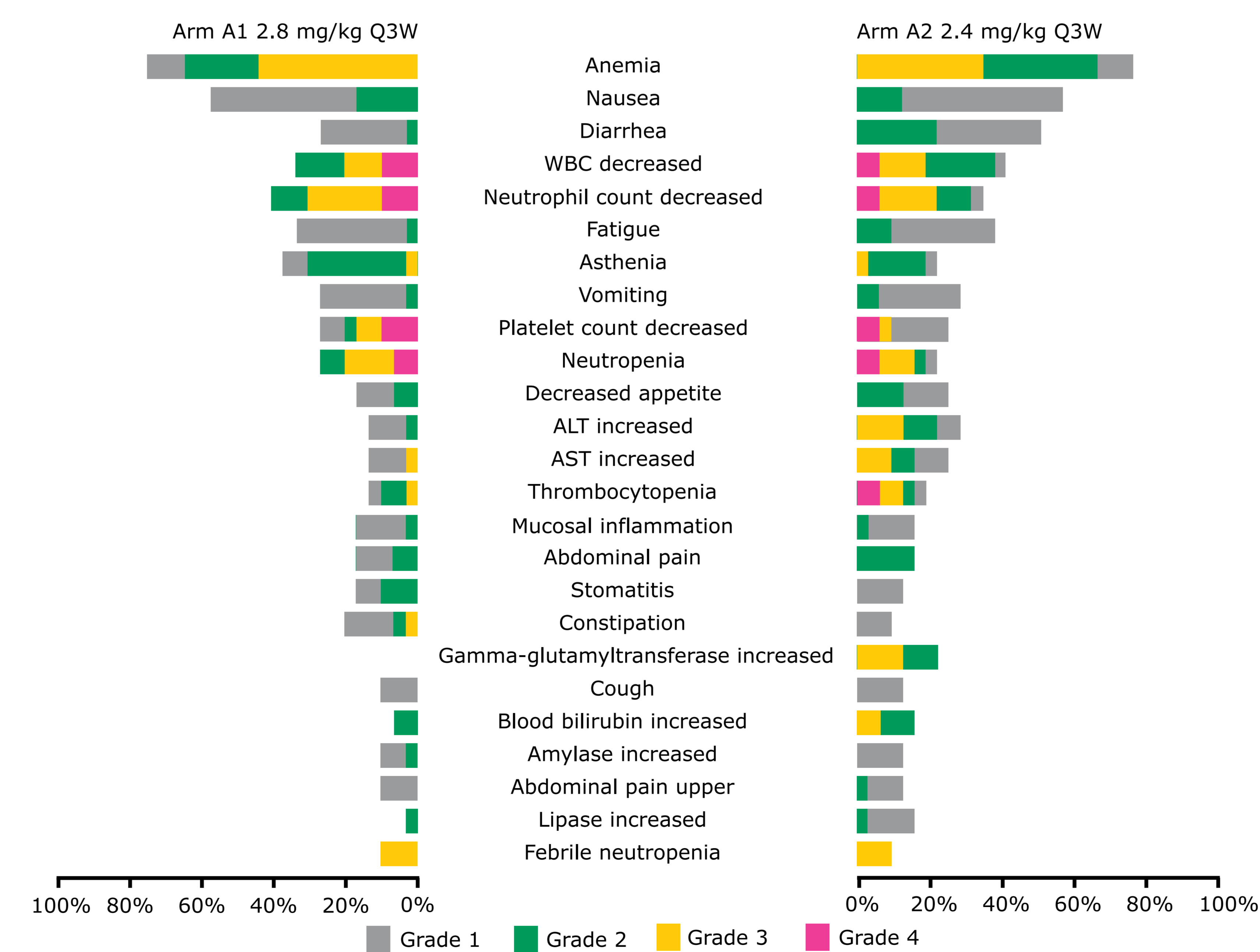


**Table S2. Selected<sup>a</sup> grade ≥3 TEAEs**

TEAEs, n (%)	2.8 mg/kg Q3W n=29	2.4 mg/kg Q3W n=31	Total N=60
Any grade ≥3 TEAE	22 (75.9)	21 (67.7)	43 (71.7)
Blood and lymphatic system disorders	17 (58.6)	15 (48.4)	32 (53.3)
Anemia	13 (44.8)	11 (35.5)	24 (40.0)
Neutropenia	6 (20.7)	5 (16.1)	11 (18.3)
Febrile neutropenia	3 (10.3)	3 (9.7)	6 (10.0)
Thrombocytopenia	1 (3.4)	4 (12.9)	5 (8.3)
Investigations	11 (37.9)	14 (45.2)	25 (41.7)
Neutrophil count decreased	9 (31.0)	7 (22.6)	16 (26.7)
WBC count decreased	6 (20.7)	6 (19.4)	12 (20.0)
Platelet count decreased	5 (17.2)	3 (9.7)	8 (13.3)
ALT increased	0 (0.0)	4 (12.9)	4 (6.7)
