MSD's Science-led Approach to Oncology Research & Development: ESMO 2025

MSD Press Briefing

19 October 2025

Agenda

Kristen Drake
Executive Director, Head of Oncology Communications

Dr. Marjorie Green
SVP, Head of Oncology, Global Clinical Development

Dr. Jane Healy
VP, Early Oncology Development

Dr. M. Catherine Pietanza
VP, Global Clinical Development

- **Opening** | Kristen Drake
- **MSD's oncology strategy and continued impact** | Dr. Marjorie Green
- **Exploring the future of the oncology pipeline** | Dr. Jane Healy
- **Patient centricity in cancer care** | Dr. M. Catherine Pietanza
- **Q&A** | Moderated by Kristen Drake

Forward-looking statement of Merck & Co., Inc., Rahway, N.J., USA

This presentation of Merck & Co., Inc., Rahway, N.J., USA (the “company”) includes “forward-looking statements” within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company’s management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline candidates that the candidates will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company’s ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company’s patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company’s Annual Report on Form 10-K for the year ended December 31, 2024, and the company’s other filings with the Securities and Exchange Commission (SEC) available at the SEC’s Internet site (www.sec.gov).

MSD’s oncology strategy

MSD's broad portfolio of oncology products*

>3.6 million
patients have been treated with commercially available medicines[1]

60+
ongoing Phase 3 studies[2] in oncology across **16** assets

LENVIMA® (lenvatinib) capsules | 10 mg and 4 mg

TKI with multiple approved indications

7 FDA approved indications
5 EU approved indications

KEYTRUDA® (pembrolizumab) for Injection 50 mg

Foundational cancer treatment in numerous cancers

42 FDA approved indications
31 EU approved indications

Subcutaneous pembrolizumab**

Subcutaneously administered immune checkpoint inhibitor

39 FDA approved indications

WELIREG™ (belzutifan)

First-in-class HIF-2α inhibitor

3 FDA approved indications
2 EU approved indications

Lynparza® olaparib tablets 150 mg

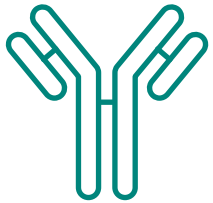
Market-leading PARPi

8 FDA approved indications
9 EU approved indications

* Approval count reflects original and supplemental marketing applications **Not approved for use in the EU; pending European Commission decision, to be marketed as KEYTRUDA SC™ approved for use in the U.S. as KEYTRUDA QLEX™ (pembrolizumab and berahyaluronidase alfa-pmph)

1. Patients treated with commercially available products as of Q2 2025. 2. Registrational studies

Our strategy to maximize benefit to patients: unambiguous efficacy, informed combinations, biomarker enrichment, curative intent settings



Combinable agents

Best outcomes occur when non-cross resistant therapies are combined or given sequentially

Develop medicines with single agent activity which can be combined with other agents

Biomarkers

Predictive biomarkers enable stratification that can improve therapeutic index of medications

Improve the therapeutic index through precision medicine

Earlier-stage disease

Early treatment improves chance for better outcomes

Develop medicines in earlier stages of disease

Select examples

Combinable agents	Biomarkers	Earlier-stage disease
sacituzumab tirumotecan (sac-TMT), MK-2010, intismeran autogene, MK-1084	MK-1084, sac-TMT	KEYTRUDA, subcutaneous pembrolizumab*, intismeran autogene, sac-TMT

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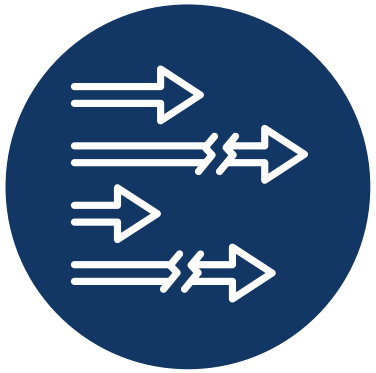
MSD

Our oncology portfolio can be described in three biological pillars

Immuno-oncology

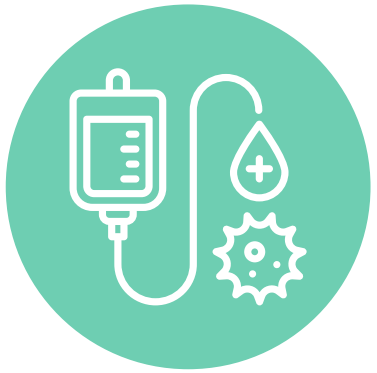
Boost anti-tumor immune responses

Precision molecular targeting



Impact pathways that can drive cancer growth

Tissue targeting



Increase cancer cell sensitivity with ADCs and immune-engagers

MSD's diverse portfolio and pipeline, with mechanistic differentiators, is uniquely positioned to further cancer care

Immuno-oncology
Boost anti-tumor immune responses

KEYTRUDA® (pembrolizumab) Injection 100 mg

Subcutaneous pembrolizumab*

quavonlimab/ pembrolizumab
(MK-1308A)
anti-CTLA-4

intismeran autogene[1]
(V940)
Individualized neoantigen therapy

MK-2010
Anti-PD1 x VEGF bispecific

Precision molecular targeting
Impact pathways that can drive cancer growth

Lynparza™ olaparib[2]

LENVIMA® (lenvatinib) capsules[3]
RESULTS THAT MATTER

WELIREG™ (belzutifan) 40 mg tablets

nemtabrutinib
(MK-1026)
BTK inhibitor

bomedemstat
(MK-3543)
LSD1 inhibitor

Opevesostat
(MK-5684)
CYP11A1 inhibitor

MK-1084[4]
KRAS G12C inhibitor

Tissue targeting
Increase cancer cell sensitivity with ADCs and immune-engagers

sac-TMT[5]
(MK-2870)
TROP2 ADC

MK-3120[5]
Nectin-4 ADC

zilovertamab vedotin
(MK-2140)
ROR1 ADC

MK-2750[5]
ADC – undisclosed target

MK-6837
ADC – undisclosed target

MK-6204[5]
ADC – undisclosed target

HER3-DXd[7]
(MK-1022)
HER3 ADC

I-DXd[7]
(MK-2400)
B7H3 ADC

R-DXd[7]
(MK-5909)
CDH6 ADC

gocatamig[7]
(MK-6070)
DLL3 TCE

MK-1045
CD3xCD19 TCE

Undisclosed preclinical ADCs[5,6]

*Not approved for use in the EU; pending European Commission decision, to be marketed as KEYTRUDA SC™; approved for use in the U.S. as KEYTRUDA QLEX™(pembrolizumab and berahyaluronidase alfa-pmph)

1. Collaboration with Moderna 2. Collaboration with AstraZeneca 3. Collaboration with Eisai 4. Collaboration with Taiho and Astex 5. Collaboration with Kelun-Biotech 6. Includes internal pipeline programs 7. Collaboration with Daiichi Sankyo

MSD

More than 10 novel candidates have advanced to late-phase development

Immuno-oncology
Boost anti-tumor immune responses

KEYTRUDA® (pembrolizumab) Injection 100 mg

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Tissue targeting
Increase cancer cell sensitivity with ADCs and immune-engagers

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CDH6 ADC

gocatamig[7]
(MK-6070)
DLL3 TCE

MK-1045
CD3xCD19 TCE

Undisclosed preclinical ADCs[5,6]

Late-phase candidates with either an ongoing Phase 3 or Phase 2/3 study

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MSD

MSD’s continued impact in immuno-oncology

In earlier stage disease, KEYTRUDA is the only IO to date to demonstrate significant OS benefit in 5 studies, and to receive 10 U.S. FDA approvals / 7 EU approvals

Lung

KN-671
Perioperative
Stage II, IIIA or IIIB (N2) NSCLC

KN-091
Adjuvant
Stage IB (T2a ≥4 cm), II or IIIA NSCLC

Head & Neck

KN-689
Perioperative resectable locally advanced H&N squamous cell carcinoma

Renal

KN-564
Adjuvant
Intermediate-high or high-risk RCC

Skin

KN-054
Adjuvant
High-risk stage III Melanoma

KN-716
Adjuvant
Stage IIB or IIC Melanoma

KN-629
Locally advanced cSCC

Breast

KN-522
Perioperative
High-risk early-stage TNBC

Cervical

KN-A18
FIGO 2014 stage III-IVA Cervical

Bladder

KN-057
High-risk NMIBC

KN-905
Cisplatin-ineligible or declined MIBC

U.S. indication for certain patients with cancer type

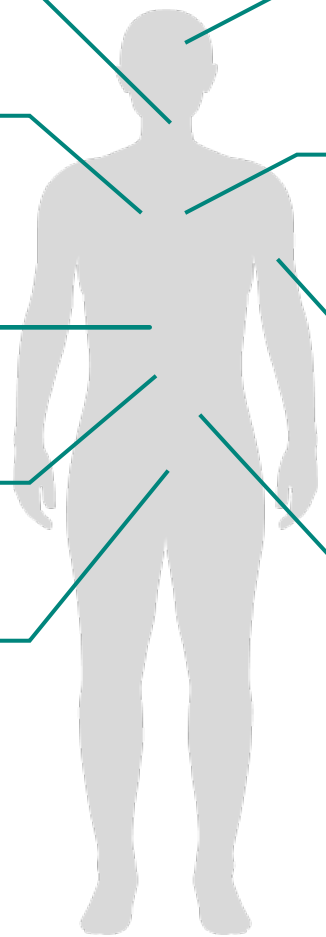
U.S. **and** EU indication for certain patients with cancer type

