Ifinatamab deruxtecan (I-DXd) in extensive-stage small cell lung cancer: Japanese subgroup analysis from IDeate-Lung01

Hidetoshi Hayashi,[1] Tetsuya Sakai,[2] Ryo Ko,[3] Haruhiro Saito,[4] Tatsuya Yoshida,[5] Kazumi Nishino,[6] Haichuan Hu,[7] Meng Qian,[8] Haruna Goto,[8] Sakiko Miyazu,[9] Mei Tang,[8] Makoto Nishio[10]

[1]Kindai University, Osaka, Japan; [2]National Cancer Center Hospital East, Kashiwa, Japan; [3]Shizuoka Cancer Center, Shizuoka, Japan; [4]Kanagawa Cancer Center, Yokohama, Japan; [5]National Cancer Center Hospital, Tokyo, Japan; [6]Osaka International Cancer Institute, Osaka, Japan; [7]Merck & Co., Inc., Rahway, NJ, USA; [8]Daiichi Sankyo, Inc., Basking Ridge, NJ, USA; [9]Daiichi Sankyo Co., Ltd., Tokyo, Japan; [10]The Cancer Institute Hospital of Japanese Foundation for Cancer Research, Tokyo, Japan.

March 27, 2026

Presentation number: PS3-4

JSMO2026 YOKOHAMA 2026 the Japanese Society of Medical Oncology Annual Meeting

Conflict of Interest disclosure slide for representative speakers or investigators

Research fund	✓Scientific research fund □Contract □Donation □Other （ ） □N/A	Sponsor	Daiichi Sankyo, Inc.
Name of lead presenter	**Hidetoshi Hayashi**	**Institution or company/position**	**Kindai University, Osaka, Japan**

	No	If yes, please specify the name of company, organization, your status.
Employee or adviser of company and/or profit-making organization	X	
Profit of stock	X	
Patent fee	X	
Lecturer fee		AstraZeneca K.K., Bristol-Myers Squibb K.K., Chugai Pharmaceutical Co., Ltd., Takeda Pharmaceutical Company Limited, Daiichi Sankyo Co., Ltd., Eli Lilly Japan K.K., MSD K.K., AbbVie GK, Ono Pharmaceutical Co., Ltd., Amgen K.K.
Manuscript fee		Guardant Health Japan Corp., Ono Pharmaceutical Co., Ltd.
Research expenses from company		A2 Healthcare Corporation, IQVIA Services Japan G.K., Shin Nippon Kagaku PPD Co., Ltd., Synos Health Clinical Co., Ltd., MSD K.K., GlaxoSmithKline K.K., ICON Clinical Research GK, AbbVie GK, Astellas Pharma Inc., Amgen K.K., AstraZeneca K.K., Taiho Pharmaceutical Co., Ltd., CMIC HOLDINGS Co., Ltd., Chugai Pharmaceutical Co., Ltd., Nippon Boehringer Ingelheim Co., Ltd., WJOG (West Japan Oncology Group), Sysmex Corporation, Eisai Inc., PRA Health Sciences Japan K.K., Pfizer R&D LLC, Daiichi Sankyo Co., Ltd., EPS Corporation, Bristol-Myers Squibb K.K., Janssen Pharmaceutical K.K., Sanofi K.K.
Contributions or endowed chair	X	
Fees of testimony, judgment, comment, etc.	X	
Presents or other payment		Chugai Pharmaceutical Co., Ltd., Eisai Co., Ltd.
Representative of organization for clinical study receiving research expenses from company	X	

I-DXd demonstrated encouraging efficacy and a manageable safety profile in previous analyses

- Treatment options beyond 1L for patients with ES-SCLC are limited and associated with poor outcomes, with 2L options offering ORRs of 7–35% and mOS of 5.6–13.6 months in studies of patients with previously treated SCLC[1–7]
- I-DXd is a B7-H3–directed ADC, composed of a humanized anti–B7-H3 IgG1 mAb covalently linked to a topoisomerase I inhibitor payload (DXd), that is designed to enhance selective tumor-cell death and reduce systemic exposure[8]
- In the first-in-human I-DXd study, IDeate-PanTumor01 (NCT04145622), cORR was 40.0% (95% CI, 5.3–85.3) and mPFS was 4.7 months (95% CI, 2.8–NE) among the 5 Japanese patients with SCLC (all received I-DXd 8 or 12 mg/kg)[9]
- In the subsequent IDeate-Lung01 (NCT05280470) study in patients with previously treated ES-SCLC, promising efficacy and a manageable safety profile were seen in the total I-DXd 12-mg/kg population (N=137)[10]

IDeate-Lung01 total I-DXd 12-mg/kg population (N=137)[10,a]	
Efficacy	
cORR, % (95% CI)	48.2 (39.6–56.9)
mDOR (95% CI), months	5.3 (4.0–6.5)
mTTR (range), months	1.4 (1.0–8.1)
mPFS (95% CI), months	4.9 (4.2–5.5)
mOS (95% CI), months	10.3 (9.1–13.3)
Safety[b]	
Any-grade TRAEs, n (%)	123 (89.8)
Grade ≥3 TRAEs, n (%)	50 (36.5)
TRAEs associated with treatment discontinuation, n (%)	13 (9.5)

We present efficacy and safety data for Japanese patients treated with I-DXd 12 mg/kg across the dose-optimization and extension parts of IDeate-Lung01[a]

[a]Data cutoff: March 3, 2025. [b]Number of patients (%) with event.

1L, first-line; 2L, second-line; ADC, antibody–drug conjugate; B7-H3, B7 homolog 3; CI, confidence interval; IgG1, immunoglobulin G1; mAb, monoclonal antibody; mDOR, median duration of response; mOS, median overall survival; mPFS, median progression-free survival; mTTR, median time to response; NE, not estimable; (c)ORR, (confirmed) objective response rate; (ES-) SCLC; (extensive-stage) small cell lung cancer; TRAE, treatment-related adverse event.

