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DS-3939, a tumor-associated mucin 1 (TA-MUC1)–directed antibody–drug conjugate, in patients with advanced/metastatic solid tumors: Initial results from a first-in-human study

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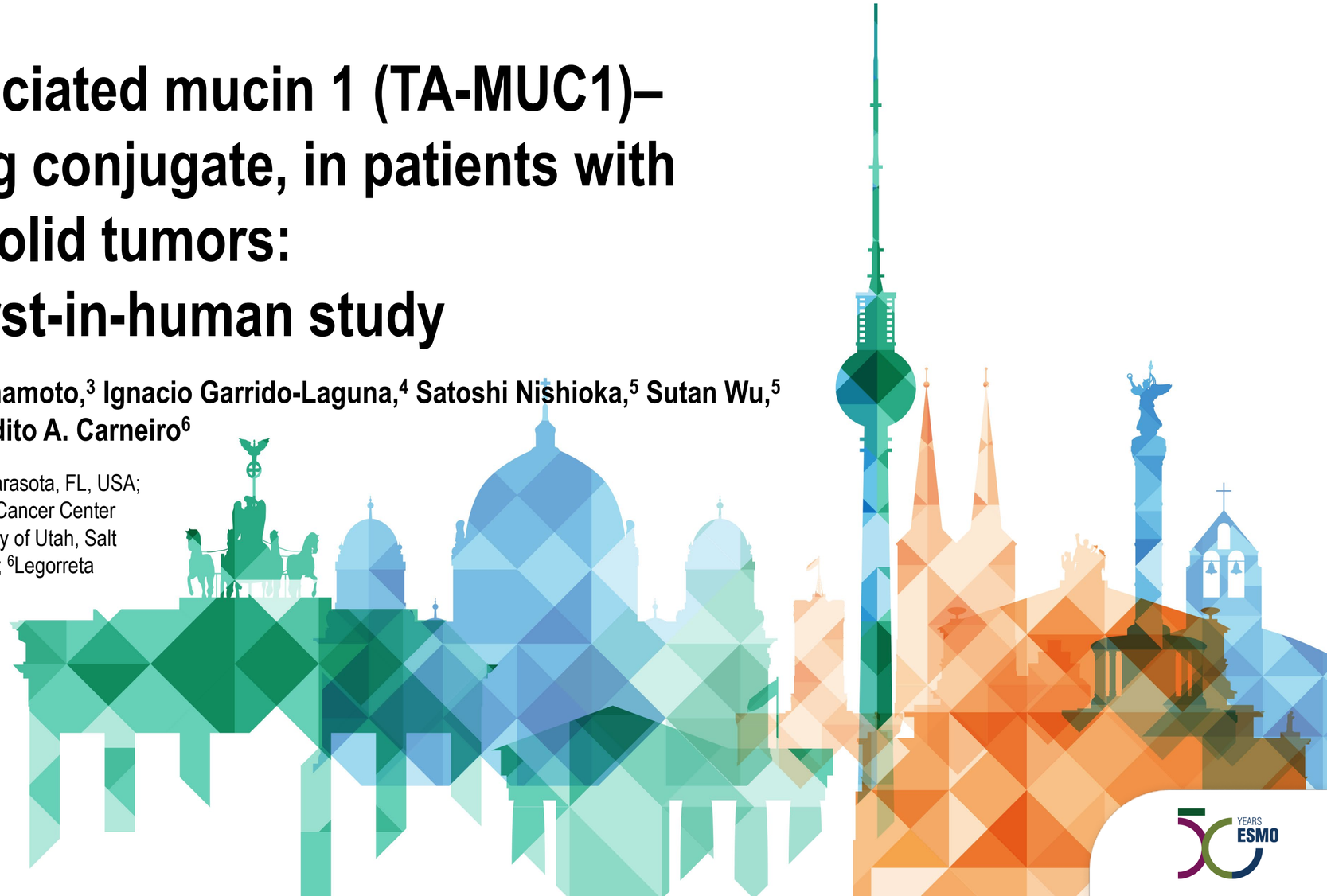

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Declaration of interests

Manish R. Patel

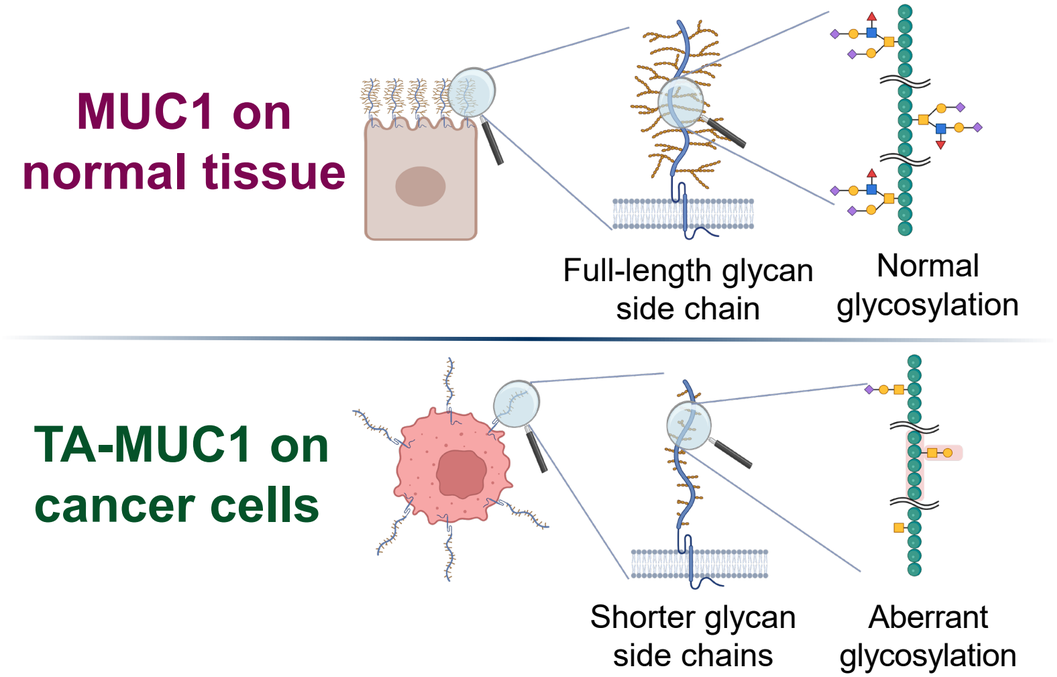
Leadership: iON Pharma

Consultant/advisor: Accutar Biotech, Daiichi Sankyo, iON Pharma, Janssen Oncology, Kura Oncology, Mitsubishi Tanabe Pharma, Nurix, Shivanka Research, UCB Japan