Achieved OS in cancer type

MSD

Extensive ongoing, late-phase clinical development program for earlier stages of cancer[1]

More than **30,000 patients[2]** in **>30 active Phase 3 trials[3]** in earlier stages of disease across **10 tumor types**



Esophageal
KN-975

Lung
***KN-091** INTerpath-002
***KN-671** INTerpath-009
TroFuse-019

Liver
LEAP-012

Renal
***KN-564** LITESPARK-022

Bladder
KN-057 KN-905 KN-866 KN-B15
KN-123 KN-992 KN-676

Head & Neck
KN-689

Breast
***KN-522** KN-242
***OLYMPIA** TroFuse-012
KN-756 TroFuse-032

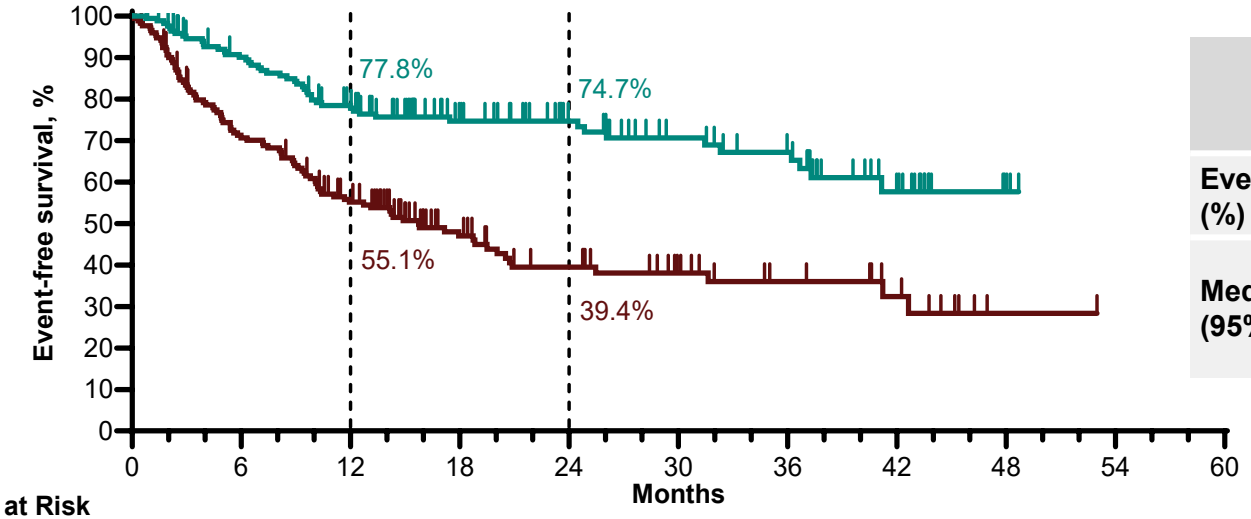
Skin
***KN-054** INTerpath-001
***KN-716**
KN-629

Cervical
***KN-A18**

Approved Indication (U.S.)
***Denotes EU indication**
Announced IA Results

1. Operable and/or no/limited spread to other parts of the body. 2. Includes targeted number of enrolled patients based upon clinical trial design. 3. Reflects ongoing trials including approved studies.

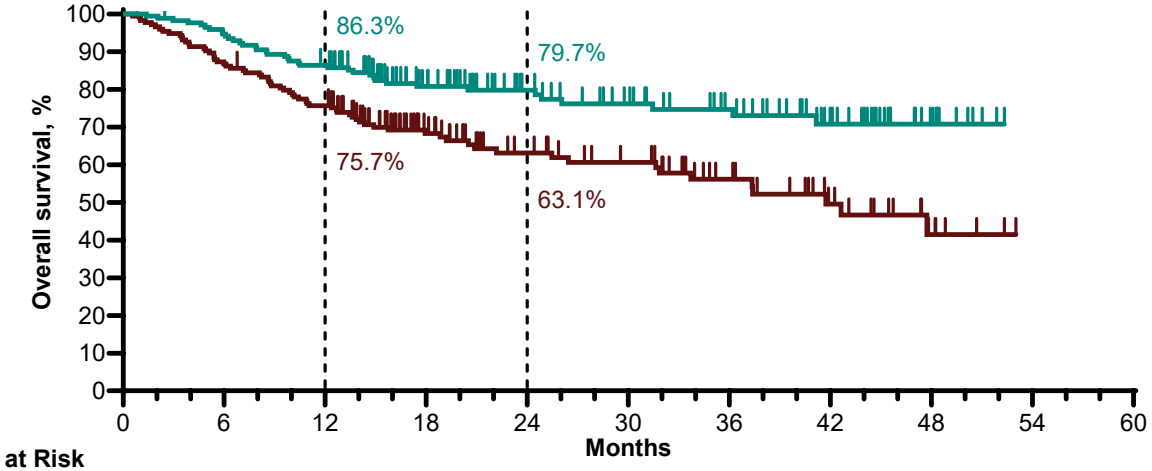
Perioperative enfortumab vedotin (EV) plus pembrolizumab in participants with muscle-invasive bladder cancer (MIBC) who are cisplatin-ineligible: Phase 3 KEYNOTE-905 study



No. at Risk											
EV + pembro	170	140	116	73	56	42	35	16	3	0	0
Control	174	116	84	48	33	22	14	9	1	0	0

	EV + pembrolizumab (N = 170)	RC + PLND (control) (N = 174)
Events, n (%)	48 (28.2)	95 (54.6)
Median, mo (95% CI)	NR* (37.3–NR)	15.7 (10.3–20.5)

HR 0.40, 95% CI 0.28-0.57, one-sided *P* <.0001[a]



No. at Risk											
EV + pembro	170	159	144	94	68	56	45	28	10	0	0
Control	174	150	130	75	54	45	30	18	6	0	0

	EV + pembrolizumab (N = 170)	RC + PLND (Control) (N = 174)
Events, n (%)	38 (22.4)	68 (39.1)
Median, mo (95% CI)	NR* (NR–NR)	41.7 (31.8–NR)

HR 0.50, 95% CI 0.33-0.74, one-sided *P* =.0002[b]

Key findings

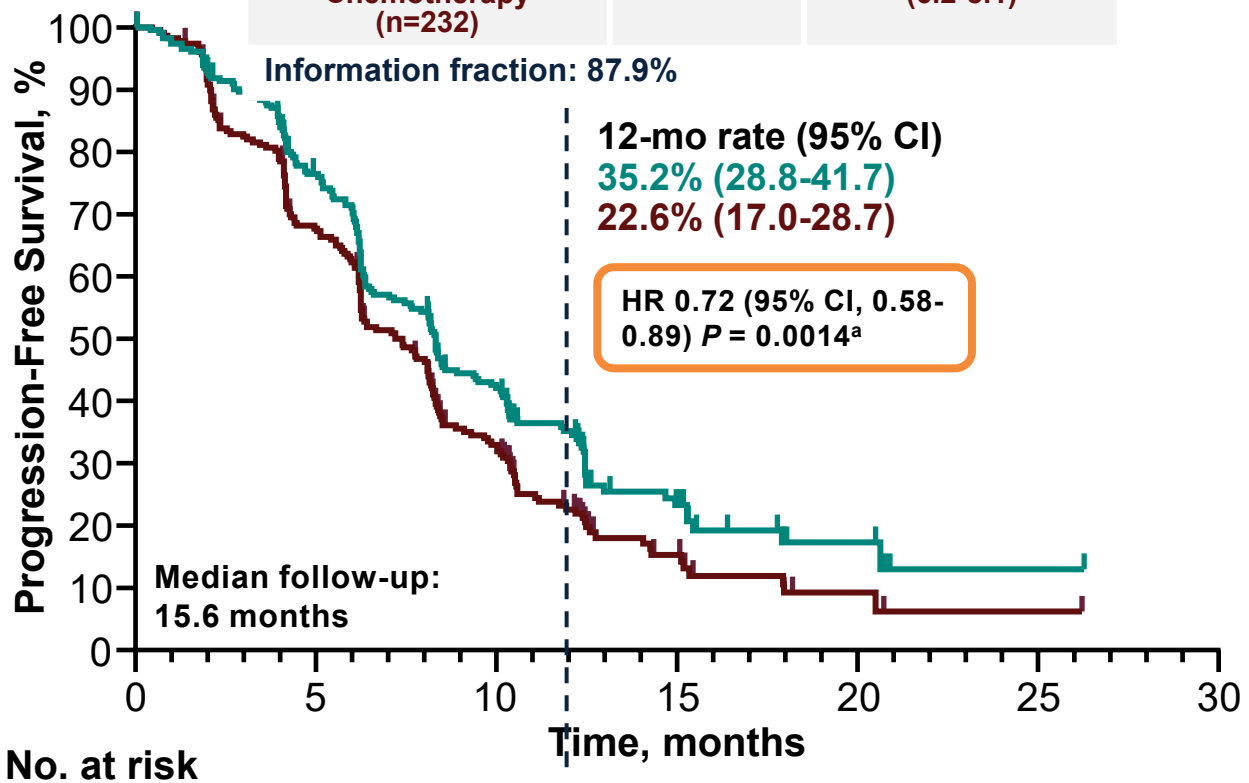
- ✓ Neoadjuvant EV + pembrolizumab, radical cystectomy with standard pelvic lymph node dissection (RC + PLND), and adjuvant EV + pembrolizumab significantly and meaningfully improved EFS and OS in patients with MIBC who are ineligible for or declined cisplatin-based chemotherapy

a. denotes statistical significance (one-sided boundary 0.0097), b. denotes statistical significance (one-sided boundary 0.00488)