AST increased	1 (3.4)	3 (9.7)	4 (6.7)
GGT increased	0 (0.0)	4 (12.9)	4 (6.7)
Lymphocyte count decreased	1 (3.4)	2 (6.5)	3 (5.0)
Blood bilirubin increased	0 (0.0)	2 (6.5)	2 (3.3)
General disorders and administration site conditions	1 (3.4)	2 (6.5)	3 (5.0)
Asthenia	1 (3.4)	1 (3.2)	2 (3.3)
Nervous system disorders	1 (3.4)	1 (3.2)	2 (3.3)
Hepatobiliary disorders	2 (6.9)	5 (16.1)	7 (11.7)
Hepatic failure	1 (3.4)	1 (3.2)	2 (3.3)
GI disorders	3 (10.3)	2 (6.5)	5 (8.3)
Infections and infestations	5 (17.2)	0 (0.0)	5 (8.3)
Pneumonia	2 (6.9)	0 (0.0)	2 (3.3)

<sup>a</sup>Preferred term ≥2 patients

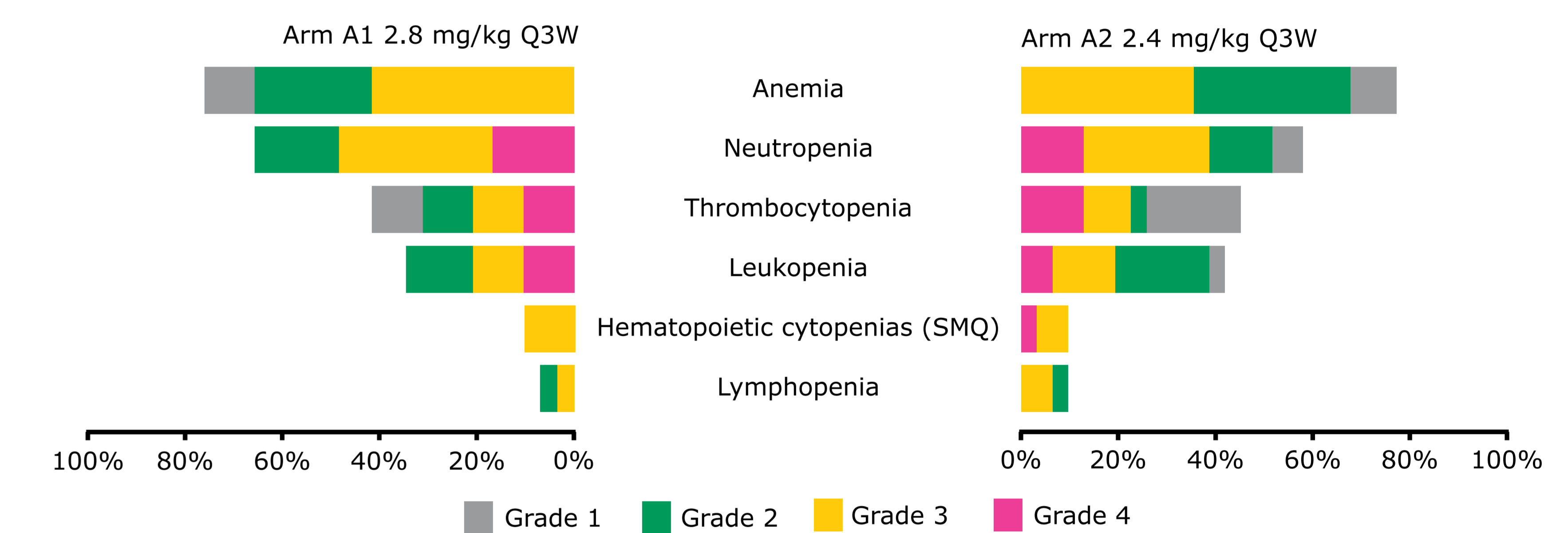
**Figure S2. Most common (≥10%) TEAEs by grade**