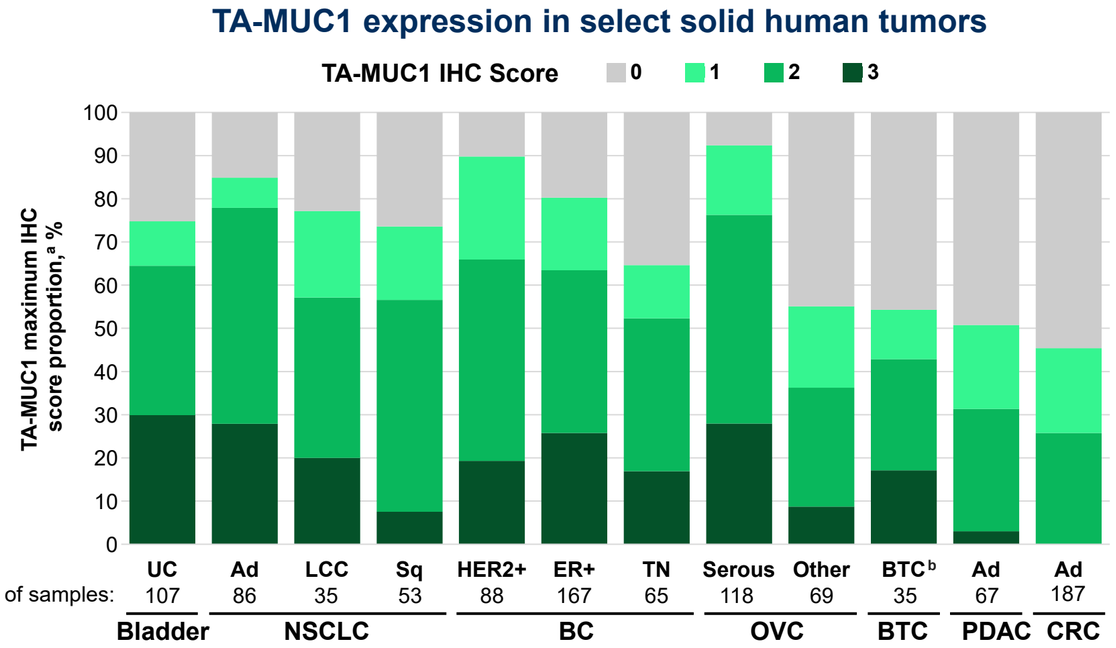
Travel and accommodation expenses: Daiichi Sankyo

TA-MUC1 is a tumor-specific target

- MUC1 is a transmembrane protein with highly glycosylated tandem repeat sequences that localizes to the apical membrane of epithelial cells[1–3]
- In many cancers, MUC1 is upregulated, redistributed over the cell surface, and aberrantly glycosylated, leading to the emergence of tumor-associated MUC1 (TA-MUC1)[1–7]
- TA-MUC1 is expressed across a broad range of solid tumors, but has limited expression in normal human tissues[1,3–7]



Created with BioRender.com. Adapted from Yukiura M, et al. AACR 2024.[5]



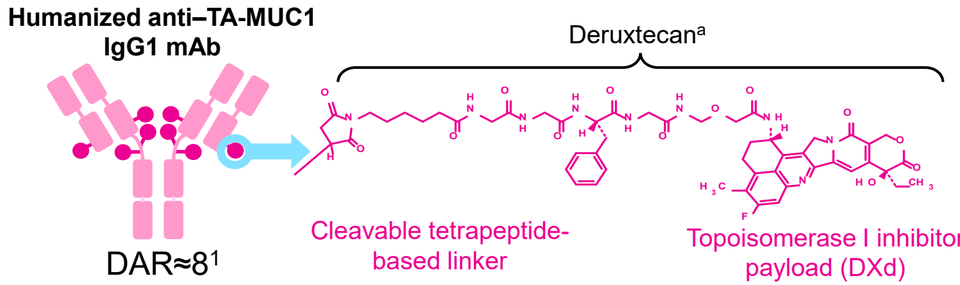
Adapted from Takano K, et al. *Mol Cancer Ther.*[4]

[a]IHC score of TA-MUC1 (staining using anti–human TA-MUC1 antibody) in the membrane, apical membrane, or cytoplasm regions was visually scored as 0, 1+, 2+, or 3+ based on the highest intensity occupying ≥10% of the evaluated area, then using the maximum score of the 3 regions. [b]Cholangiocarcinoma.
Ad, adenocarcinoma; BC, breast cancer; BTC, biliary tract cancer; CRC, colorectal cancer; ER+, estrogen receptor positive; HER2+, human epidermal growth factor receptor 2 positive; IHC, immunohistochemistry; LCC, large cell carcinoma; MUC1, mucin 1; NSCLC, non-small cell lung cancer; OVC, ovarian cancer; PDAC, pancreatic ductal adenocarcinoma; Sq, squamous; TA-MUC1, tumor-associated mucin 1; TN, triple-negative; UC, urothelial carcinoma.

1. Nath S and Mukherjee P. *Trends Mol Med*. 2014;20:332–342. 2. Gao T, et al. *Biomed Pharmacother.* 2020;132:110888. 3. Chen W, et al. *Int J Mol Sci.* 2021;22:6567. 4. Takano K, et al. *Mol Cancer Ther.* Published online July 10, 2025.
5. Yukiura M, et al. Oral presentation at the AACR Annual Meeting. April 5–10, 2024; San Diego, CA. Abstract 6579. 6. Lee DH, et al. *Pharmaceuticals (Basel)*. 2021;14:1053. 7. Lan Y, et al. *Mol Clin Oncol*. 2022;17:161.

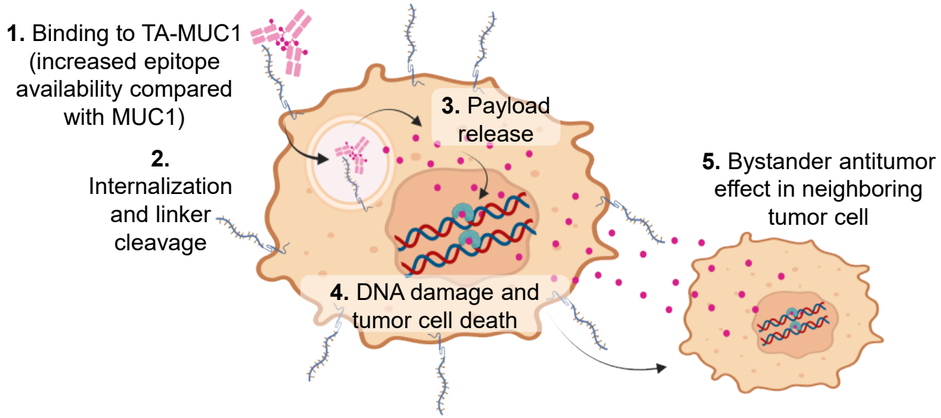
DS-3939: Novel TA-MUC1–directed ADC with significant preclinical activity

- **DS-3939** was designed with 3 components[1–5]:



- **DS-3939 specifically binds to TA-MUC1** by recognizing both its glycan and backbone peptide moieties, promoting **high payload delivery into tumor cells**[1–3,6]

DS-3939 MOA[1,6]