*Not reached; **In collaboration with Pfizer/Astellas

Pembrolizumab vs placebo plus weekly paclitaxel with or without bevacizumab for platinum-resistant recurrent ovarian cancer: Results from the randomized, double-blind Phase 3 ENGOT-ov65/KEYNOTE-B96 study: Progression-free survival in the CPS ≥1 and ITT populations at IA1

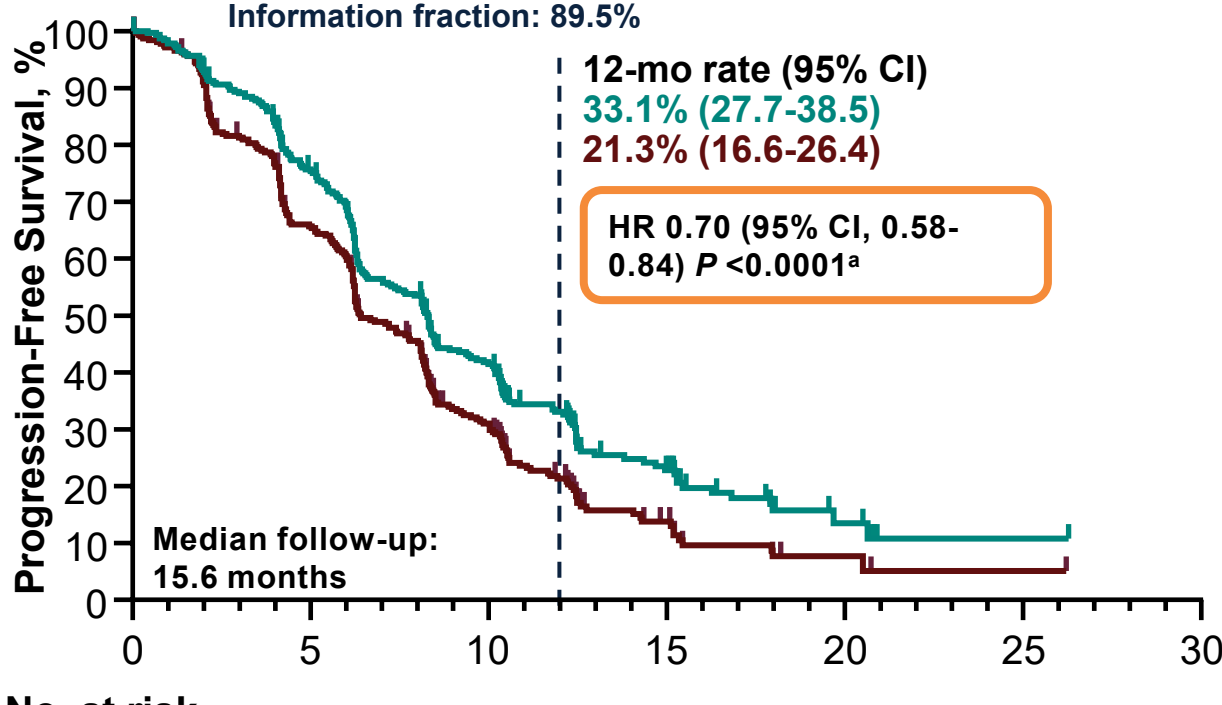
CPS ≥1 Patient Population	Pts w/ Event	Median, mo (95% CI)
Pembrolizumab + Chemotherapy (n=234)	69.2%	8.3 (7.0-9.4)
Placebo + Chemotherapy (n=232)	77.6%	7.2 (6.2-8.1)



No. at risk

234	170	87	21	5	1	0
232	150	64	16	3	1	0

ITT Patient Population	Pts w/ Event	Median, mo (95% CI)
Pembrolizumab + Chemotherapy (n=322)	71.7%	8.3 (7.2-8.6)
Placebo + Chemotherapy (n=321)	78.8%	6.4 (6.2-8.1)

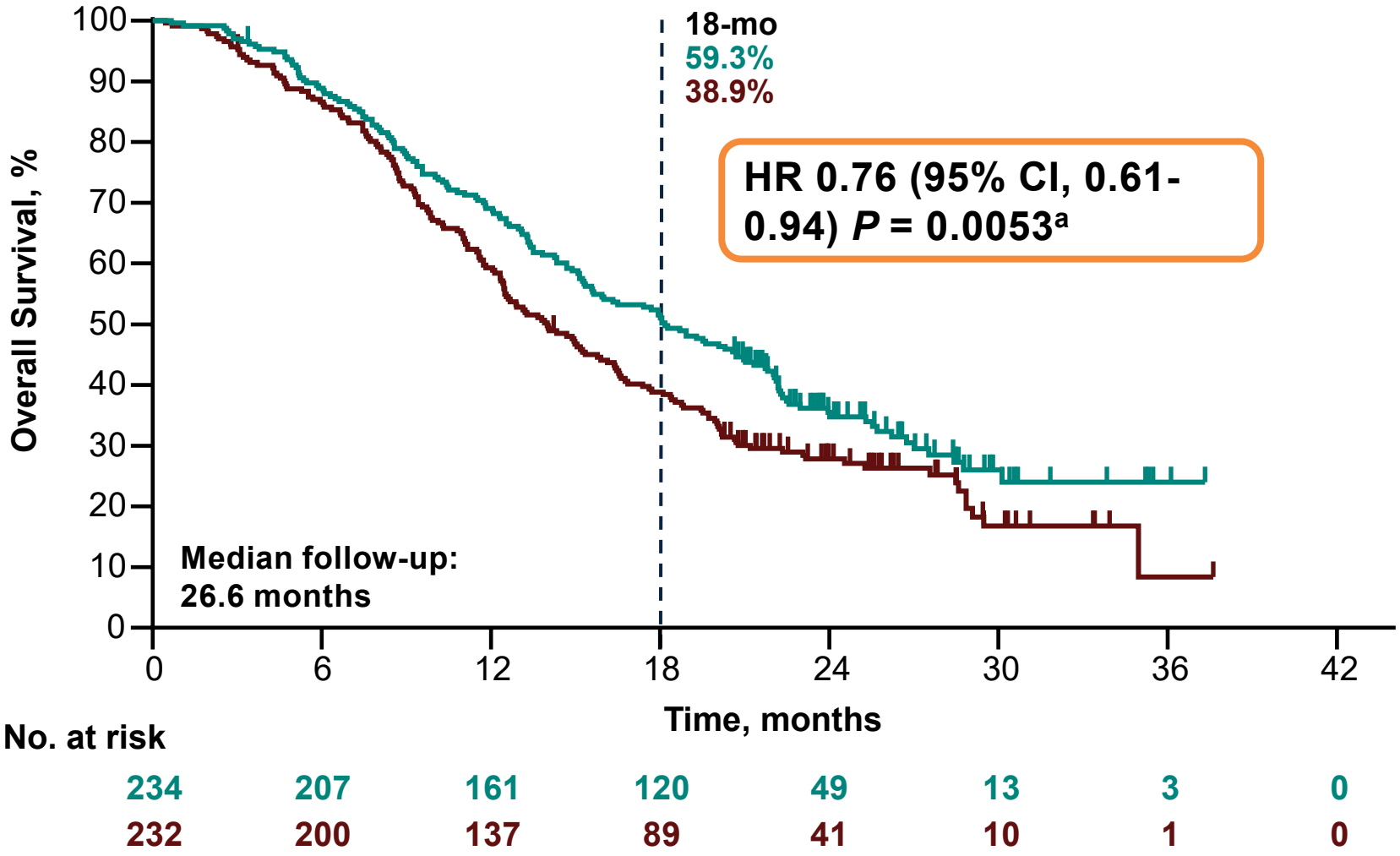


No. at risk

322	233	119	34	6	1	0
321	200	84	19	3	1	0

[a]The observed p-value crossed the prespecified nominal boundary of 0.0023 at this planned first interim analysis; since the success criterion of the PFS hypothesis was met, no formal testing of PFS will be performed at later analyses. Data cutoff date: April 3, 2024.