**Table S3. All grade ≥3 TRAEs**

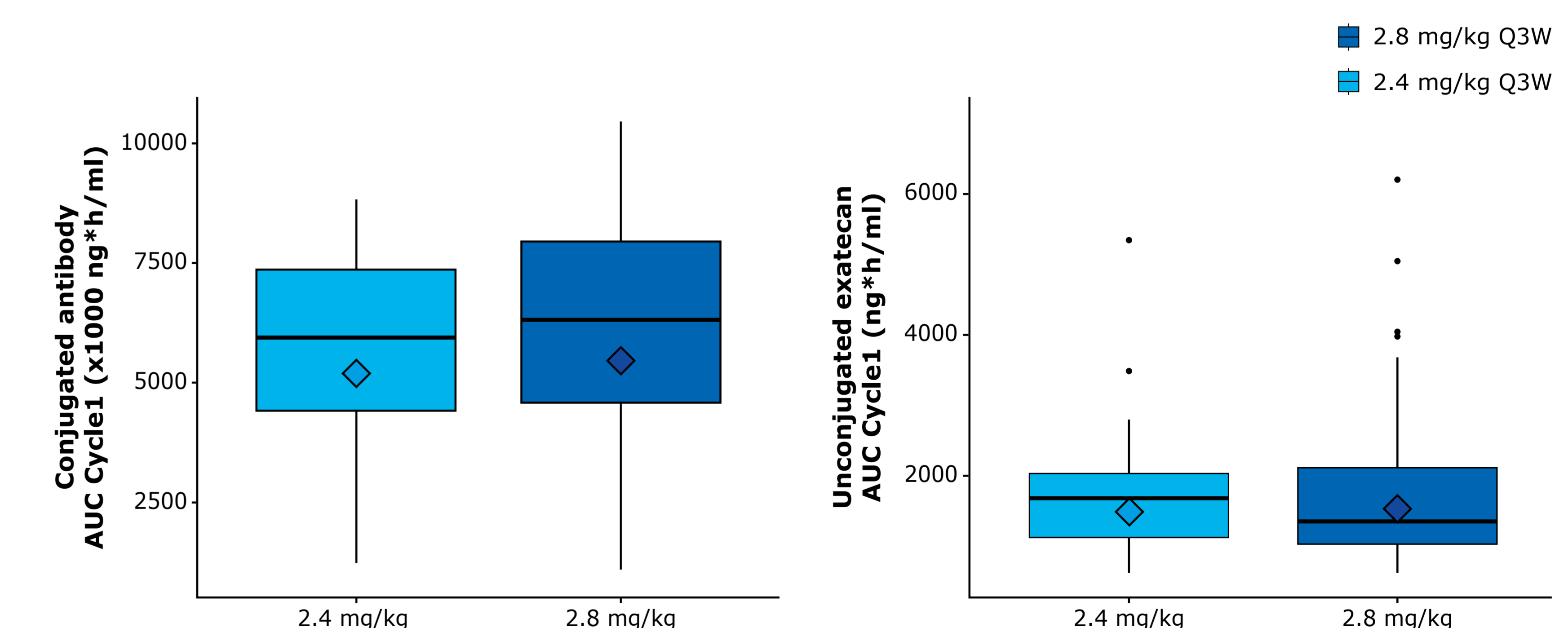
TRAEs, n (%)	2.8 mg/kg Q3W n=29	2.4 mg/kg Q3W n=31	Total N=60
Any grade ≥3 TRAE	22 (75.9)	21 (67.7)	43 (71.7)
Blood and lymphatic system disorders	17 (58.6)	15 (48.4)	32 (53.3)
Anemia	13 (44.8)	11 (35.5)	24 (40.0)
Neutropenia	6 (20.7)	5 (16.1)	11 (18.3)
Febrile neutropenia	3 (10.3)	3 (9.7)	6 (10.0)
Thrombocytopenia	1 (3.4)	4 (12.9)	5 (8.3)
Pancytopenia	0 (0.0)	1 (3.2)	1 (1.7)
Investigations	10 (34.5)	8 (25.8)	18 (30.0)
Neutrophil count decreased	9 (31.0)	7 (22.6)	16 (26.7)
WBC count decreased	6 (20.7)	6 (19.4)	12 (20.0)
Platelet count decreased	5 (17.2)	3 (9.7)	8 (13.3)
Lymphocyte count decreased	1 (3.4)	1 (3.2)	2 (3.3)
Hepatobiliary disorders	0 (0.0)	1 (3.2)	1 (1.7)
Hepatic function abnormal	0 (0.0)	1 (3.2)	1 (1.7)