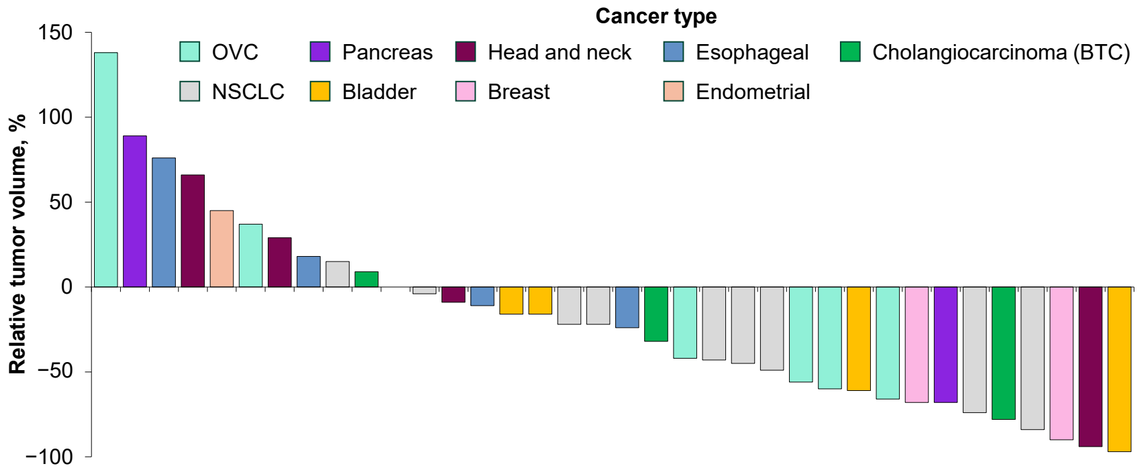


Created with BioRender.com. Adapted from Yukiura M, et al. AACR 2024.[6]

Preclinical activity of DS-3939

- **DS-3939** has exhibited **significant antitumor effects** in multiple TA-MUC1–positive preclinical CDX and PDX models, including in OVC, PDAC, NSCLC, BC, UC, and BTC[1]
- **DS-3939** exhibited antitumor effects in bladder PDX and TNBC PDX models following treatment with other cytotoxic ADCs[1]

Tumor regression was exhibited in 25/36 PDX models treated with DS-3939[1]



Adapted from Takano K, et al. *Mol Cancer Ther.*[1]

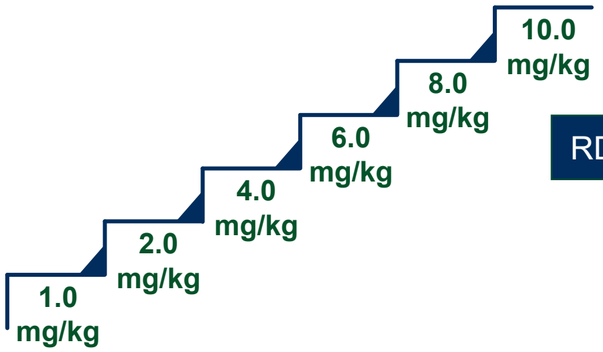
[a]Refers to the linker and payload.
ADC, antibody–drug conjugate; BC, breast cancer; BTC, biliary tract cancer; CDX, cell-derived xenograft; DAR, drug-to-antibody ratio; IgG1, immunoglobulin G1; mAb, monoclonal antibody; MOA, mechanism of action; NSCLC, non-small cell lung cancer; OVC, ovarian cancer; PDAC, pancreatic ductal adenocarcinoma; PDX, patient-derived xenograft; TA-MUC1, tumor-associated mucin 1; TNBC, triple-negative breast cancer; UC, urothelial carcinoma.
1. Takano K, et al. *Mol Cancer Ther*. Published online July 10, 2025. 2. Danielczyk A, et al. *Cancer Immunol Immunother*. 2006;55:1337–1347. 3. Fan XN, et al. *Pathol Res Pract*. 2010;206:585–589. 4. Nakada T, et al. *Bioorg Med Chem Lett*. 2016;26:1542–1545. 5. Ogitani Y, et al. *Bioorg Med Chem Lett*. 2016;26:5069–5072. 6. Yukiura M, et al. Oral presentation at the AACR Annual Meeting. April 5–10, 2024; San Diego, CA. Abstract 6579.

DS3939-077: First-in-human study (NCT05875168)[1,2]

Key eligibility criteria (Part 1):

- Adults with histologically or cytologically documented locally advanced, metastatic, or unresectable solid tumors not amenable to SOC therapy
- ECOG PS 0–1
- Adequate organ function
- No history of, current, or suspected ILD/pneumonitis
- No prior treatment targeting MUC1 or TA-MUC1
- Patients who received prior treatment with a DXd ADC can be eligible (Part 1 only)

Part 1: Dose escalation (N=64)



DS-3939 monotherapy IV Q3W

Part 2: Dose expansion

Multiple expansion cohorts targeting various advanced solid tumors

Dose expansion, including dose optimization, is ongoing

Primary endpoints:

- Safety (DLTs [Part 1 only], TEAEs, SAEs)
- ORR[a] (Part 2 only)

Secondary endpoints:

- ORR[a] (Part 1 only)
- DCR[a]
- DOR[a]
- TTR[a]
- PFS[a]
- OS
- TA-MUC1 expression detected by IHC at baseline and correlation with DS-3939 efficacy
- Pharmacokinetics
- Immunogenicity

Exploratory endpoints:

- Antitumor activity by G-score
- Exposure–response relationships

- In the dose-escalation portion of this Phase 1/2 study, patients with BC, BTC, CRC, NSCLC, OVC, PDAC, and UC were enrolled due to broad TA-MUC1 expression in these cancer types
- **Results from the dose-escalation portion of the study are presented here**

Data cutoff: August 1, 2025.

[a]By investigator per RECIST 1.1.

ADC, antibody–drug conjugate; BC, breast cancer; BTC, biliary tract cancer; CRC, colorectal cancer; DCR, disease control rate; DLT, dose-limiting toxicity; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; IHC, immunohistochemistry; ILD, interstitial lung disease; IV, intravenous; MUC1, mucin 1; NSCLC, non-small cell lung cancer; ORR, objective response rate; OS, overall survival; OVC, ovarian cancer; PDAC, pancreatic ductal carcinoma; PFS, progression-free survival; Q3W, once every 3 weeks; RDE, recommended dose for expansion; RECIST 1.1, Response Evaluation Criteria in Solid Tumours, version 1.1; SAE, serious adverse event; SOC, standard-of-care; TA-MUC1, tumor-associated mucin 1; TEAE, treatment-emergent adverse event; TTR, time to response; UC, urothelial carcinoma.

1. ClinicalTrials.gov. https://clinicaltrials.gov/study/NCT05875168. Accessed September 16, 2025. 2. Yamamoto N, et al. *Cancer Res*. 2024; 84(Suppl. 7). Abstract CT291.