Pembrolizumab vs placebo plus weekly paclitaxel with or without bevacizumab for platinum-resistant recurrent ovarian cancer: Results from the randomized, double-blind Phase 3 ENGOT-ov65/KEYNOTE-B96 study: Secondary endpoint OS in the CPS ≥1 population at IA2



CPS ≥1 Patient Population	Pts w/ Event	Median, mo (95% CI)
Pembrolizumab + Chemotherapy (n=234)	67.1%	18.2 (15.3-21.0)
Placebo + Chemotherapy (n=232)	75.4%	14.0 (12.5-16.1)

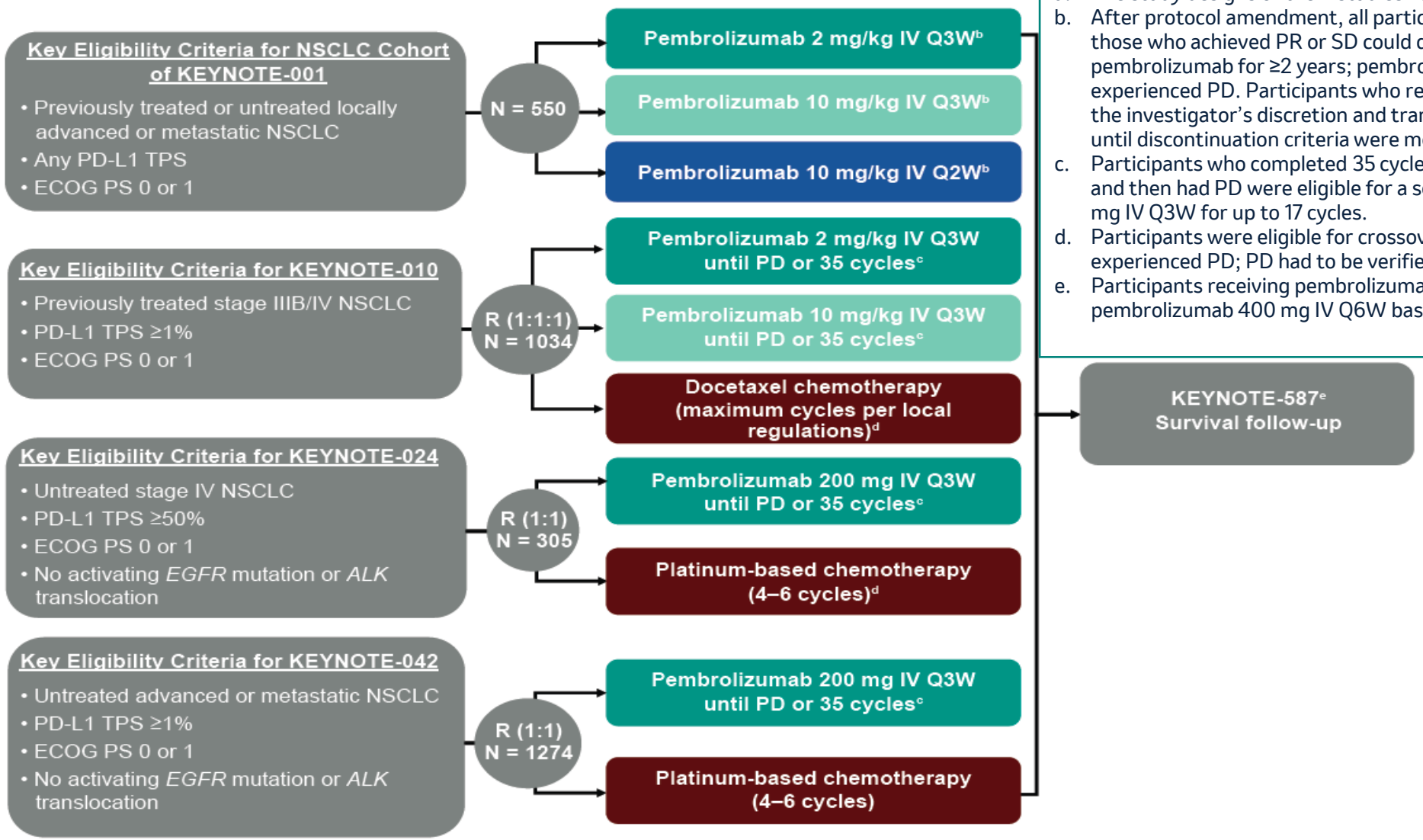
Information fraction: 90.0%

Key findings

- Pembrolizumab, in combination with weekly paclitaxel, with or without bevacizumab, demonstrated statistically significant and clinically meaningful improvements in PFS regardless of PD-L1 status and in OS in PD-L1-expressing tumors in participants with PRROC
- The observed OS showed a clinically meaningful benefit of this regimen relative to the most active standard-of-care control arm, weekly paclitaxel with bevacizumab for bevacizumab-eligible patients

[a]The observed p-value crossed the prespecified nominal boundary of 0.0083 at this planned second interim analysis. Data cutoff date: March 5, 2025.

Long-term outcomes from select clinical trials of pembrolizumab monotherapy for certain patients with locally advanced or metastatic non–small cell lung cancer



a. The study designs of the 4 studies have been previously published.
b. After protocol amendment, all participants received pembrolizumab 200 mg IV Q3W, and those who achieved PR or SD could discontinue treatment if they received pembrolizumab for ≥2 years; pembrolizumab monotherapy could resume if participants experienced PD. Participants who received pembrolizumab monotherapy beyond PD at the investigator's discretion and transitioned to KEYNOTE-587 could continue treatment until discontinuation criteria were met.
c. Participants who completed 35 cycles or who stopped pembrolizumab after achieving CR and then had PD were eligible for a second course of pembrolizumab monotherapy 200 mg IV Q3W for up to 17 cycles.
d. Participants were eligible for crossover to pembrolizumab monotherapy if participants experienced PD; PD had to be verified by BICR for participants enrolled in KEYNOTE-024.
e. Participants receiving pembrolizumab 200 mg IV Q3W were permitted to switch to pembrolizumab 400 mg IV Q6W based on investigator discretion and participant consent.

BICR, blinded independent central review; CR, complete response; IV, intravenous; PR, partial response; Q2W, every 2 weeks; Q3W, every 3 weeks; SD, stable disease.

OS results from KEYNOTE-001, 010, 024 and 042*

	Pembrolizumab	Chemotherapy
KEYNOTE-024[a]		
TPS ≥50%	n/N = 36/154	n/N = 14/151
8y OS rate	24.3% (17.6%–31.5%)	12.8% (7.6%–19.3%)
HR (95% CI)	0.65 (0.50–0.83)	
Median OS (95% CI), months	26.3 (18.3–40.4)	13.4 (9.4–18.3)
KEYNOTE-042[a]		
TPS ≥1%	n/N = 66/637	n/N = 27/637
8y OS rate	12.0% (9.5%–14.8%)	4.7% (3.1%–6.9%)
HR (95% CI)	0.78 (0.69–0.88)	
Median OS (95% CI), months	16.4 (14.0–19.6)	12.1 (11.3–13.3)
TPS ≥50%	n/N = 41/299	n/N = 13/300
8y OS rate	16.6% (12.5%–21.1%)	6.8% (4.1%–10.5)%
HR (95% CI)	0.70 (0.59–0.83)	
Median OS (95% CI) months	20.0 (15.9–24.2)	12.2 (10.4–14.6)

	Pembrolizumab	Chemotherapy
KEYNOTE-001[a,b]		
Any TPS	n/N = 54/550	N/A
10y OS rate (95% CI)	11.3% (8.5%–14.5%)	N/A
Median OS (95% CI) months	13.2 (10.5–15.3)	N/A
TPS ≥50%	n/N = 25/165	N/A
10y OS rate	19.3% (13.1%–26.5%)	N/A
Median OS (95% CI) months	17.3 (13.7–24.8)	N/A
KEYNOTE-010[b]		
TPS ≥1%	n/N = 53/690	n/N = 9/343
10y OS rate	9.3% (7.0%–12.1%)	1.9% (0.7%–4.6%)
HR (95% CI)	0.66 (0.58–0.76)	
Median OS (95% CI) months	11.8 (10.3–13.0)	8.3 (7.5–9.5)
TPS ≥50%	n/N = 35/290	n/N = 6/152
10y OS rate	15.5% (11.1%–20.5%)	2.7% (0.7%–7.4%)
HR (95% CI)	0.55 (0.44–0.68)	
Median OS (95% CI) months	16.6 (12.1–21.2)	8.2 (6.4–9.8)