**Figure S3. Hematologic TEAEs (blood and lymphatic system disorders)<sup>a</sup>**



<sup>a</sup>Anemia: includes anaemia, haemoglobin decreased, RBC count decreased, and haematocrit decreased; neutropenia: includes neutropenia and neutrophil count decreased; thrombocytopenia: includes thrombocytopenia and platelet count decreased; leukopenia: includes leukopenia and WBC count decreased; lymphopenia: includes lymphopenia and lymphocyte count decreased; haematopoietic cytenias excludes the Preferred Terms contained in the anaemia, neutropenia, thrombocytopenia, leukopenia, and lymphopenia.

**Figure S4. PK of Precem-TcT at 2.4 mg/kg and 2.8 mg/kg**



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**Abbreviations:** 3L+, third or later line of therapy; 5-FU, 5-fluorouracil; ADA, anti-drug antibody; ADC, antibody-drug conjugate; AE, adverse event; ALT, alanine aminotransferase; AST, aspartate aminotransferase; AUC, area under curve; CEACAM5, carcinoembryonic antigen-related cell adhesion molecule 5; CI, confidence interval; CR, complete response; CRC, colorectal cancer; DCR, disease control rate; DL, dose level; ECG, electrocardiogram; ECOG PS, Eastern Cooperative Oncology Group performance status; FIH, first-in-human; GGT, gamma-glutamyl transferase; GI, gastrointestinal; ICI, immune checkpoint inhibitor; ILD, interstitial lung disease; IV, intravenous; MoA, mechanism of action; Ia/m, locally advanced or metastatic; mCRC, metastatic colorectal cancer; MSI-H, microsatellite instability-high; NE, not estimable; NR, not reached; ORR, objective response rate; OS, overall survival; PD, progressive disease; PFS, progression-free survival; PK, pharmacokinetics; PR, partial response; PT, Preferred Term; Q3W, once every three weeks; RDE, recommended dose for expansion; RECIST v1.1, Response Evaluation Criteria in Solid Tumors version 1.1; SD, stable disease; SMQ, Standardized MedDRA Query; SoC, standard of care; TEAE, treatment-emergent adverse event; TOP1i, topoisomerase 1 inhibitor; TRAE, treatment-related adverse event; WBC, white blood cell.

**References:** 1. Dasari A, et al. *Lancet*. 2023;402:41-53; 2. Weinberg BA, et al. *Clin Adv Hematol Oncol*. 2016;14:630-638; 3. Mayer RJ, et al. *N Engl J Med*. 2015;372:1909-1919; 4. Grothey A, et al. *Lancet*. 2013;381:303-312; 5. Prager GW, et al. *N Engl J Med*. 2023;388:1657-1667; 6. Beauchemin N & Arabzadeh A. *Cancer Metastasis Rev*. 2013;32(3-4):643-671; 7. Zhang X, et al. *J Int Med Res*. 2020;48(9):300060520959478; 8. Decary S, et al. *Clin Cancer Res*. 2020;26(24):6589-6599; 9. Raab-Westphal S, et al. *Cancer Res*. 2024;84(6\_suppl):2362; 10. Boni V, et al. *Ann Oncol*. 2024;35(2\_suppl):S428-S481; 11. Kopetz S, et al. *J Clin Oncol*. 2024;42(16\_suppl):3000.

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