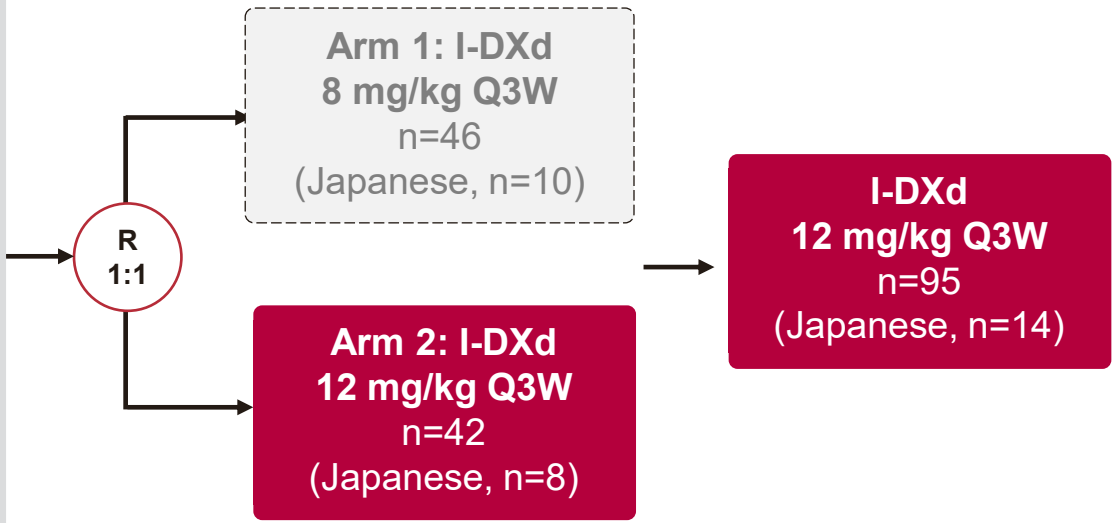
1. Trigo J, et al. *Lancet Oncol*. 2020;21:645–654. 2. Mountzios G, et al. *N Engl J Med*. 2025;393:349–361. 3. Shaw J, et al. *Oncologist*. 2024;29:1079–1089. 4. Borghaei H, et al. *Lung Cancer*. 2024;193:107819. 5. Von Pawel J, et al. *J Clin Oncol*. 2014;32:4012–4019. 6. Eckardt JR, et al. *J Clin Oncol.* 2007;25:2086–2092. 7. O'Brien ME, et al. *J Clin Oncol.* 2006;24:5441–5447. 8. Yamato M, et al. *Mol Cancer Ther*. 2022;21:635–664. 9. Doi T, et al. Oral presentation at the Japanese Society of Medical Oncology. February 22–24, 2024; Nagoya City, Japan. Presentation PS3-3. 10. Rudin CM, et al. *J Clin Oncol.* 2026;44:261–273.

IDeate-Lung01 study design

Phase 2, multicenter, randomized, open-label study (NCT05280470)

Patient eligibility

- Histologically or cytologically documented ES-SCLC
- Age ≥18 years[a]
- ≥1 prior line of PBC and ≤3 prior lines of systemic therapy[b]
- Radiologically documented PD on or after most recent prior systemic therapy
- ECOG PS 0–1
- ≥1 measurable lesion per RECIST 1.1[c]
- Patients with asymptomatic brain metastases (untreated or previously treated) were eligible



Primary endpoint:

- ORR by BICR[d]

Secondary endpoints:

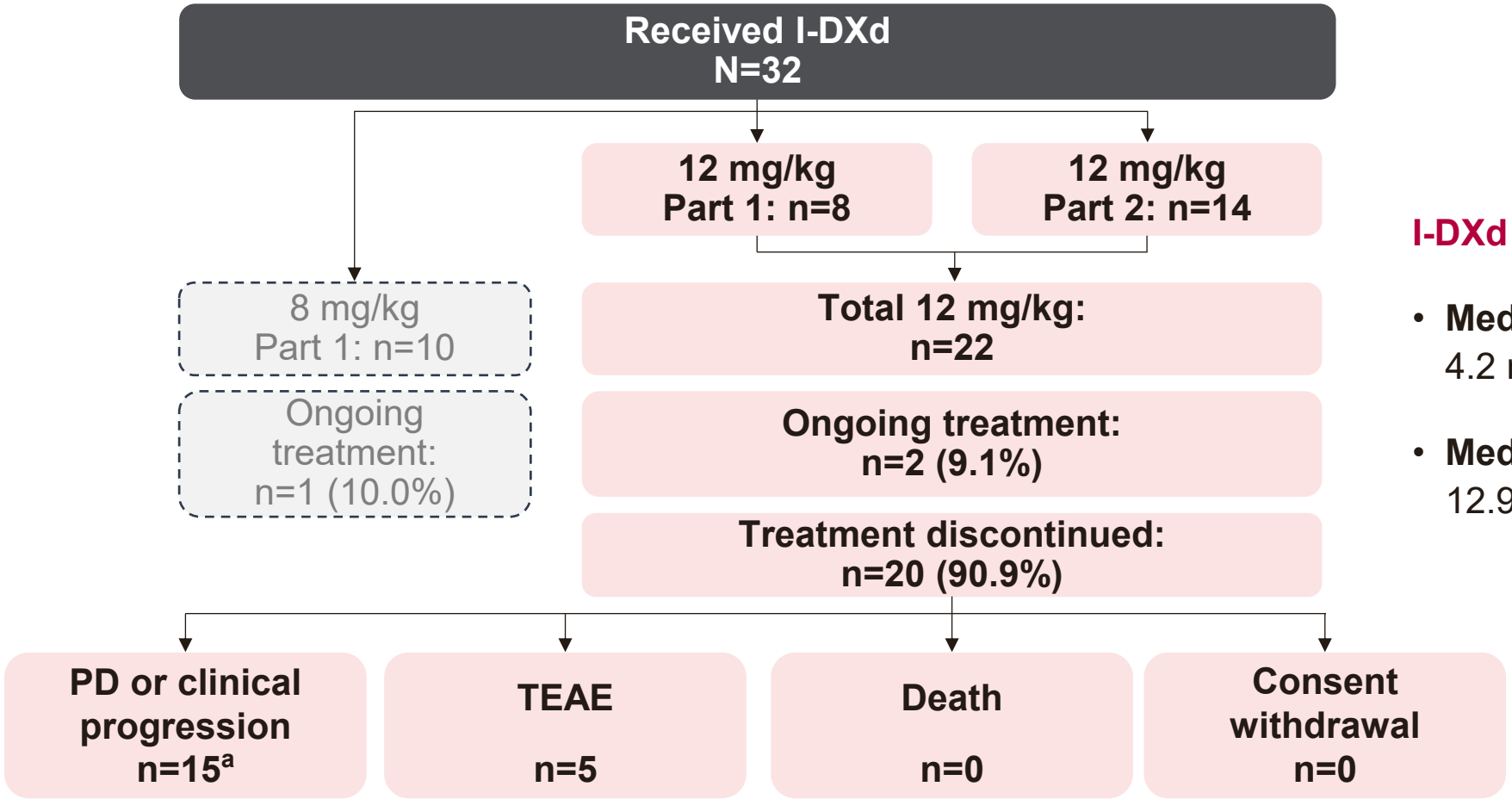
- DOR by BICR and inv[d]
- PFS by BICR and inv[d]
- OS
- DCR by BICR and inv[d]
- TTR by BICR and inv[d]
- ORR by inv[d]
- Safety
- PK
- Immunogenicity