DS-3939: Baseline Characteristics and Disposition

- At the August 1, 2025 data cutoff, 64 patients had been enrolled and received treatment with DS-3939, with a median follow-up of 8.8 months (range, 0.6–22.9)
- ~Two-thirds of patients had an ECOG PS of 1 (62.5%), over half of patients had ≥3 prior LOTs in the locally advanced/metastatic setting (53.1%), and over one-third of patients had treatment with prior topoisomerase I inhibitors (37.5%)
- 15/64 patients (23.4%) had ongoing DS-3939 treatment; 49/64 patients (76.6%) discontinued treatment, including 34/64 (53.1%) due to clinical or disease progression and 13/64 (20.3%) due to TEAEs[a]

DS-3939 dose, mg/kg	1.0 (n=3)	2.0 (n=3)	4.0 (n=19)	6.0 (n=17)	8.0 (n=21)	10.0 (n=1)	Total (N=64)
Age, median (range), years	68.0 (66–69)	56.0 (52–64)	66.0 (32–82)	66.0 (46–78)	64.0 (39–79)	52.0 (52–52)	64.5 (32–82)
Male sex, n (%)	2 (66.7)	0	10 (52.6)	6 (35.3)	15 (71.4)	1 (100)	34 (53.1)
ECOG PS, n (%)							
0	1 (33.3)	3 (100)	4 (21.1)	5 (29.4)	10 (47.6)	1 (100)	24 (37.5)
1	2 (66.7)	0	15 (78.9)	12 (70.6)	11 (52.4)	0	40 (62.5)
Primary diagnosis, n (%)							
BC	0	0	3 (15.8)	2 (11.8)	0	0	5 (7.8)
BTC	1 (33.3)	0	1 (5.3)	0	5 (23.8)	0	7 (10.9)
CRC	0	0	5 (26.3)	0	2 (9.5)	0	7 (10.9)
NSCLC	0	0	6 (31.6)	9 (52.9)	1 (4.8)	0	16 (25.0)
OVC	0	3 (100)	1 (5.3)	2 (11.8)	2 (9.5)	0	8 (12.5)
PDAC	2 (66.7)	0	1 (5.3)	2 (11.8)	7 (33.3)	0	12 (18.8)
UC	0	0	2 (10.5)	2 (11.8)	4 (19.0)	1 (100)	9 (14.1)
Prior LOTs for locally adv/met disease, median (range)	2.0 (1–3)	4.0 (3–8)	2.0 (1–8)	4.0 (1–17)	3.0 (1–8)	3.0 (3–3)	3.0 (1–17)
1, n (%)	1 (33.3)	0	6 (31.6)	3 (17.6)	3 (14.3)	0	13 (20.3)
2, n (%)	1 (33.3)	0	7 (36.8)	4 (23.5)	5 (23.8)	0	17 (26.6)
3, n (%)	1 (33.3)	1 (33.3)	2 (10.5)	1 (5.9)	3 (14.3)	1 (100)	**9 (14.1)**
≥4, n (%)	0	2 (66.7)	4 (21.1)	9 (52.9)	10 (47.6)	0	**25 (39.1)**
Prior topoisomerase I inhibitor,[b] n (%)	3 (100)	0	8 (42.1)	4 (23.5)	9 (42.9)	0	**24 (37.5)**
Treatment duration, median (range), months	1.4 (1.4–2.1)	9.4 (5.6–17.3)	3.2 (1.4–14.5)	3.5 (0.7–14.8)	3.4 (0.7–10.8)	4.7 (4.7–4.7)	3.4 (0.7–17.3)
DS-3939 treatment ongoing, n (%)	0	1 (33.3)	4 (21.1)	4 (23.5)	6 (28.6)	0	**15 (23.4)**

Data cutoff: August 1, 2025.

[a]Included investigator-reported pneumonitis (n=9), cough (n=2), cerebrovascular accident (n=1), and intracranial hemorrhage (n=1). [b]Included 20 patients who received irinotecan, 2 patients who received trastuzumab deruxtecan, and 2 patients who received both trastuzumab deruxtecan and sacituzumab govitecan.

Adv/met, advanced/metastatic; BC, breast cancer; BTC, biliary tract cancer; CRC, colorectal cancer; ECOG PS, Eastern Cooperative Oncology Group performance status; LOT, line of therapy; NSCLC, non-small cell lung cancer; OVC, ovarian cancer; PDAC, pancreatic ductal adenocarcinoma; TEAE, treatment-emergent adverse event; UC, urothelial carcinoma.

DS-3939: Safety summary

DS-3939 dose, mg/kg	1.0 (n=3)	2.0 (n=3)	4.0 (n=19)	6.0 (n=17)	8.0 (n=21)	10.0 (n=1)	Total (N=64)
TEAEs, n with event (%)							
Any grade	3 (100)	3 (100)	18 (94.7)	17 (100)	21 (100)	1 (100)	**63 (98.4)**
Treatment-related	2 (66.7)	3 (100)	13 (68.4)	17 (100)	20 (95.2)	1 (100)	**56 (87.5)**
Grade ≥3	0	0	7 (36.8)	7 (41.2)	15 (71.4)	1 (100)	30 (46.9)
Treatment-related	0	0	3 (15.8)	5 (29.4)	13 (61.9)	1 (100)	22 (34.4)
Serious	0	0	4 (21.1)	4 (23.5)	9 (42.9)	0	17 (26.6)
Treatment-related	0	0	3 (15.8)	1 (5.9)	4 (19.0)	0	8 (12.5)
Associated with:							
Treatment discontinuation	0	1 (33.3)	4 (21.1)	2 (11.8)	6 (28.6)	0	13 (20.3)[b]
Treatment-related	0	1 (33.3)	3 (15.8)	2 (11.8)	5 (23.8)	0	11 (17.2)
Dose reduction	0	0	1 (5.3)	2 (11.8)	7 (33.3)	1 (100)	11 (17.2)
Treatment-related	0	0	1 (5.3)	2 (11.8)	7 (33.3)	1 (100)	11 (17.2)
Treatment interruption[c]	0	0	2 (10.5)	5 (29.4)	1 (4.8)	0	8 (12.5)
Treatment-related[c]	0	0	1 (5.3)	5 (29.4)	1 (4.8)	0	7 (10.9)
Treatment delay[d]	0	0	5 (26.3)	9 (52.9)	8 (38.1)	1 (100)	23 (35.9)
Treatment-related[d]	0	0	4 (21.1)	6 (35.3)	7 (33.3)	1 (100)	18 (28.1)
Death	0	0	1 (5.3)	0	2 (9.5)	0	3 (4.7)
Treatment-related	0	0	0	0	1 (4.8)	0	1 (1.6)
DLTs	0	0	1 (5.3)	1 (5.9)	2 (9.5)[a]	0	**4 (6.3)[a]**