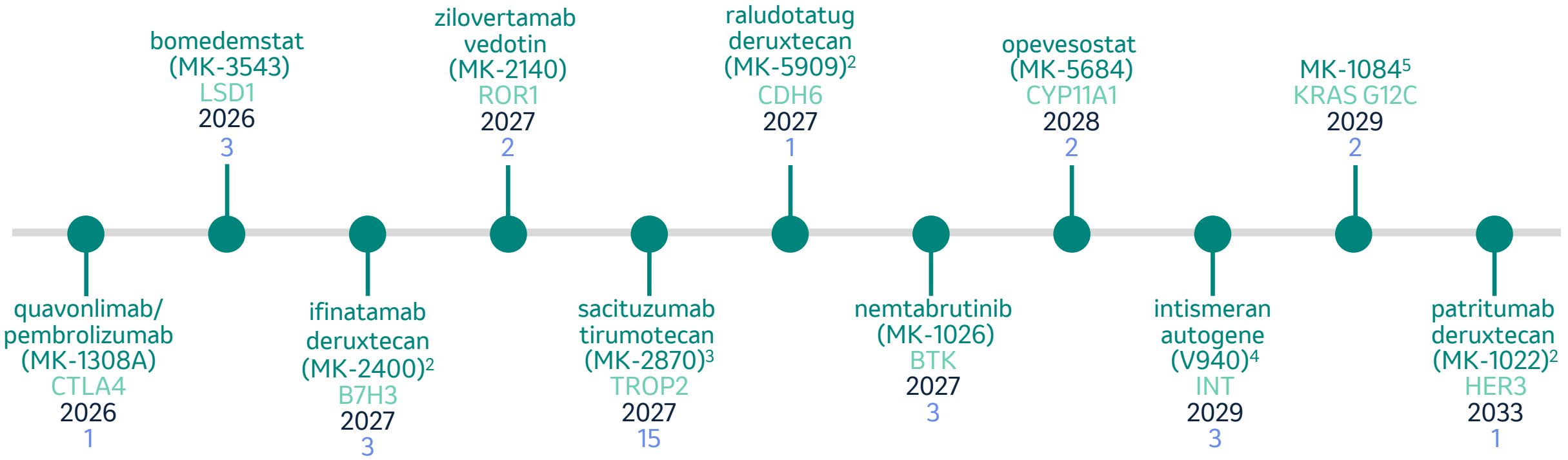
Key findings

In this 8- or 10-year exploratory follow-up analysis, pembrolizumab monotherapy continued to provide long-term survival benefits vs chemotherapy in certain patients with advanced or metastatic NSCLC, supporting its use as a standard of care in this setting

n/N, number of pts in KN-587/number of pts in parent study.
[a]1L therapy
[b]2L+ therapy
*KEYNOTE-042 not approved in the EU

Exploring the future of the oncology pipeline

>30 ongoing late-phase[1] oncology read-outs expected across pipeline candidates with additional studies being planned



[Asset]
[Target]
[Earliest estimated primary completion date on ClinicalTrials.gov]
[# of late-phase studies]

1. Candidates with ongoing Phase 3 or Phase 2/3 study. 2. Collaboration with Daiichi Sankyo. 3. Collaboration with Kelun-Biotech. 4. Collaboration with Moderna. 5. Collaboration with Taiho and Astex.

Advancing one of the industry's broadest ADC programs

	MK-2870	MK-2400	MK-5909	MK-1022	MK-2140	MK-3120	MK-2750	MK-6204	MK-6837
Generic Name	sacituzumab tirumotecan (sac-TMT)	ifinatamab deruxtecan (I-DXd)	raludotatug deruxtecan (R-DXd)	patritumab deruxtecan (HER3-DXd)	zilovertamab vedotin	Undisclosed	Undisclosed	Undisclosed	Undisclosed
Target	TROP2	B7H3	CDH6	HER3	ROR1	Nectin-4	Undisclosed	Undisclosed	Undisclosed
Partner	Kelun-Biotech	Daiichi Sankyo	Daiichi Sankyo	Daiichi Sankyo	N/A	Kelun-Biotech	Kelun-Biotech	Kelun-Biotech	N/A
Status	Phase 3	Phase 3	Phase 2/3	Phase 3	Phase 3	Phase 1	Phase 1	Phase 1	Phase 1
Current Tumor Types	Breast, Cervical, Endometrial, Gastric, NSCLC, Ovarian	ESCC, SCLC, Prostate	Ovarian	Breast	DLBCL	Advanced Solid Tumors	Advanced Solid Tumors	Advanced Solid Tumors	Advanced Solid Tumors

R-DXd monotherapy demonstrated promising antitumor activity in patients with platinum-resistant OC: Phase 2 (dose optimization) part of the Phase 2/3 REJOICE-Ovarian01 trial

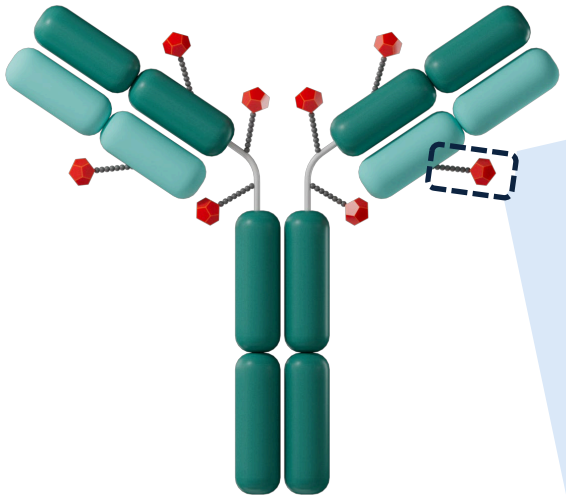
Confirmed response by BICR[a]	R-DXd 4.8 mg/kg n=36	R-DXd 5.6 mg/kg n=36	R-DXd 6.4 mg/kg n=35	R-DXd 4.8–6.4 mg/kg N=107
ORR, % (95% CI)	44.4 (27.9–61.9)	50.0 (32.9–67.1)	57.1 (39.4–73.7)	50.5 (40.6–60.3)
BOR,[b] n (%)				
CR	1 (2.8)	2 (5.6)	0	3 (2.8)
PR	15 (41.7)	16 (44.4)	20 (57.1)	51 (47.7)
SD	17 (47.2)	15 (41.7)	10 (28.6)	42 (39.3)
PD	2 (5.6)	2 (5.6)	4 (11.4)	8 (7.5)
Not evaluable	1 (2.8)[c]	1 (2.8)[d]	1 (2.9)[c]	3 (2.8)
DCR,[e] % (95% CI)	75.0 (57.8–87.9)	80.6 (64.0–91.8)	77.1 (59.9–89.6)	77.6 (68.5–85.1)
TTR, median (range), weeks	7.1 (5.4–18.7)	6.6 (5.1–18.3)	7.2 (5.3–19.1)	7.1 (5.1–19.1)

Key findings

- Confirmed ORR was 50.5%, including three CRs and 51 PRs for patients (n=107) treated across three R-DXd doses 4.8 mg/kg, 5.6 mg/kg and 6.4 mg/kg
- The Phase 3 part of the REJOICE-Ovarian01 study will evaluate R-DXd 5.6 mg/kg versus TPC (gemcitabine, PLD, topotecan, or paclitaxel) in patients with platinum-resistant OC

sac-TMT is a TROP2-directed ADC with a unique, bifunctional linker designed to reliably maximize payload delivery to the tumor cells