Exploratory analysis:

- Intracranial ORR by BICR[e]

[a]Or local legal age of consent. [b]Following implementation of a protocol amendment, patients in Part 2 had to have received ≥2 but ≤3 prior lines of systemic therapy. [c]Patients must also have had ≥1 lesion that had not been irradiated and was amenable to biopsy. [d]Per RECIST 1.1. [e]Assessed using a version of RECIST 1.1 modified for assessment of CNS tumors.
BICR, blinded independent central review; CNS, central nervous system; DCR, disease control rate; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; ES-SCLC, extensive-stage small cell lung cancer; inv, investigator; ORR, objective response rate; OS, overall survival; PBC, platinum-based chemotherapy; PD, progressive disease; PFS, progression-free survival; PK, pharmacokinetics; Q3W, every 3 weeks; R, randomization; RECIST 1.1, Response Evaluation Criteria in Solid Tumours, version 1.1; TTR, time to response.

Patient disposition: Japanese subgroup



I-DXd 12-mg/kg Japanese subgroup:

- **Median treatment duration:**
  4.2 months (range, 0.7–12.4)[b]
- **Median follow-up:**
  12.9 months (95% CI, 10.6–NE)[c]

Data cutoff: March 3, 2025.

[a]Included 1 patient with clinical progression. [b]Median treatment duration in the total 12-mg/kg population (N=137) was 4.8 months (range, 0.7–22.7). [c]Median follow-up in the total 12-mg/kg population (N=137) was 12.8 months (95% CI, 12.2–13.1).

CI, confidence interval; NE, not estimable; PD, progressive disease; TEAE, treatment-emergent adverse event.

Patient baseline characteristics

Characteristic	I-DXd 12-mg/kg Japanese subgroup (n=22)	Total I-DXd 12-mg/kg population (N=137)
Age, median (range), years	67 (34–77)	63 (34–79)
Male, n (%)	19 (86.4)	90 (65.7)
Region / country, n (%)		
Asia	22 (100.0)	66 (48.2)
Japan	22 (100.0)	22 (16.1)
Europe	0	40 (29.2)
North America	0	31 (22.6)
ECOG PS 1, n (%)	16 (72.7)	106 (77.4)
ES-SCLC at diagnosis, n (%)	18 (81.8)	111 (81.0)
Brain / liver metastases at baseline,[a] n (%)	7 (31.8) / 7 (31.8)	52 (38.0) / 55 (40.1)
CTFI, n (%)		
≤30 days / >30 to <90 days / ≥90 days	**8 (36.4)** / 8 (36.4) / 6 (27.3)	**18 (13.1)** / 40 (29.2) / 72 (52.6)
Prior lines of systemic therapy, median (range)	2 (1–3)	2 (1–3)
1 / 2 / 3, n (%)	6 (27.3) / 13 (59.1) / 3 (13.6)	32 (23.4) / 75 (54.7) / 30 (21.9)
Select prior anticancer therapy, n (%)		
Topoisomerase I inhibitor	3 (13.6)	44 (32.1)
Amrubicin	12 (54.5)	12 (8.8)
Lurbinectedin	0	29 (21.2)
DLL3-targeting T-cell engager	0	11 (8.0)[b]
Prior anti–PD-(L)1 therapy, n (%)	18 (81.8)	111 (81.0)

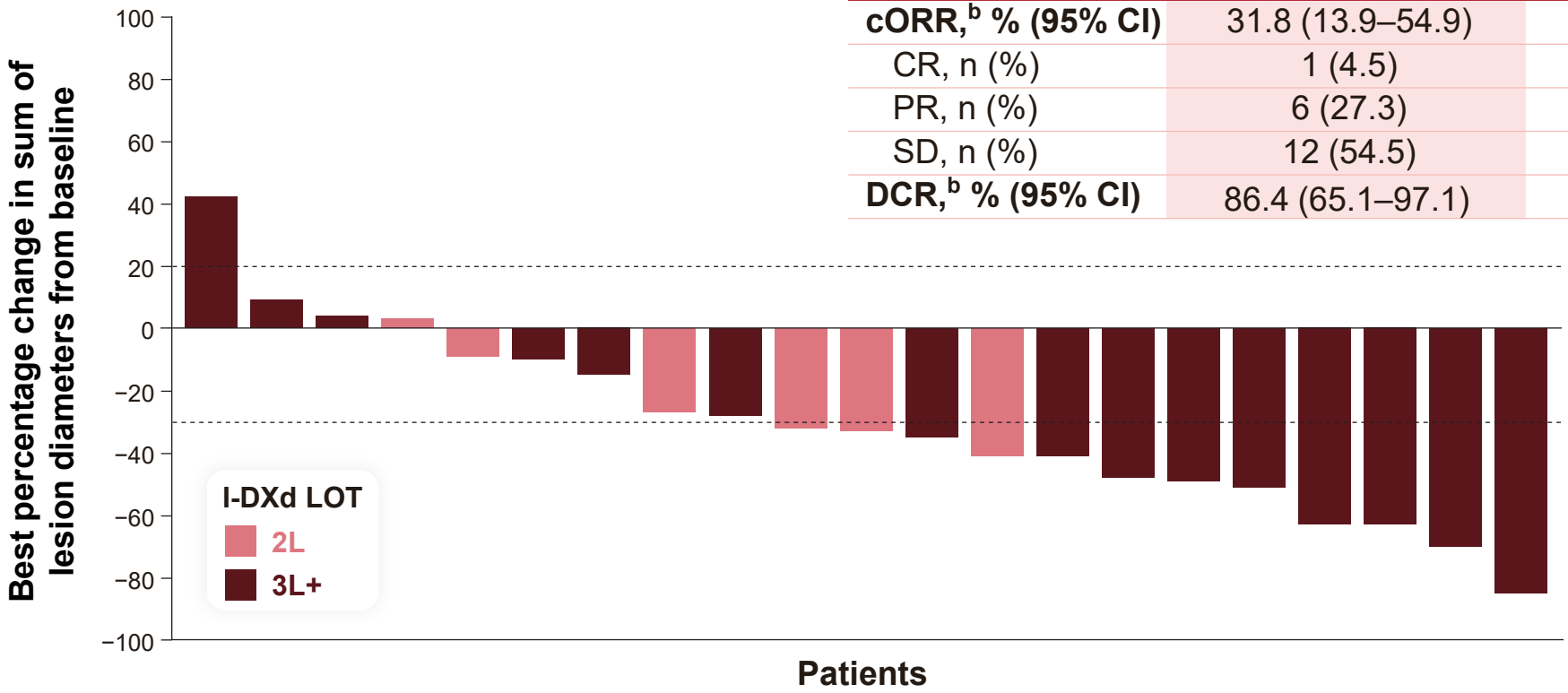
Data cutoff: March 3, 2025.