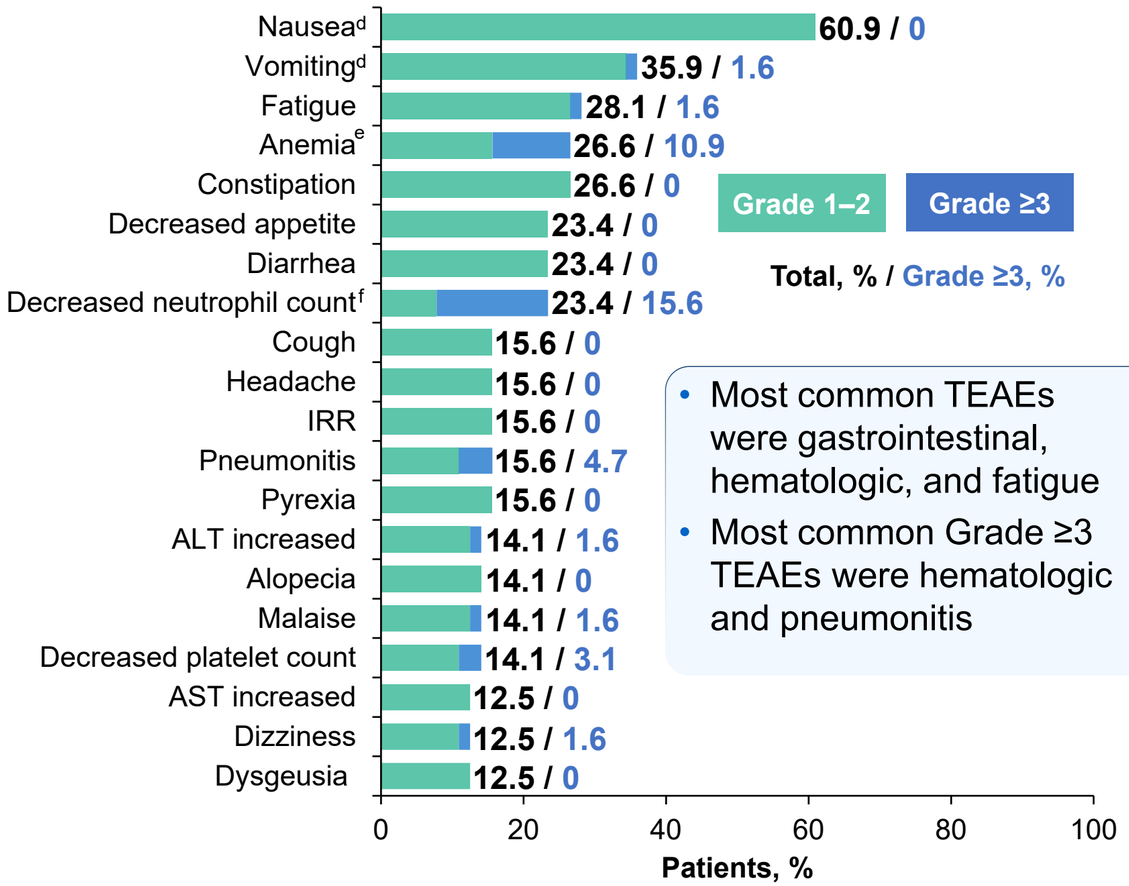
- Any-cause and treatment-related TEAEs reported in 63/64 (98.4%) and 56/64 (87.5%) patients, respectively
- Doses of ≥8 mg/kg associated with higher rates of dose reduction and treatment discontinuation
  - 6 mg/kg was determined as the RDE
- DLTs reported in 4/64 patients (6.3%)[a]
  - Grade 3 anemia needing transfusion (4.0 mg/kg)
  - Grade 3 abdominal pain (6.0 mg/kg)
  - Grade 4 decreased platelet count (8.0 mg/kg)
- Treatment discontinuations[b] and interruptions[c] were primarily due to ILD/pneumonitis and IRRs, respectively

Data cutoff: August 1, 2025.

[a]An event of Grade 1 malaise was reported as a DLT but was later confirmed as a data entry error. [b]Included investigator-reported pneumonitis (n=9), cough (n=2), cerebrovascular accident (n=1), and intracranial hemorrhage (n=1). [c]Treatment interruption: study drug infusion was temporarily stopped and then restarted during the same study visit/dosing cycle. [d]Treatment delay: study drug was not administered at the scheduled cycle/dosing visit but was administered at a later date.
DLT, dose-limiting toxicity; ILD, interstitial lung disease; IRR, infusion-related reaction; RDE, recommended dose for expansion; TEAE, treatment-emergent adverse event.

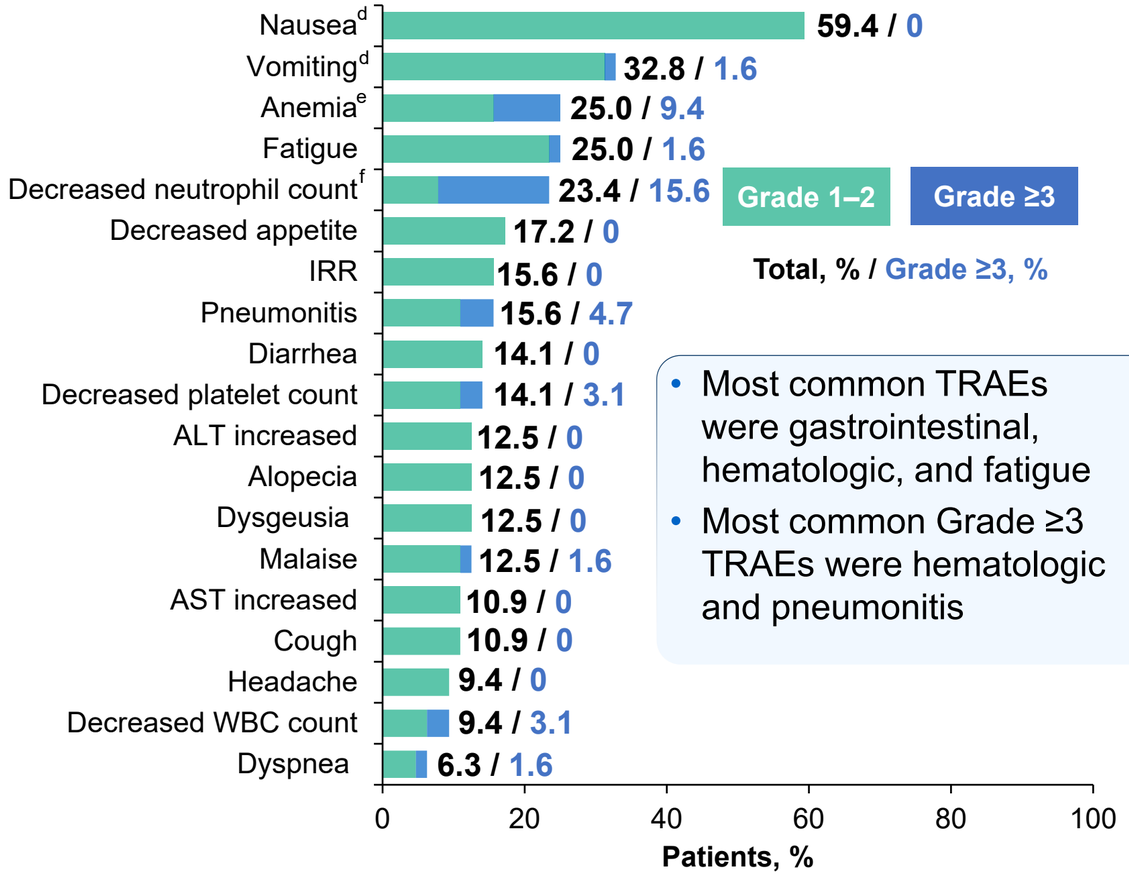
DS-3939: Most common TEAEs and TRAEs

Any-grade TEAEs (≥12% of patients)[a,b]



- Most common TEAEs were gastrointestinal, hematologic, and fatigue
- Most common Grade ≥3 TEAEs were hematologic and pneumonitis

Any-grade TRAEs (≥5% of patients)[b,c]



- Most common TRAEs were gastrointestinal, hematologic, and fatigue
- Most common Grade ≥3 TRAEs were hematologic and pneumonitis

Data cutoff: August 1, 2025.