Antibody
anti-TROP2

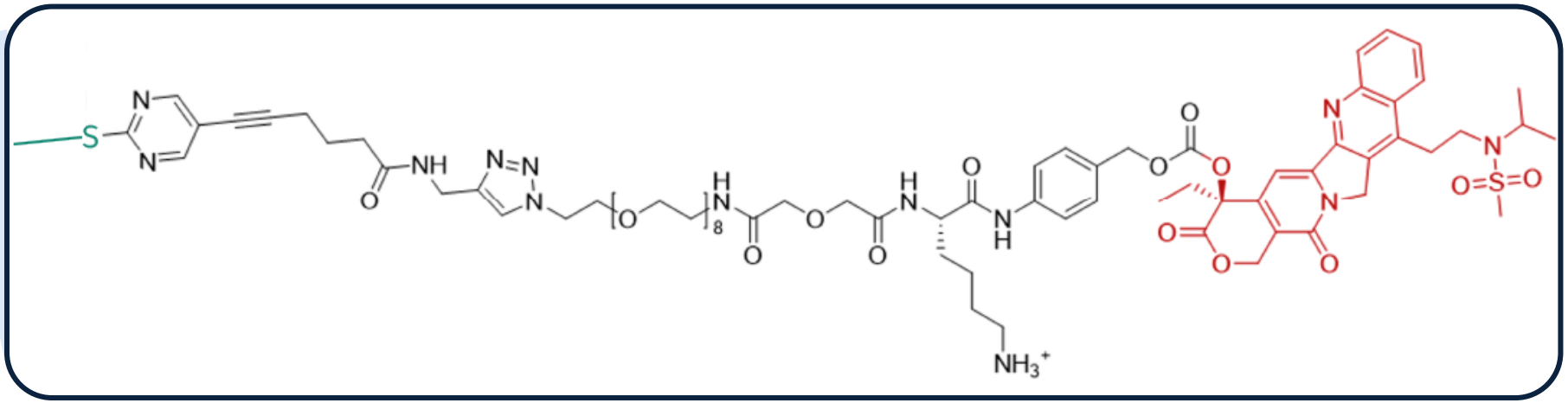


Unique, bifunctional linker

irreversible connection with the antibody

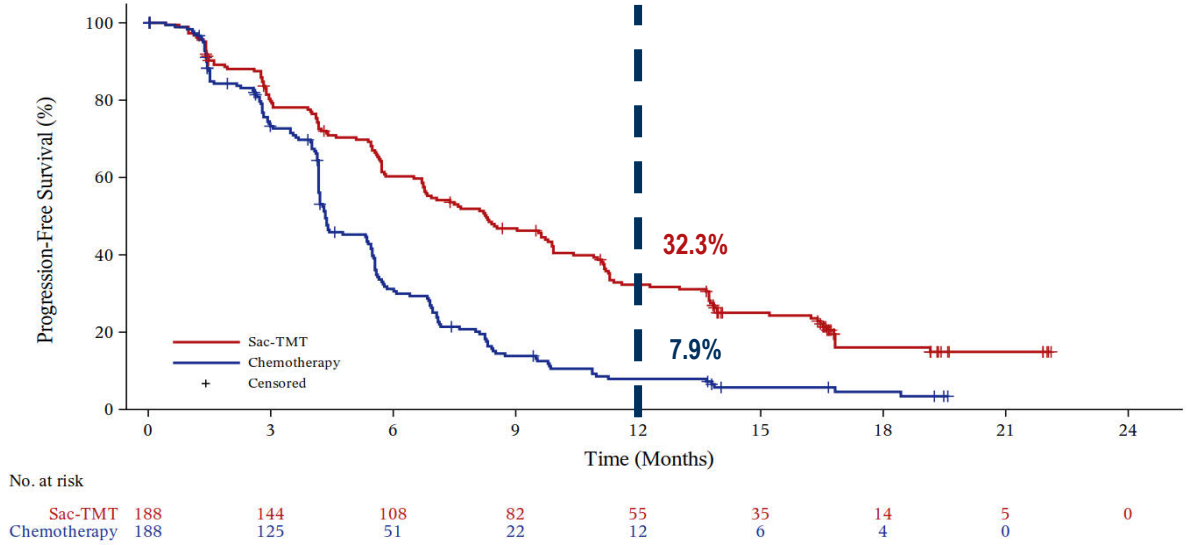
pH-sensitive cleavage to release the payload

Cytotoxic payload
membrane permeable



sac-TMT is part of collaboration with Kelun-Biotech; clinical trials ongoing to evaluate sac-TMT efficacy and safety

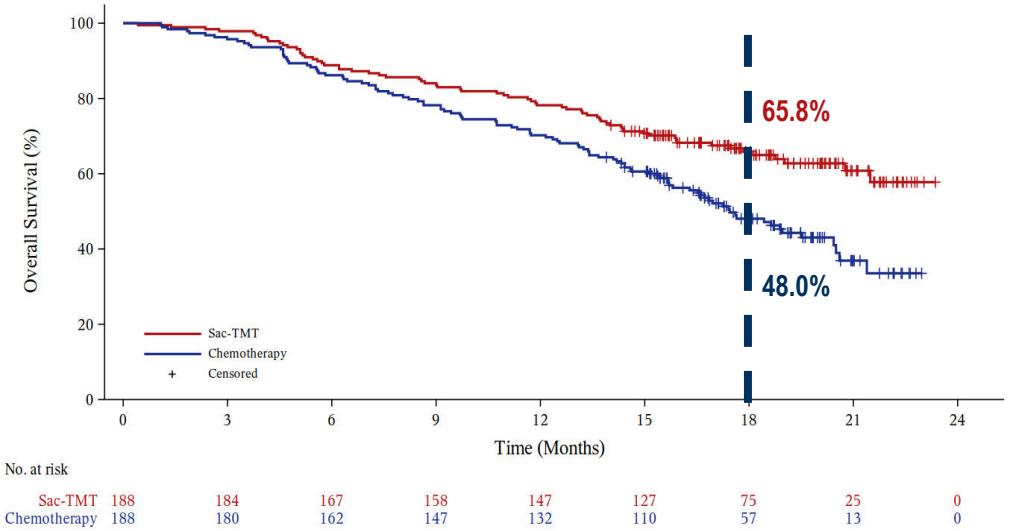
Sacituzumab tirumotecan (sac-TMT) vs platinum-based chemotherapy in EGFR-mutated (EGFRm) non-small cell lung cancer (NSCLC) following progression on EGFR-TKIs: Results from the randomized, multi-center Phase 3 OptiTROP-Lung04 study in China



HR 0.49 (95% CI: 0.39 - 0.62)

***P* < 0.0001**

	Sac-TMT 5 mg/kg (n = 188)	Chemotherapy (n = 188)
PFS events, n (%)	144 (76.6)	159 (84.6)
Median PFS, mo (95% CI)	**8.3** (6.7 - 9.9)	**4.3** (4.2 - 5.5)
12-mo PFS rate, % (95% CI)	32.3 (25.5 - 39.2)	7.9 (4.4 - 12.8)



HR 0.60 (95% CI: 0.44 - 0.82)

Two-sided *P* = 0.001 *

	Sac-TMT 5 mg/kg (n = 188)	Chemotherapy (n = 188)
OS events, n (%)	67 (35.6)	101 (53.7)
Median OS, mo (95% CI)	**NR**** (21.5 – NE***)	**17.4** (15.7 - 20.4)
18-mo OS rate, % (95% CI)	65.8 (58.3 – 72.3)	48.0 (40.2 - 55.4)

* Based on pre-specified OS IA, two-sided P value was less than the pre-specified efficacy boundary to achieve statistically significant improvement **Not Reached; ***Not Evaluable; Sponsored by Kelun-Biotech

Key findings

- Results from multiple studies being presented by Kelun-Biotech showed that sac-TMT continued to demonstrate promising antitumor efficacy with a manageable safety profile across patient populations and tumor types.
- sac-TMT 5 mg/kg demonstrated statistically significant and clinically meaningful improvements in PFS and OS compared to chemotherapy in patients with EGFR-mutated NSCLC following progression on EGFR-TKIs, as part of Opti-TROPLung04 study

Comprehensive development strategy for sac-TMT

TroFuse ONCOLOGY CLINICAL TRIALS

Registrational Study	Tumor Type	Patient Population	Combo/ Novel Approach	Biomarker Approach
TroFuse-004	NSCLC	3L EGFRm NSCLC		
TroFuse-005	Endometrial	Post platinum & post I/O endometrial cancer		
TroFuse-007	NSCLC	PD-L1 TPS ≥ 50%		
TroFuse-009	NSCLC	2L non-squamous EGFRm NSCLC		
TroFuse-010	Breast	HR+/HER2- unresectable LA or mBC	✓	
TroFuse-011	Breast	LA or mTNBC PD-L1 at CPS <10	✓	
TroFuse-012	Breast	TNBC did not achieve pCR at surgery		
TroFuse-015	Gastric	3L+ advanced/metastatic gastroesophageal adenocarcinoma		
TroFuse-019	NSCLC	Adjuvant NSCLC (no pCR post surgery)	✓	
TroFuse-020	Cervical	2L metastatic cervical cancer		✓
TroFuse-022	Ovarian	Platinum sensitive recurrent OC		✓
TroFuse-023	NSCLC	mNSCLC maintenance treatment (post KEYTRUDA + chemo)	✓	
TroFuse-032	Breast	Neoadjuvant TNBC or HR-low/HER2- breast cancer	✓	
TroFuse-033	Endometrial	pMMR endometrial cancer	✓	✓
TroFuse-036	Cervical	P/R/1L maintenance cervical cancer	✓	

sac-TMT is part of collaboration with Kelun Biotech

Comprehensive companion diagnostic work ongoing, including digital pathology

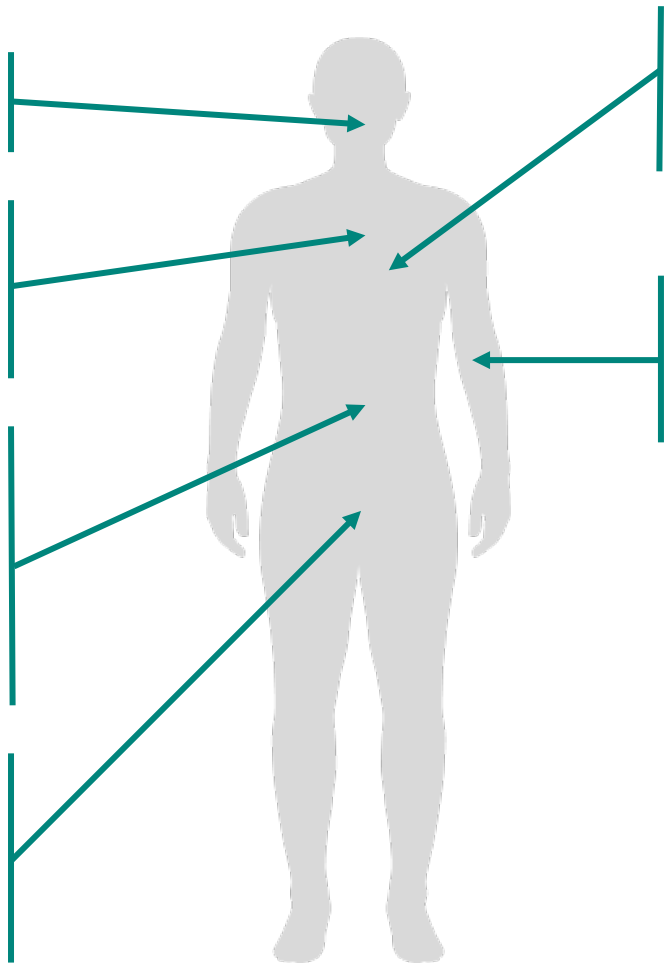
MSD

Patient centricity in cancer care

Pembrolizumab has changed the treatment paradigm of numerous malignancies, with 42 U.S. FDA-approved indications in 18+ tumor types[1]