[a]By blinded independent central review. [b]Seven patients in the total 12-mg/kg population received prior tarlatamab.

CTFI, chemotherapy-free interval; DLL3, delta-like ligand 3; ECOG PS, Eastern Cooperative Oncology Group performance status; ES-SCLC, extensive-stage small cell lung cancer; PD-(L)1, programmed death (ligand) 1.

I-DXd 12 mg/kg demonstrated promising disease control[a]

	I-DXd 12-mg/kg Japanese subgroup (n=22)	Total I-DXd 12-mg/kg population (N=137)
cORR,[b] % (95% CI)	31.8 (13.9–54.9)	48.2 (39.6–56.9)
CR, n (%)	1 (4.5)	3 (2.2)
PR, n (%)	6 (27.3)	63 (46.0)
SD, n (%)	12 (54.5)	54 (39.4)
DCR,[b] % (95% CI)	86.4 (65.1–97.1)	87.6 (80.9–92.6)



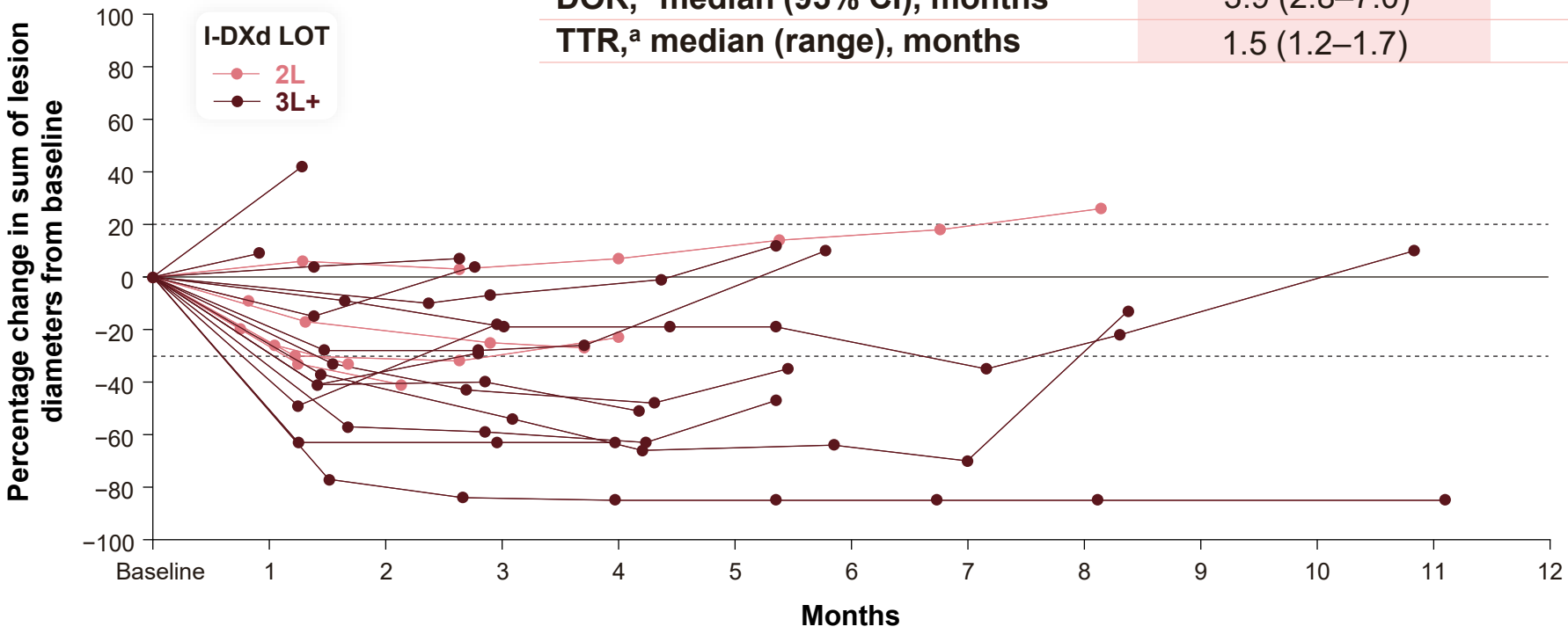
Data cutoff: March 3, 2025. Median follow-up in the Japanese subgroup (n=22): 12.9 months (95% CI, 10.6–NE). Median follow-up in the total 12-mg/kg population (N=137): 12.8 months (95% CI, 12.2–13.1).

[a]Only patients with measurable disease at baseline and ≥1 post-baseline assessment are included in the plot (n=21). [b]By blinded independent central review per Response Evaluation Criteria in Solid Tumours, version 1.1. Best overall responses of CR or PR were confirmed.

2L, second-line; 3L+, third-line and beyond; CI, confidence interval; cORR, confirmed objective response rate; CR, complete response; DCR, disease control rate; LOT, line of therapy; NE, not estimable; PR, partial response; SD, stable disease.