[a]TEAEs occurring at any grade in ≥12% of patients and Grade ≥3 TEAEs occurring for those preferred terms in the overall population (N=64). [b]Adverse events were coded using the MedDRA dictionary, Version 28.0. [c]TRAEs occurring at any grade in ≥5% of patients and Grade ≥3 TRAEs occurring for those preferred terms in the overall population (N=64). [d]Premedication for the prevention of nausea and vomiting was required before each dose of DS-3939. [e]There were no Grade ≥4 anemia events. [f]Included "decreased neutrophil count" and "neutropenia." Three patients experienced Grade 4 decreased neutrophil count. One patient experienced Grade 3 febrile neutropenia (not included in figure).

ALT, alanine aminotransferase; AST, aspartate aminotransferase; IRR, infusion-related reaction; TEAE, treatment-emergent adverse event; TRAE, treatment-related adverse event; WBC, white blood cell.

DS-3939: Majority of ILD and IRR events were Grade 1 or 2

Adjudicated treatment-related ILD/pneumonitis

DS-3939 dose, mg/kg	1.0 (n=3)	2.0 (n=3)	4.0 (n=19)	6.0 (n=17)	8.0 (n=21)	10.0 (n=1)	Total (N=64)
Events, n (%)							
Any grade	0	1 (33.3)	2 (10.5)	0	4 (19.0)	0	**7 (10.9)**
Grade 1	0	0	0	0	0	0	**0**
Grade 2	0	1 (33.3)	1 (5.3)	0	4 (19.0)	0	**6 (9.4)**
Grade 3	0	0	1 (5.3)	0	0	0	**1 (1.6)**
Grade ≥4	0	0	0	0	0	0	**0**

- Adjudicated treatment-related ILD/pneumonitis reported in 7/64 patients (10.9%)
  - Per protocol, DS-3939 was permanently discontinued for Grade ≥2 ILD/pneumonitis
  - Median time to onset of adjudicated treatment-related ILD/pneumonitis was 68 days
  - Post data cutoff: 2/4 ILD cases previously pending adjudication were adjudicated as Grade 5; 2 cases still pending adjudication

IRRs

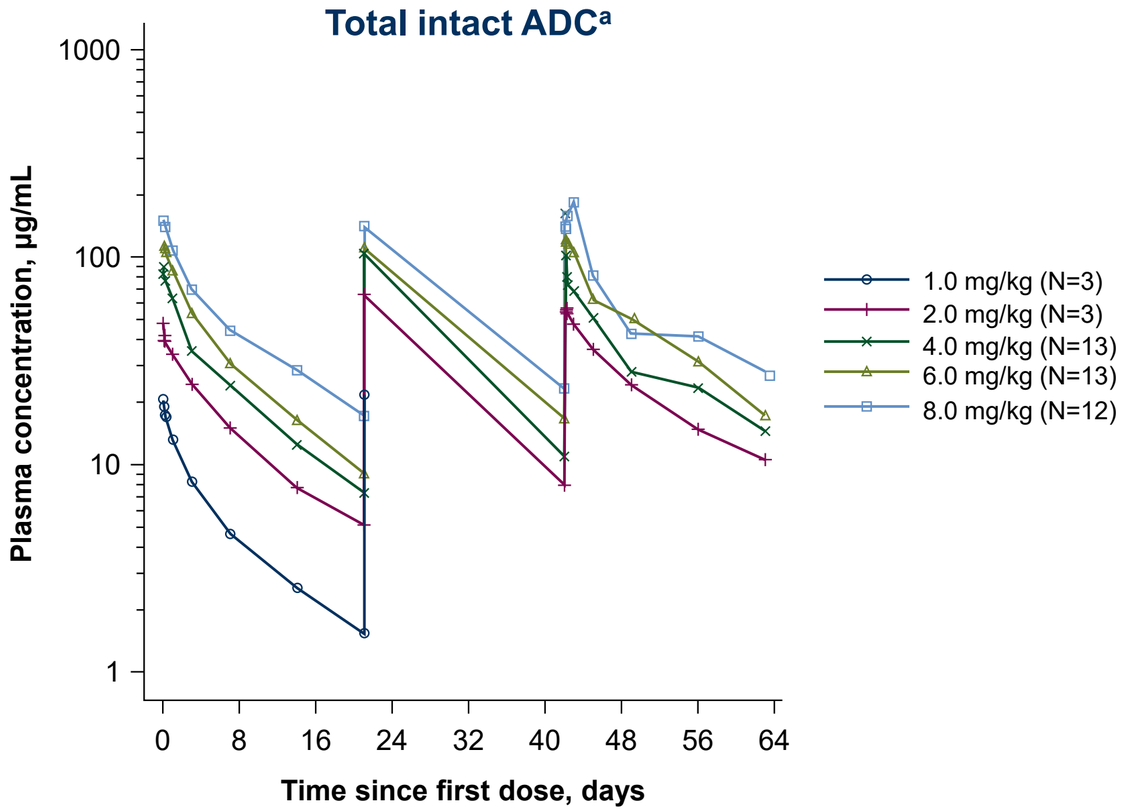
DS-3939 dose, mg/kg	1.0 (n=3)	2.0 (n=3)	4.0 (n=19)	6.0 (n=17)	8.0 (n=21)	10.0 (n=1)	Total (N=64)
Events, n (%)							
Any grade	0	1 (33.3)	1 (5.3)	6 (35.3)	2 (9.5)	0	**10 (15.6)**
Grade 1	0	1 (33.3)	0	2 (11.8)	1 (4.8)	0	**4 (6.3)**
Grade 2	0	0	1 (5.3)	4 (23.5)	1 (4.8)	0	**6 (9.4)**
Grade 3	0	0	0	0	0	0	**0**
Grade ≥4	0	0	0	0	0	0	**0**