KEYTRUDA®: Foundational Therapy

- First PD-1 therapy approved for melanoma in U.S. and China
- 1st broad Global approval of a PD-1 inhibitor
- 2 tumor-agnostic approvals
- Q6W dosing schedule approved globally



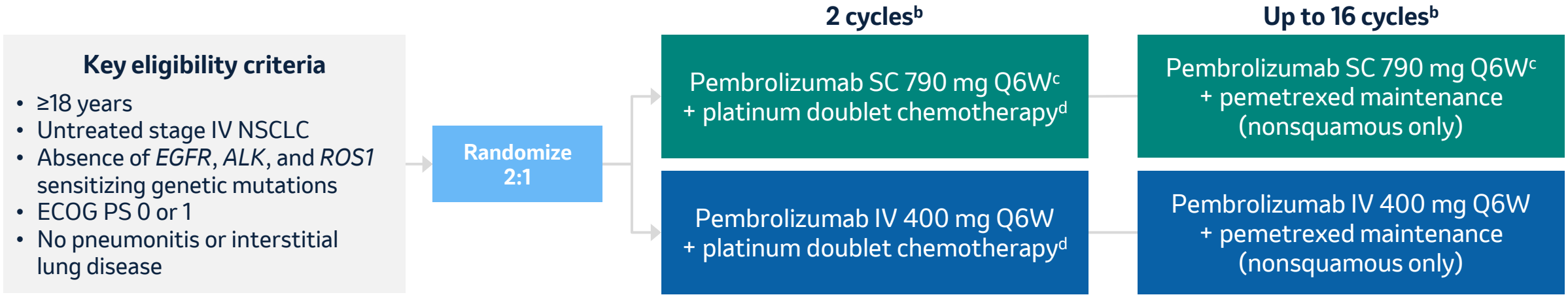
- Head and Neck Squamous Cell Cancer
- Non-Small Cell Lung Cancer
- Malignant Pleural Mesothelioma
- Gastric Cancer
- Hepatocellular Carcinoma
- MSI-H* Colorectal Cancer
- Esophageal Cancer
- Biliary Tract Cancer
- Urothelial Cancer
- Cervical Cancer
- Endometrial Carcinoma
- Renal Cell Carcinoma
- Triple-Negative Breast Cancer
- Melanoma
- Merkel Cell Carcinoma
- Cutaneous Squamous Cell Carcinoma

Other

- TMB-High** Cancer
- MSI-High* Cancer
- Classical Hodgkin Lymphoma
- Primary Mediastinal Large B-Cell Lymphoma

Current FDA Approved Indications (10/2025)
1. In the EU, pembrolizumab is approved for 31 indications in 14+ tumor types*
*MSI-H: Microsatellite instability-high cancer **TMB-H: Tumor mutational burden-high cancer (accelerated approval)

A Phase 3, randomized, open-label study of pembrolizumab SC* (pembrolizumab with berahyaluronidase alfa) vs pembrolizumab IV, in combination with platinum-doublet chemotherapy[a] (MK-3475A-D77)



Stratification factors

- ECOG performance status (0 *vs* 1)
- Histology (squamous *vs* nonsquamous)
- PD-L1 TPS (<50% *vs* ≥50%)
- Geographic region (East Asia *vs* N America / W Europe / Australia / New Zealand *vs* rest of the world)

Dual primary endpoints: Cycle 1 $AUC_{0\text{-}6\ wks}$ and steady-state (Cycle 3) C_{trough}

Secondary endpoints: Immunogenicity, ORR, PFS, and DOR by BICR; OS; safety and tolerability; and QOL measures

[a] Clinical trial ID: NCT05722015. [b]Each cycle = 6 weeks. [c]Pembrolizumab SC 790 mg at 165 mg/mL (injection volume 4.8 mL). [d]Pemetrexed with investigator's choice of cisplatin or carboplatin followed by pemetrexed maintenance (nonsquamous) or carboplatin with investigator's choice of paclitaxel or nab-paclitaxel (squamous).

$AUC_{0\text{-}6\ wks}$, area under the curve from week 0 to week 6; BICR, blinded independent central review; C_{trough}, trough concentration.

*Not approved for use in the EU; pending European Commission decision, to be marketed as KEYTRUDA SC™

Pembrolizumab SC* was shown to be noninferior to pembrolizumab IV with respect to cycle 1 overall exposure and steady state trough concentration

Prespecified noninferiority margin for $AUC_{0\text{-}6\ wks}$ (overall exposure) and C_{trough} (steady state) geometric mean ratios: 0.8

	Pembrolizumab SC + chemotherapy	Pembrolizumab IV + chemotherapy
Cycle 1 $AUC_{0\text{-}6wks}$ (µg·day/mL)	N=245	N=126
Geometric mean (95% CI)	1633.24 (1555.23-1715.15)	1437.58 (1373.68-1504.46)
Geometric %CV	40.4	26.2
Geometric mean ratio (96% CI)	1.14 (1.06-1.22); p<0.0001	
Steady state (Cycle 3) C_{trough} (µg/mL)	N=202	N=101
Geometric mean (95% CI)	39.23 (37.04-41.55)	23.49 (21.61-25.54)
Geometric %CV	43.3	44.2
Geometric mean ratio (94% CI)	1.67 (1.52-1.84); p<0.0001	

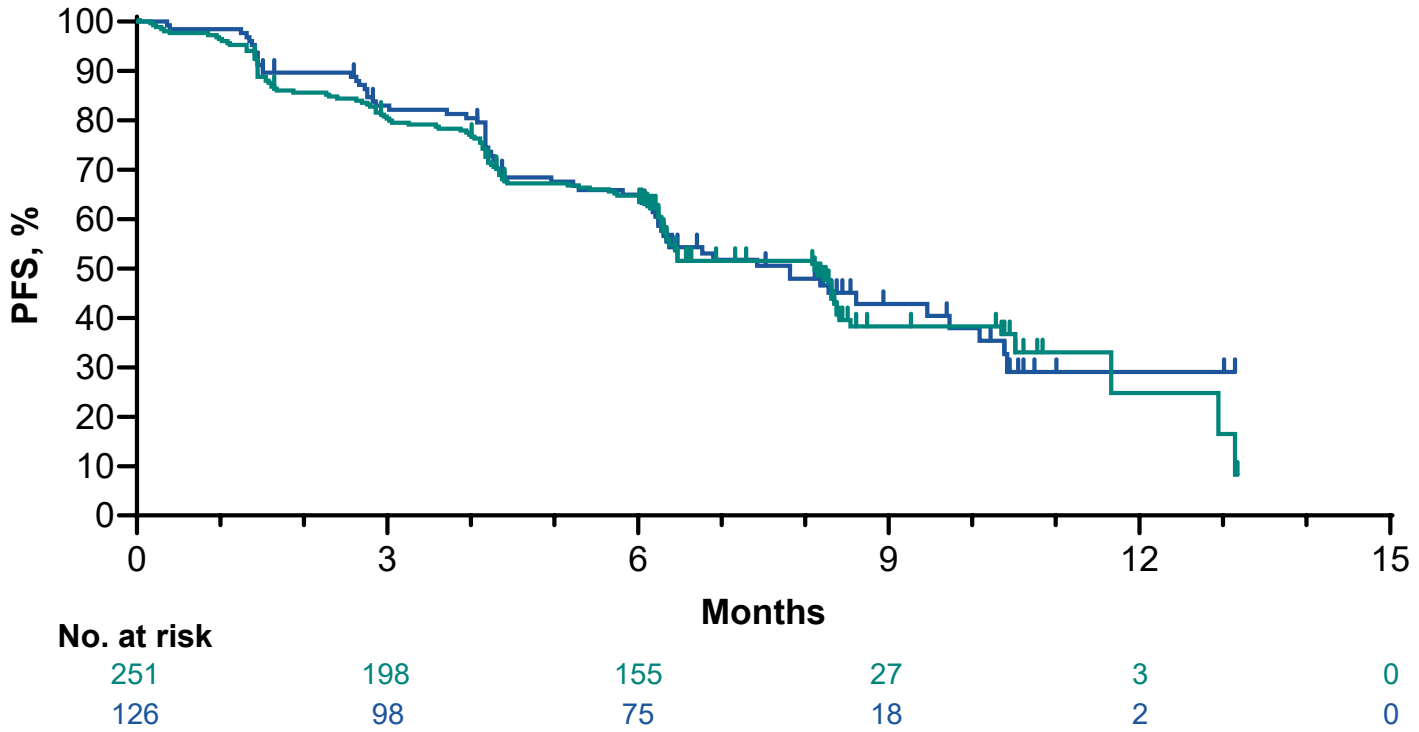
The observed incidence of treatment-emergent anti-pembrolizumab antibodies was comparable between the pembrolizumab SC and pembrolizumab IV arms (1.4% and 0.9%, respectively).
Date of data cutoff 12 JUL 2024; median study follow-up: 9.6 months (range 6.2-16.4).