Responses to I-DXd 12 mg/kg were rapid

	I-DXd 12-mg/kg Japanese subgroup (n=22)	Total I-DXd 12-mg/kg population (N=137)
Patients with confirmed CR/PR, n (%)	7 (31.8)	66 (48.2)
DOR,[a] median (95% CI), months	3.9 (2.8–7.0)	5.3 (4.0–6.5)
TTR,[a] median (range), months	1.5 (1.2–1.7)	1.4 (1.0–8.1)



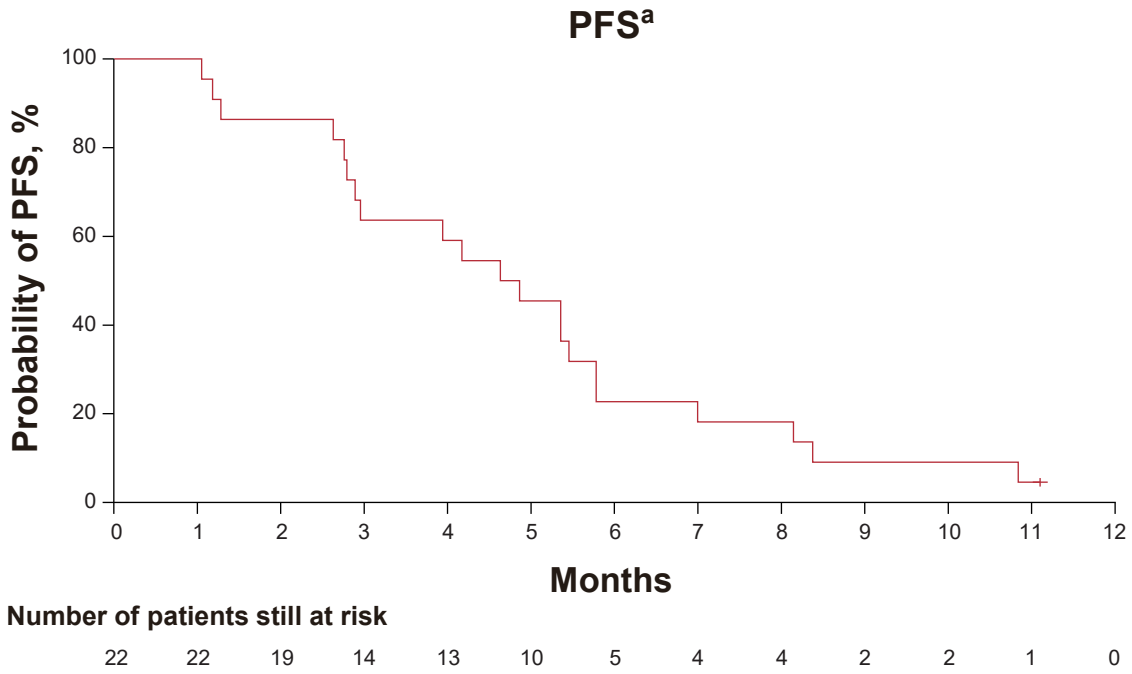
Data cutoff: March 3, 2025. Median follow-up in the Japanese subgroup (n=22): 12.9 months (95% CI, 10.6–NE). Median follow-up in the total 12-mg/kg population (N=137): 12.8 months (95% CI, 12.2–13.1).

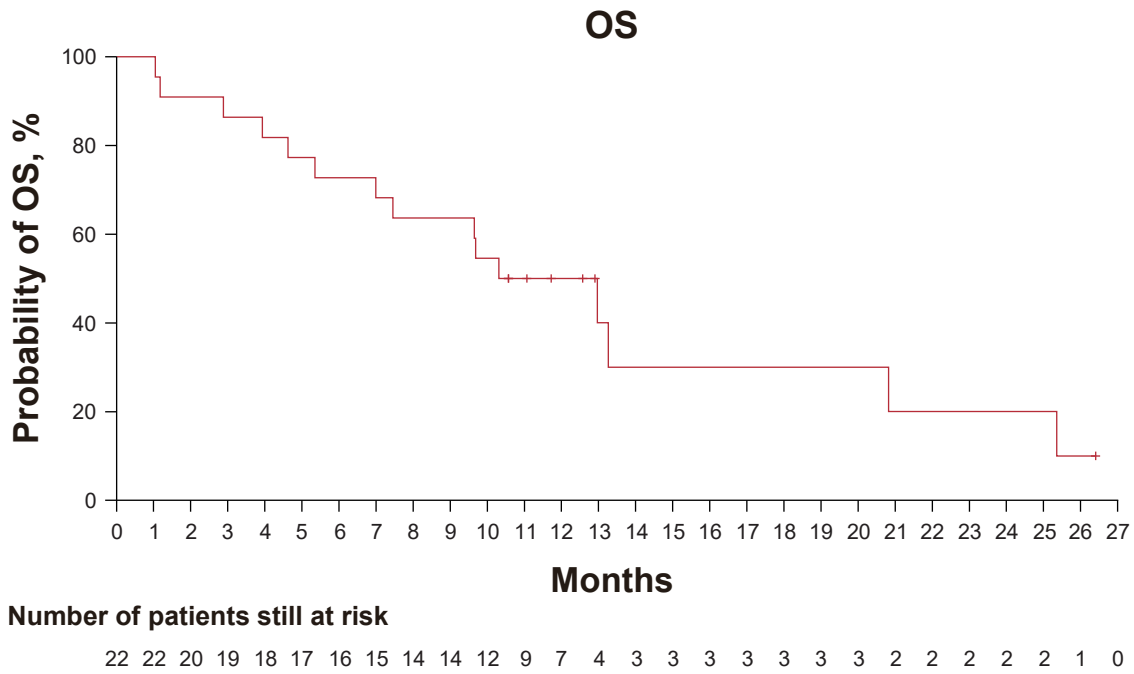
[a]By blinded independent central review per Response Evaluation Criteria in Solid Tumours, version 1.1.

2L, second-line; 3L+, third-line and beyond; CI, confidence interval; CR, complete response; DOR, duration of response; LOT, line of therapy; NE, not estimable; PR, partial response; TTR, time to response.

mPFS was 4.7 months and mOS was 11.6 months with I-DXd 12 mg/kg in the Japanese subgroup

	I-DXd 12-mg/kg Japanese subgroup (n=22)	Total I-DXd 12-mg/kg population (N=137)
PFS,[a] median (95% CI), months	4.7 (2.8–5.8)	4.9 (4.2–5.5)
OS, median (95% CI), months	11.6 (5.4–20.8)	10.3 (9.1–13.3)





Data cutoff: March 3, 2025. Median follow-up in the Japanese subgroup (n=22): 12.9 months (95% CI, 10.6–NE). Median follow-up in the total 12-mg/kg population (N=137): 12.8 months (95% CI, 12.2–13.1).

[a]By blinded independent central review per Response Evaluation Criteria in Solid Tumours, version 1.1.