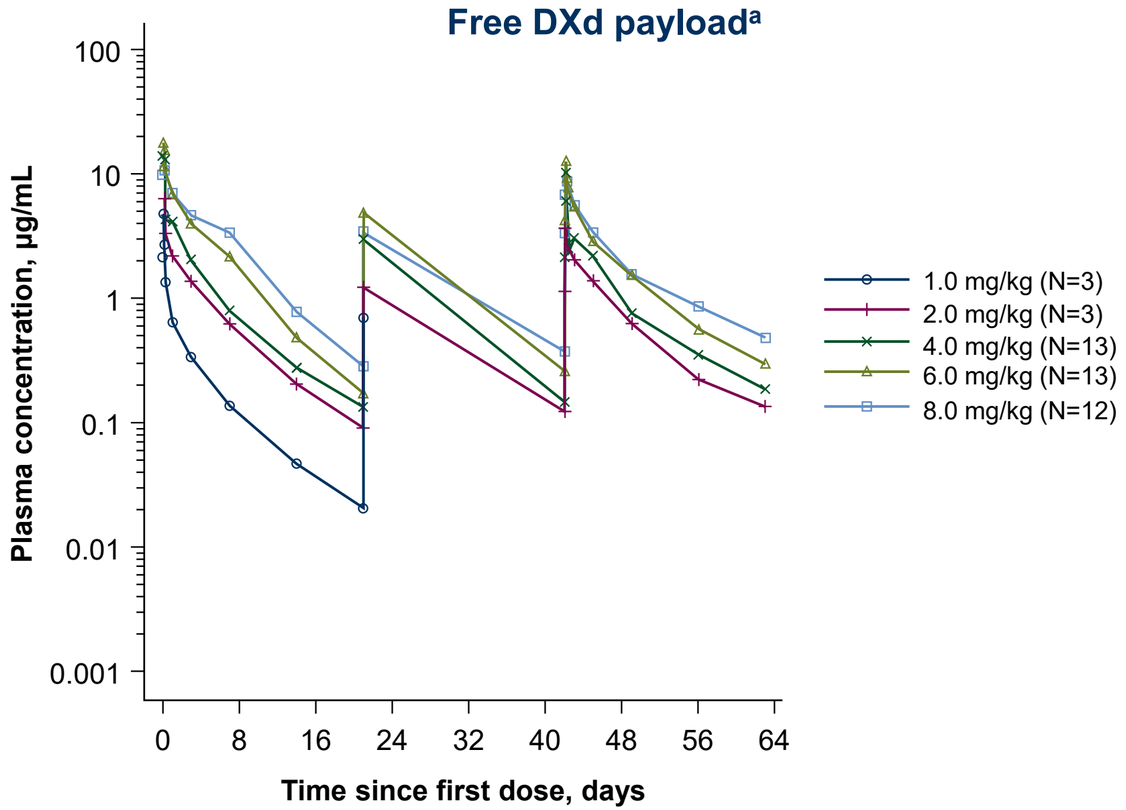
- IRRs reported in 10/64 patients (15.6%)
  - No Grade ≥3 events
  - No treatment discontinuations due to IRRs
  - Infusion interrupted due to IRRs in 6/64 patients (9.4%)
  - 7 patients (10.9%) experienced IRRs during Cycle 1; for most of those patients, IRR did not reoccur later in treatment

Data cutoff: August 1, 2025.
ILD, interstitial lung disease; IRR, infusion-related reaction.

DS-3939: PK profile supports Q3W dosing

- Total DS-3939 ADC and free DXd payload increased in a dose-proportional manner
- Intact DS-3939 elimination half-life ranged from ~7–11 days, supporting Q3W dosing



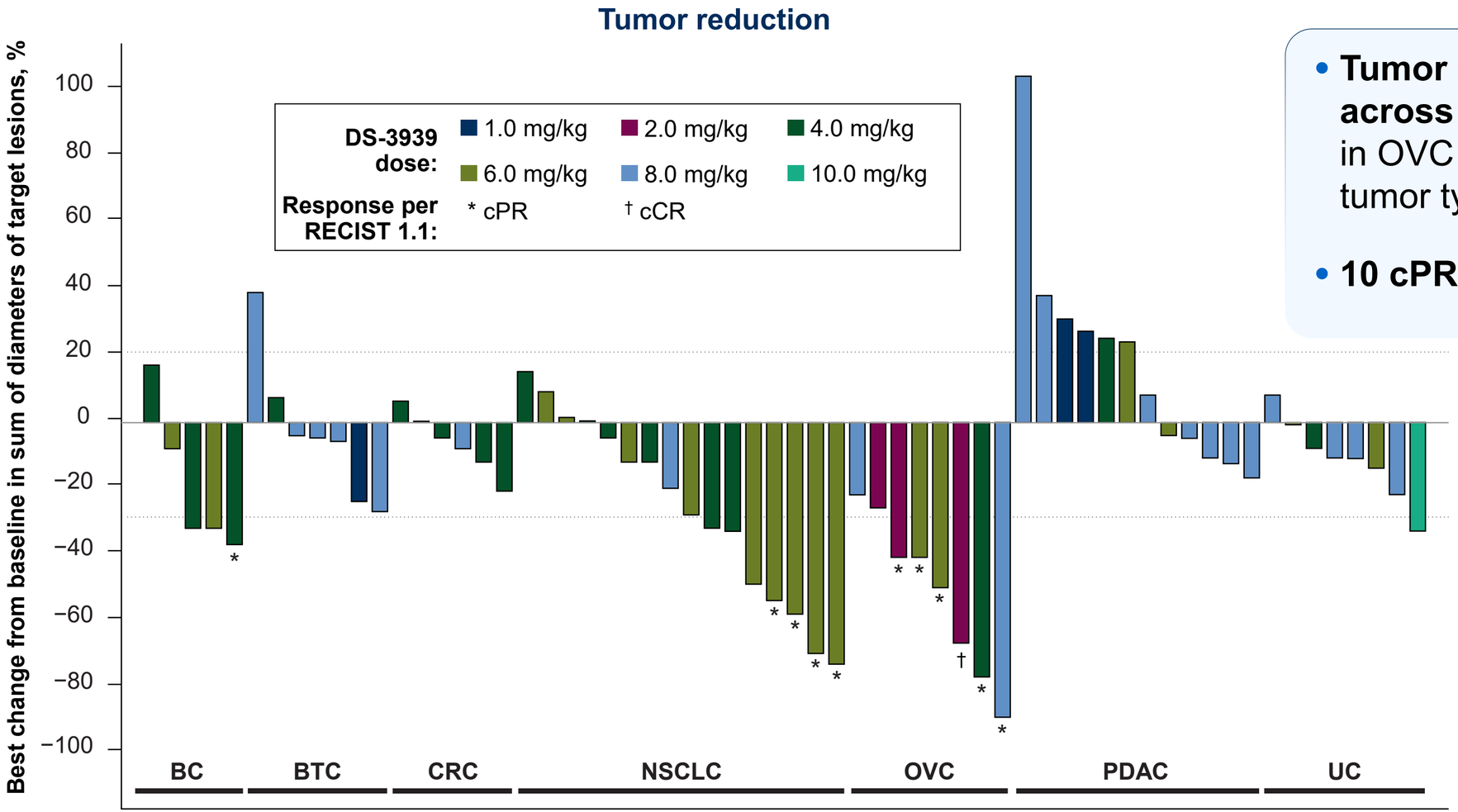


Data cutoff: February 7, 2025

[a]Mean plasma concentration versus time curve over Cycles 1–3. Data points were included where samples were available from ≥2 patients.

ADC, antibody–drug conjugate; PK, pharmacokinetic; Q3W, once every 3 weeks.