*Not approved for use in the EU; pending European Commission decision, to be marketed as KEYTRUDA SC™

Descriptive efficacy endpoints, such as ORR, PFS and OS were consistent between pembrolizumab SC* and pembrolizumab IV[1]

Pembrolizumab SC + chemotherapy *vs* Pembrolizumab IV + chemotherapy:

- ORR (95% CI): 45.4% (39.1-51.8) *vs* 42.1% (33.3-51.2); ORR ratio 1.08 (95% CI 0.85-1.37)
- Median DOR (95% CI): 9.1 months (6.9-NR) *vs* 8.0 months (7.4-NR)
- PFS 8.1 months (95% CI, 6.3-8.3) *vs* 7.8months (95% CI, 6.2-9.7) (HR=1.05 [95% CI,0.78-1.43])
- OS: median NR in both arm; HR 0.81 (95% CI 0.53-1.22)



[1]MK-3475A-D77 was not designed as a noninferiority study with respect to the secondary efficacy endpoints.

Date of data cutoff 12 JUL 2024; median study follow-up: 9.6 months (range 6.2-16.4).

*Not approved for use in the EU; pending European Commission decision, to be marketed as KEYTRUDA SC™

A Phase 2 study of participant-reported preference for pembrolizumab SC* versus pembrolizumab IV

Primary Endpoint: Participant preference for route of administration, pembrolizumab SC or pembrolizumab IV, as assessed by the Patient Preference Questionnaire® (PPQ) question 1

Crossover Period:

Arm A: 3 cycles of pembrolizumab SC 395 mg Q3W followed by 3 cycles of pembrolizumab IV 200 mg Q3W
Arm B: 3 cycles of pembrolizumab IV 200 mg Q3W followed by 3 cycles of pembrolizumab SC 395 mg Q3W

Continuation Period:

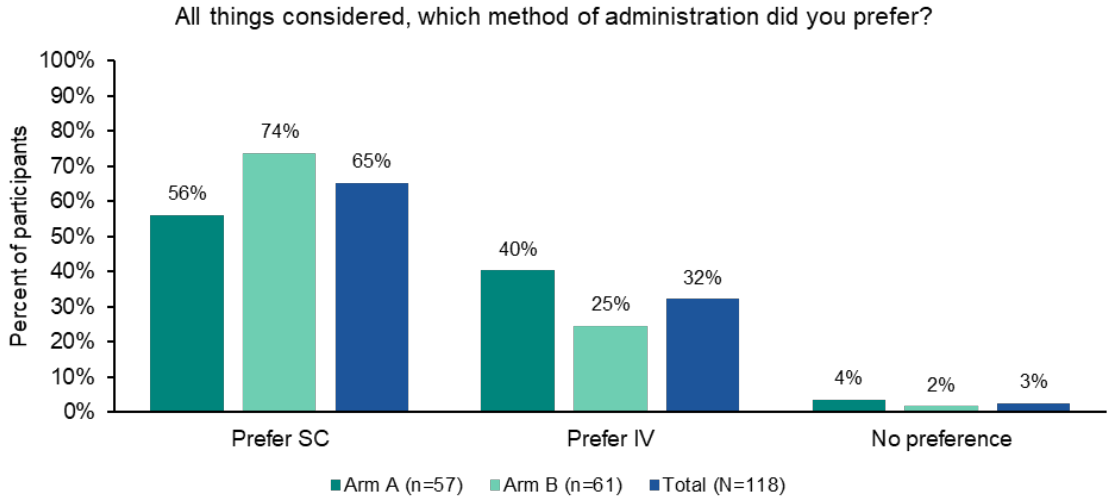
Participant's Choice: pembrolizumab IV 200mg Q3W OR pembrolizumab SC 395 mg Q3W

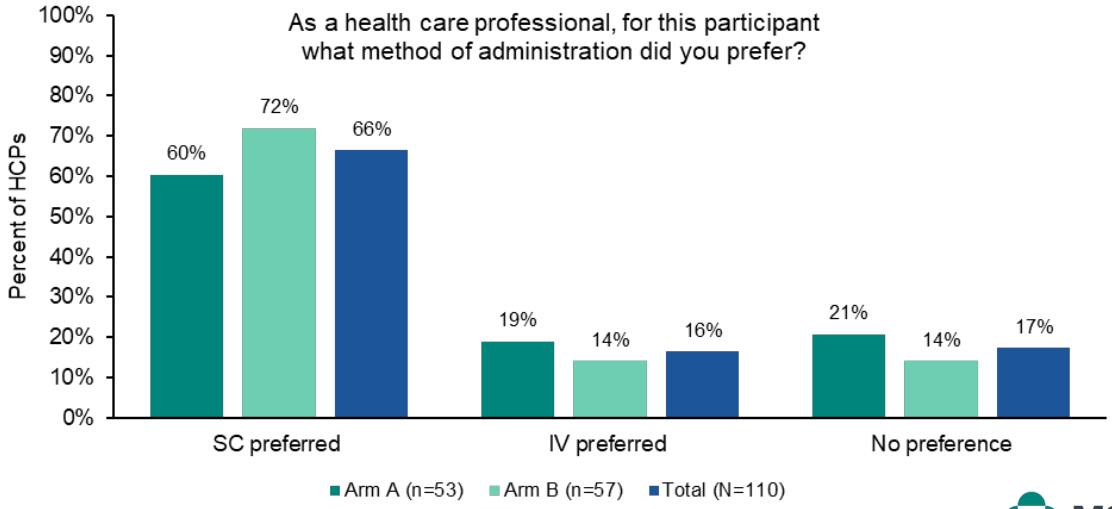
Key findings

Results showed that both participants and HCPs prefer pembrolizumab SC injections over pembrolizumab IV infusions

The participant preference rate for pembrolizumab SC was 65% (95% CI 56%-74%) and for HCPs, was 66% (95% CI 60%-72%)

Participant Preference





*Not approved for use in the EU; pending European Commission decision, to be marketed as KEYTRUDA SC™

MSD

Q&A

Marjorie Green, M.D.

Senior Vice President
Head of Oncology Clinical Development

Dr. Marjorie Green is senior vice president and head of late-stage oncology at MSD Research Laboratories. She leads all late-stage clinical development programs for oncology.

Marjorie joined MSD from Seagen, where she was senior vice president and head of late-stage oncology, leading clinical development of a diverse portfolio of oncology candidates including multiple antibody drug conjugates. She previously held positions of increasing responsibility at Genentech culminating in her tenure as vice president, Global Product Development, head of breast and gynecologic tumor franchise. Previously, she was assistant professor and medical director of the Nellie B. Connally Breast Center and vice-chair of the Institutional Review Board at the MD Anderson Cancer Center, Houston, Texas. During her tenure a MD Anderson, Marjorie established herself as a nationally recognized clinical expert in the management of breast cancer and the treatment and prevention of associated bone metastases and has authored multiple manuscripts and book chapters on preoperative chemotherapy.

Marjorie received her Bachelor of Arts from the University of Notre Dame and her medical degree from the University of Texas Medical Branch. She conducted an internal medicine residency at University of Virginia School of Medicine and completed fellowships in medical oncology and hematology at the MD Anderson Cancer Center.

Jane Healy, M.D.

Vice President,
Head of Early Oncology Development

Dr. Jane Healy is vice president and head of early oncology development at MSD Research Laboratories. In this role, Dr. Healy is responsible for overseeing the early clinical development of numerous candidates in early-phase clinical trials, or those expected to soon enter the clinic. She also oversees clinical pharmacology and translational studies for oncology.

Dr. Healy joined MSD Research Labs in 2016 and rapidly assumed leadership roles of increasing responsibility. She led early clinical development of key pipeline candidates, as well as led the integration team for intismeran autogene – the individualized neoantigen therapy (INT) being developed in collaboration with Moderna. Here, she played a crucial role in asset strategy and transition of intismeran autogene to Phase 3 trials. Prior to MSD, Dr. Healy specialized in the treatment of hematologic malignancies.

Dr. Healy is a medical oncologist by training and a physician scientist with a passion for innovative drug development aimed at improving outcomes for patients. Dr. Healy completed her residency in Internal Medicine at the Brigham and Women's Hospital and subsequently conducted a fellowship in hematology/oncology at Duke University.

M. Catherine Pietanza, M.D.

Vice President,
Head of Early Oncology Development

Dr. M. Catherine (Cathy) Pietanza is vice president and therapeutic area head for gastrointestinal and genitourinary cancers, global clinical development at MSD Research Laboratories. In this role, Dr. Pietanza is responsible for overseeing the development of assets in the GI and GU tumor space and also leads the subcutaneous pembrolizumab development program.

Dr. Pietanza joined MSD Research Labs in 2016 and rapidly assumed leadership roles of increasing responsibility. Prior to her current role, Dr. Pietanza led MSD's thoracic malignancies development team where she was responsible for overseeing the strategic design and execution of studies for MSD assets in the thoracic disease area. Dr. Pietanza has extensive development experience, having led multiple phase 3 studies as well as US and global marketing authorizations.

Dr. Pietanza received her medical degree from The State University of New York Health Science Center at Brooklyn/Downstate in Brooklyn, New York and completed her residency in Internal Medicine at New York Presbyterian Hospital/Weill Cornell Medical Center. She then went on to complete her fellowship in Medical Oncology and Hematology at Mount Sinai School of Medicine, where she was also a chief fellow.