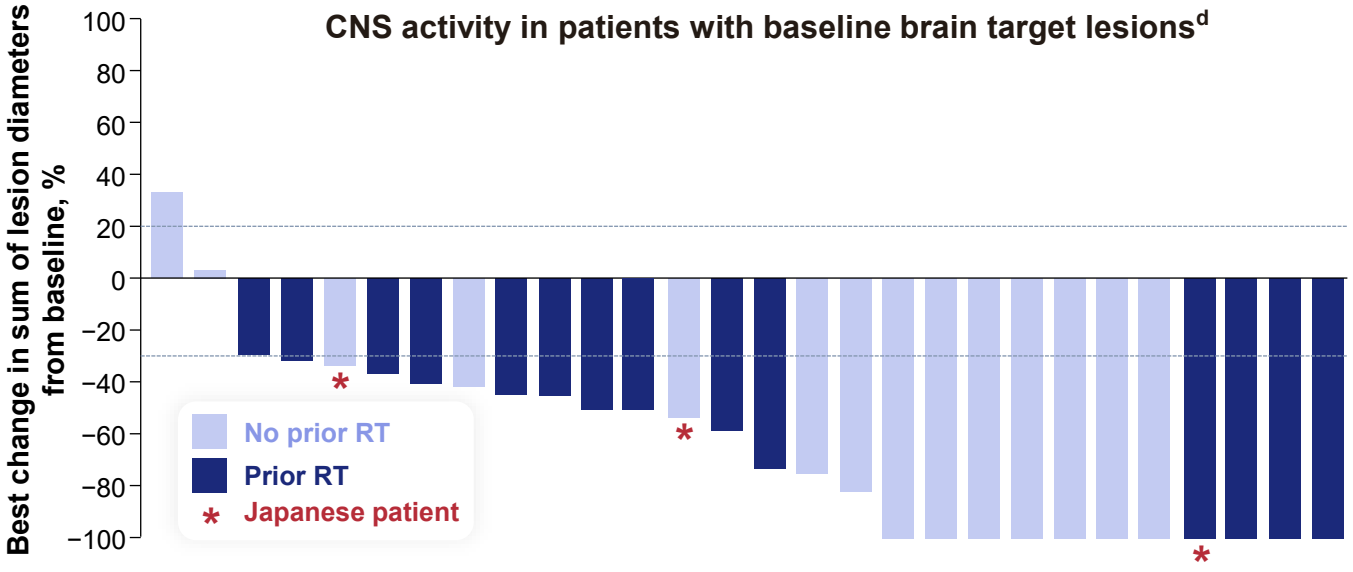
CI, confidence interval; NE, not estimable, (m)OS, (median) overall survival; (m)PFS, (median) progression-free survival.

I-DXd demonstrated encouraging intracranial activity in patients with baseline BM in the total 12-mg/kg population

- Among the total 12-mg/kg population (N=137), a subgroup analysis of 65 patients with asymptomatic (previously treated or untreated) BM at baseline[a] and a subset analysis of 29 patients with baseline brain target lesions[a,b] were reported[1]

	With baseline BM[a] (n=65)	With baseline brain target lesions[a,b] (n=29)
CNS cORR,[c] % (95% CI)	46.2 (33.7–59.0)	65.5 (45.7–82.1)
CR, n (%)	20 (30.8)	9 (31.0)
PR, n (%)	10 (15.4)	10 (34.5)
CNS cDCR,[c] % (95% CI)	90.8 (81.0–96.5)	96.6 (82.2–99.9)

- In patients with **brain target lesions with no prior RT** for BM (n=14), **CNS cORR was 71.4%** (95% CI, 41.9–91.6)[c]
- Among the **3 Japanese patients with brain target lesions, 2 (66.7%)** had a **CNS PR** and **1 (33.3%)** had **CNS SD**



Data cutoff: March 3, 2025.

[a]Identified by CNS BICR, detectable by CT/MRI brain scan at baseline. [b]Defined as ≥1 CNS target lesion with a longest diameter of ≥10 mm or twice the slice thickness by CT/MRI scan, whichever was larger. [c]Intracranial response was assessed by CNS BICR using a version of Response Evaluation Criteria in Solid Tumours, version 1.1 modified for assessment of CNS tumors. Best overall responses of CR or PR were confirmed. [d]Only patients with measurable disease at baseline and ≥1 post-baseline assessment are included in the plot (n=28); 1 patient was excluded due to a lack of post-baseline assessment.

BICR, blinded independent central review; BM, brain metastases; cDCR, confirmed disease control rate; CI, confidence interval; CNS, central nervous system; cORR, confirmed objective response rate; CR, complete response; CT, computed tomography; MRI, magnetic resonance imaging; PR, partial response; RT, radiotherapy; SD, stable disease.

1. Rocha P, et al. Oral presentation at the European Society for Medical Oncology congress. October 17–21, 2025; Berlin, Germany. Presentation 2760MO.

The safety profile of I-DXd 12 mg/kg was generally manageable

	I-DXd 12-mg/kg Japanese subgroup (n=22)	Total I-DXd 12-mg/kg population (N=137)
Median treatment duration,[a] months (range)	4.2 (0.7–12.4)	4.8 (0.7–22.7)
Median cycles, n (range)	6.0 (1.0–17.0)	7.0 (1.0–32.0)
Any-grade TRAEs, n (%)[b]	20 (90.9)	123 (89.8)
Grade ≥3	9 (40.9)	50 (36.5)
Associated with dose delay	5 (22.7)	35 (25.5)
Associated with dose reduction	4 (18.2)	21 (15.3)
Associated with treatment discontinuation[c]	**4 (18.2)**	**13 (9.5)**
Associated with death[d]	**3 (13.6)**	**6 (4.4)**

Data cutoff: March 3, 2025.

[a]Treatment duration (months) was calculated as (date of the last dose − date of the first dose + 21 days) × 12 ÷ 365.25. For patients who were still on treatment at data cutoff, the last available date of dose prior to data cutoff was used. [b]Number of patients (%) with event. [c]Grade 1: pneumonitis (Japanese, n=1; total population, n=1); Grade 2: ILD (total population, n=3), pneumonitis (total population, n=2), radiation pneumonitis (Japanese, n=1; total population, n=1), and fatigue (total population, n=1); Grade 3: ILD (Japanese, n=1; total population, n=2), *Pneumocystis jirovecii* pneumonia (Japanese, n=1; total population, n=2), and nausea (total population, n=1). [d]ILD/pneumonitis (Japanese, n=1; total population, n=3); *Pneumocystis jirovecii* pneumonia (Japanese, n=2; total population, n=2); pulmonary sepsis (total population, n=1). Of the 3 ILD/pneumonitis events associated with death per investigator, only 1 (in a Japanese patient) was subsequently adjudicated as Grade 5 treatment-related ILD/pneumonitis by the ILD adjudication committee.