DS-3939: Tumor reductions across doses: 10 cPRs and 1 cCR



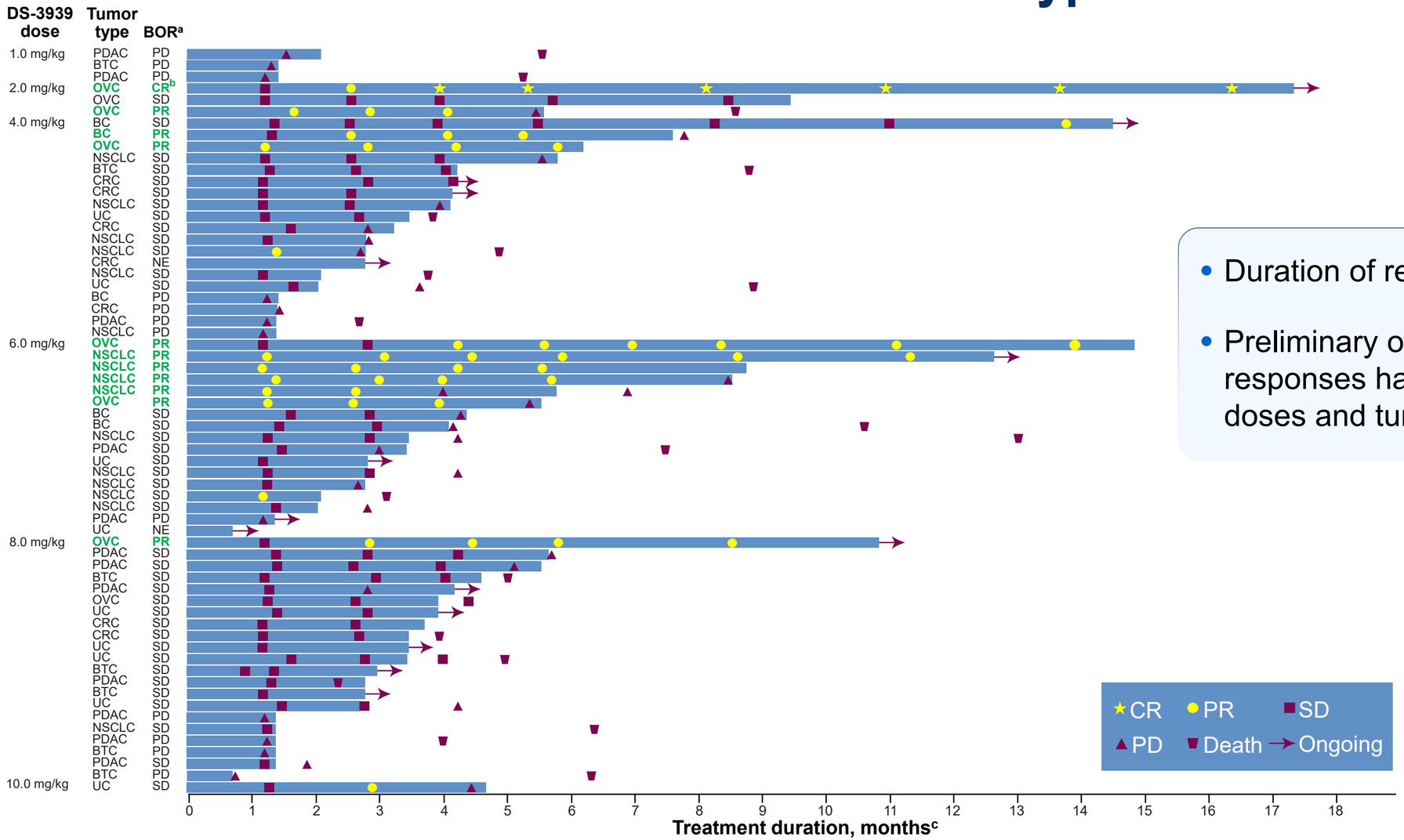
- **Tumor reduction was observed across dose levels,** from 2.0 mg/kg in OVC and 4.0 mg/kg in most other tumor types
- **10 cPRs and 1 cCR[a]**

Data cutoff: August 1, 2025. Median follow-up: 8.8 months (range, 0.6–22.9).

[a]The patient with cCR had lymph nodes only as target lesion.

BC, breast cancer; BTC, biliary tract cancer; cCR, confirmed complete response; cPR, confirmed partial response; CRC, colorectal cancer; NSCLC, non-small cell lung cancer; OVC, ovarian cancer; PD, progressive disease; PDAC, primary ductal adenocarcinoma; RECIST 1.1, Response Evaluation Criteria in Solid Tumours, version 1.1; SD, stable disease; UC, urothelial carcinoma.

DS-3939: Treatment duration across tumor types



- Duration of response data yet to mature
- Preliminary observation is that durable responses have been observed across doses and tumor types

Data cutoff: August 1, 2025. Median follow-up: 8.8 months (range, 0.6–22.9).

[a]BOR per RECIST 1.1; CRs and PRs were confirmed. [b]The patient had lymph nodes only as the target lesion. [c]Treatment duration (months) was calculated as (date of the last dose−date of the first dose+21)/30.4375. For patients who were still on treatment at the data cutoff date, the most recent available date of administered dose was used.

BC, breast cancer; BOR, best overall response; BTC, biliary tract cancer; CR, complete response; CRC, colorectal cancer; NE, not evaluable; NSCLC, non-small cell lung cancer; OVC, ovarian cancer; PD, progressive disease; PDAC, pancreatic ductal adenocarcinoma; PR, partial response; RECIST 1.1, Response Evaluation Criteria in Solid Tumours, version 1.1; SD, stable disease; UC, urothelial carcinoma.

DS3939-077 Study Update

At data cutoff, August 1, 2025:

- **Study status**
  - Enrollment ongoing; 157 patients enrolled across dose escalation and expansion
  - RDE=6.0 mg/kg for tumor-specific cohorts
- **Safety**
  - Most common AEs and overall safety profile in dose expansion consistent with data from dose escalation
  - Additional potential ILD cases have been reported and are undergoing adjudication
- **Efficacy**
  - PRs observed in BC, BTC, NSCLC, OVC, and UC
- **Future updates**
  - More detailed data from the Expansion Cohort, including biomarker data, will be presented at future congresses

Data cutoff: August 1, 2025.
AE, adverse event; BC, breast cancer; BTC, biliary tract cancer; CR, complete response; ILD, interstitial lung disease; NSCLC, non-small cell lung cancer; OVC, ovarian cancer; PR, partial response; RDE, recommended dose for expansion; UC, urothelial carcinoma.

DS-3939: Conclusions

Preliminary data from the novel TA-MUC1 ADC DS-3939 FIH study, DS3939-077, show:

- **A manageable safety profile in patients with previously treated advanced/metastatic solid tumors**
  - Most common TRAEs were gastrointestinal, hematologic, and fatigue; most were Grade 1 or 2
  - Adjudicated treatment-related ILD/pneumonitis was reported in 7/64 patients (10.9%); most were Grade 2[a]
  - IRRs in 10/64 patients (15.6%); all were Grade 1 or 2
- **DS-3939 demonstrated promising preliminary antitumor activity across dose levels and tumor types in previously treated patients**
- **Dose expansion and optimization are ongoing; patients with various tumor types are being enrolled**

Data cutoff: August 1, 2025.
[a]Post data cutoff: 2/4 ILD cases previously pending adjudication were adjudicated as Grade 5; 2 cases still pending adjudication.
ADC, antibody-drug conjugate; BC, breast cancer; FIH, first-in-human; ILD, interstitial lung disease; IRR, infusion-related reaction; RDE, recommended dose for expansion; PR, partial response; TA-MUC1, tumor-associated mucin 1; TEAE, treatment-emergent adverse event.

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