ILD, interstitial lung disease; TRAE, treatment-related adverse event.

Adjudicated treatment-related ILD/pneumonitis events were mainly low grade

	I-DXd 12-mg/kg Japanese subgroup (n=22)	Total I-DXd 12-mg/kg population (N=137)
Any-grade adjudicated treatment-related ILD/pneumonitis,[a] n (%)[b]	3 (13.6)	17 (12.4)
Grade 1	1 (4.5)	3 (2.2)
Grade 2	1 (4.5)	8 (5.8)
Grade 3	0	4 (2.9)
Grade 4	0	0
Grade 5	1 (4.5)[c]	2 (1.5)[c]
Time to onset of first event, median (range), days	22 (18–86)	78 (18–332)
Outcome at data cutoff, n (%)[d]		
Resolved / not resolved / fatal	1 (33.3) / 1 (33.3) / 1 (33.3)	10 (58.8) / 4 (23.5) / 3 (17.6)
Duration of first resolved event, median (range), days	180 (180–180)	26 (6–180)

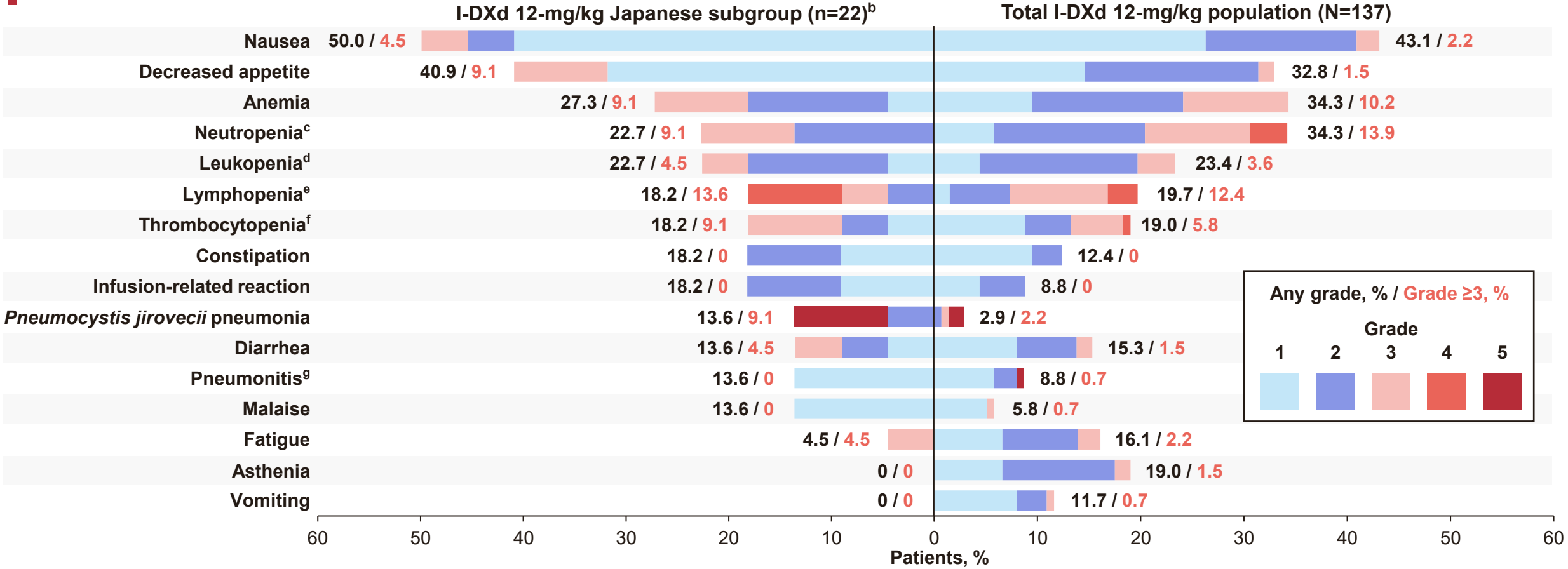
Data cutoff: March 3, 2025. Median treatment duration: Japanese subgroup, 4.2 months (range, 0.7–12.4); total 12-mg/kg population, 4.8 months (range, 0.7–22.7). Median number of cycles: Japanese subgroup, 6.0 (range, 1–17); total 12-mg/kg population, 7.0 (range, 1–32).

[a]At data cutoff, all suspected ILD/pneumonitis events had been adjudicated. [b]Number of patients (%) with event. [c]Adjudicated as treatment-related ILD (not treatment-related pneumonitis). [d]Percentages are of the total number of patients with adjudicated ILD/pneumonitis.

ILD, interstitial lung disease.

The most commonly reported TRAEs were hematologic or GI

TRAEs[a] reported at any grade in ≥10% of patients in the Japanese subgroup or total 12-mg/kg population



Data cutoff: March 3, 2025. Median treatment duration: Japanese subgroup, 4.2 months (range, 0.7–12.4); total 12-mg/kg population, 4.8 months (range, 0.7–22.7). Median number of cycles: Japanese subgroup, 6.0 (range, 1–17); total 12-mg/kg population, 7.0 (range, 1–32).

[a]Per investigator. [b]All TRAEs reported at Grade ≥3 in ≥5% of patients in the Japanese subgroup were also reported in ≥10% of patients in either group at any grade. [c]Includes the preferred terms "neutrophil count decreased" and "neutropenia." [d]Includes the preferred terms "white blood cell count decreased" and "leukopenia." [e]Includes the preferred terms "lymphocyte count decreased" and "lymphopenia." [f]Includes the preferred terms "platelet count decreased" and "thrombocytopenia." [g]Includes events assigned to the preferred term of "pneumonitis." Does not include events assigned to the preferred term of "interstitial lung disease."
GI, gastrointestinal; TRAE, treatment-related adverse event.

Conclusions

- In this subgroup analysis of patients receiving I-DXd 12 mg/kg in IDeate-Lung01, efficacy among Japanese patients was generally consistent with that seen in the total 12-mg/kg population
  - The greater proportion of patients with CTFI ≤30 days in the Japanese subgroup (36.4%) than in the total 12-mg/kg population (13.1%) may have contributed to the observed difference in confirmed ORR between the 2 groups (31.8% and 48.2%, respectively)
- The safety profile in the Japanese subgroup was generally manageable and similar to the total 12-mg/kg population
  - The most common TRAEs were hematologic or GI, with the majority being Grade 1 or 2
  - Any-grade and Grade ≥3 adjudicated treatment-related ILD/pneumonitis were reported in 13.6% (n=3) and 4.5% (n=1) of patients in the Japanese subgroup and in 12.4% (n=17) and 4.4% (n=6) patients in the total 12-mg/kg population, respectively
  - However, any-grade TRAEs associated with treatment discontinuation (18.2% [n=4]) or death (13.6% [n=3]) were more frequent in the Japanese subgroup than in the total 12-mg/kg population (9.5% [n=13] or 4.4% [n=6], respectively)
- Comparisons are limited by the relatively small sample size in the Japanese subgroup
- The efficacy and safety of I-DXd 12 mg/kg in Japanese patients will be investigated further in subgroup analyses of the ongoing global Phase 3 IDeate-Lung02 trial (NCT06203210)[a]

Data cutoff: March 3, 2025.

[a]IDeate-Lung02 is comparing I-DXd 12 mg/kg vs physician's choice of topotecan, amrubicin, or lurbinectedin in patients with relapsed small cell lung cancer with only 1 prior line of systemic treatment, which must have included platinum-based chemotherapy.

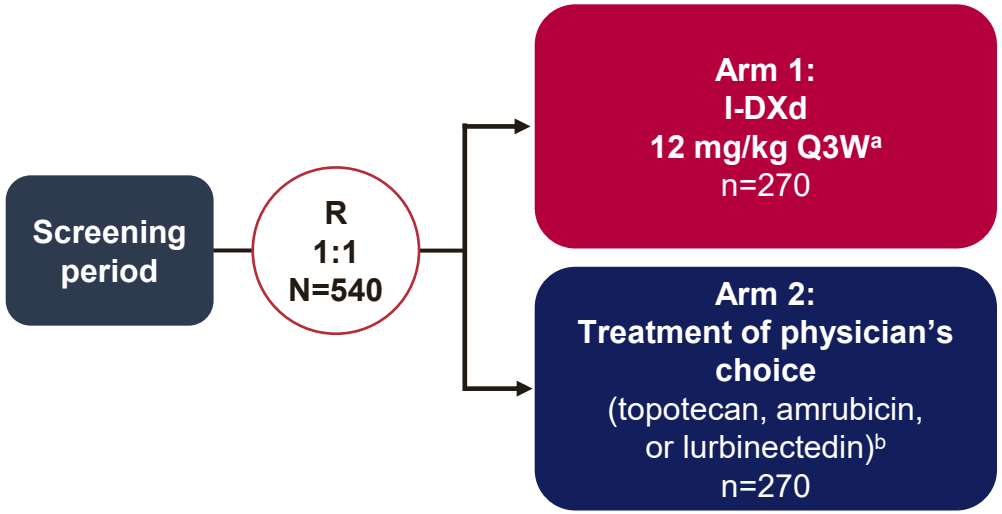
GI, gastrointestinal; ILD, interstitial lung disease; ORR, objective response rate; TRAE, treatment-related adverse event.

IDeate-Lung02 study design

Phase 3, multicenter, randomized, open-label study (NCT06203210)[1,2]

Key eligibility criteria:

- Histologically or cytologically documented ES-SCLC
- Age ≥18 years or minimum legal adult age (whichever is greater)
- Received only 1 prior line of platinum-based therapy
- Radiologically documented PD on or after platinum-based therapy
- ECOG PS 0–1
- Patients with asymptomatic brain metastases (untreated or previously treated)



Stratification

- Chemotherapy-free interval following 1L therapy (<90 vs ≥90 days)
- Treatment of physician's choice (topotecan vs amrubicin vs lurbinectedin)
- Treatment with prior PD-(L)1 inhibitors (yes vs no)
- Presence or history of brain metastases (yes vs no)

Primary endpoints:

- ORR by BICR[c]
- OS

Secondary endpoints:

- ORR by inv[c]
- PFS by BICR and inv[c]
- DOR by BICR and inv[c]
- DCR by BICR and inv[c]
- TTR by BICR and inv[c]
- PROs
- Safety
- Immunogenicity[d]
- Pharmacokinetics[d]
- Relationship between B7-H3 expression and clinical efficacy

Follow-up

Safety[e]

Long-term follow-up

Q3M[f]

[a]Until PD (per inv), unacceptable toxicity, withdrawal of consent, death, loss to follow-up, or other reasons (whichever occurs first). [b]Comparator treatments will only be utilized in countries where they are approved in the second line for patients with SCLC who progressed on or after PBC. It is planned that ≥70% of patients in the comparator group will receive topotecan. [c]Per RECIST 1.1. [d]I-DXd arm only. [e]Safety follow-up visit will occur 40 days (+7 days) after the last dose. [f]Long-term follow-up will assess survival and tumor progression (until PD for patients discontinuing for reasons other than PD), and to collect information on further anticancer treatments; Q3M (90 ± 14 days) from study drug discontinuation until death, withdrawal of consent, or a study termination criterion is met.

1L, first-line; B7-H3, B7 homolog 3; BICR, blinded independent central review; DCR, disease control rate; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; I-DXd, ifinatamab deruxtecan; inv, investigator; ORR, objective response rate; OS, overall survival; PBC, platinum-based chemotherapy; PD, progressive disease; PD-(L)1, programmed death (ligand) 1; PFS, progression-free survival; PRO, patient-reported outcome; Q3M, every 3 months; Q3W, every 3 weeks; R, randomization; RECIST 1.1, Response Evaluation Criteria in Solid Tumours, version 1.1; (ES)-SCLC, (extensive-stage) small cell lung cancer; TTR, time to response.

1. ClinicalTrials.gov. https://clinicaltrials.gov/study/NCT06203210. Accessed March 18, 2026. 2. Owonikoko TK, et al. *Future Oncol.* 2025;21:3275–3282.

Acknowledgments

- We would like to thank the patients, their families, and their caregivers for their participation, and the study staff for their contributions
- This study is sponsored by Daiichi Sankyo, Inc. In October 2023, Daiichi Sankyo entered into a global development and commercialization collaboration agreement with Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA (MSD) for ifinatamab deruxtecan (I-DXd)
- Medical writing support was provided by Jemma Dunn, PhD, of BOLDSCIENCE, Inc., and was funded by Daiichi Sankyo, Inc.
- Editorial support was provided in accordance with Good Publication Practice guidelines (https://www.ismpp.org/gpp-2022)

Thank you!