Applications for Community Oncology

ASCO Data Review

July 16, 2026

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RECENT FDA APPROVALS

METASTATIC TRIPLE NEGATIVE BREAST CANCER

On **June 24, 2026**

- **ASCENT-04/KEYNOTE D-19** – sacituzumab govitecan in combination with pembrolizumab for 1L unresectable metastatic TNBC whose tumors express PD-L1 (CPS ≥ 10)
- **ASCENT-03** – sacituzumab govitecan as a single agent for 1L unresectable metastatic TNBC who are not candidates for PD-1 or PD-L1 inhibitor-based therapy

On **May 22, 2026**

- **TROPION-Breast02** – datopotamab deruxtecan (DATO-DXd) for 1L unresectable or metastatic TNBC who are not candidates for PD-1 or PD-L1 inhibitor-based therapy

METASTATIC HR+ BREAST CANCER

On **July 14, 2026**

- **VIKTORIA-1** – gedatolisib in combination with fulvestrant, with or without palbociclib, for 2L HR+, HER2- locally advanced or metastatic breast cancer after at least one line of endocrine therapy

On **June 24, 2026**

- **PATINA** – palbociclib in combination with trastuzumab, with or without pertuzumab, and endocrine therapy for the maintenance treatmentof HR+, HER2+ locally advanced or metastatic breast cancer following induction treatment

EARLY-STAGE HER2+ BREAST CANCER

On **May 15, 2026**

- **DESTINY-Breast11** – fam-trastuzumab deruxtecan (T-DXd) followed by a taxane, trastuzumab, and pertuzumab (THP) for neoadjuvant HER2+ (IHC 3+ or ISH+) Stage II or III breast cancer
- **DESTINY-Breast05** – fam-trastuzumab deruxtecan (T-DXd) for adjuvant HER2+ (IHC 3+ or ISH+) breast cancer with residual invasive disease following neoadjuvant trastuzumab (with or without pertuzumab) and taxane-based treatment

Key Studies

Breast

- ASCENT-04
- ASCENT-03
- TROPION-Breast02
- DESTINY-Breast05

Rapid Reviews

- SERENA-6
- persevERA
- KEYNOTE-522

GU/GI

- RASolute 302*
- EMERALD-3
- PROTEUS*
- TALAPRO-3

Other Notable Studies

- frontMIND
- MajesTEC-9
- HARMONi-6*
- LIBERTTO-432*

Rapid Reviews

- SARC041*

*Plenary Session

CLINICAL QUESTION

ASCENT-04

Does sacituzumab govitecan plus pembrolizumab improve progression-free survival after next line of treatment (PFS2) and deliver consistent efficacy across biomarker-defined subgroups compared with chemotherapy plus pembrolizumab in previously untreated PD-L1+ mTNBC?

Exploratory analysis

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KEY DATA

ASCENT-04: 1L SG or chemo + pembro in PD-L1+ mTNBC

Study Design: Randomized phase III study

Previously untreated, locally advanced unresectable or metastatic TNBC
- PD-L1+ (CPS ≥ 10)
- ≥ 6 months since treatment in curative setting (prior anti-PD-L1 use allowed)

(N = 443)

R 1:1

Treatment was continued until BICR-verified progression or unacceptable toxicity

Sacituzumab govitecan + pembro
(SG 10 mg/kg IV, days 1 and 8 q21 days; pembro 200 mg, day 1 q21 days)
n = 221

Chemo + pembro
(paclitaxel OR nab-paclitaxel OR gemcitabine + carboplatin)
n = 222

Local standard of care

Participants offered (and provided) 2L SG monotherapy following BICR-verified disease progression

Primary endpoint: Progression-free survival by blinded independent central review (BICR)
Secondary endpoints: Overall survival (OS), overall response rate (ORR), and duration of response (DOR) by BICR, safety, and quality of life (QOL)
Exploratory endpoints: Progression-free survival after next line of treatment (PFS2), time to first subsequent therapy (TFST), and time to second subsequent therapy (TSST)

N Engl J Med 2026;394:354-366
ASCO 2026. LBA1000.

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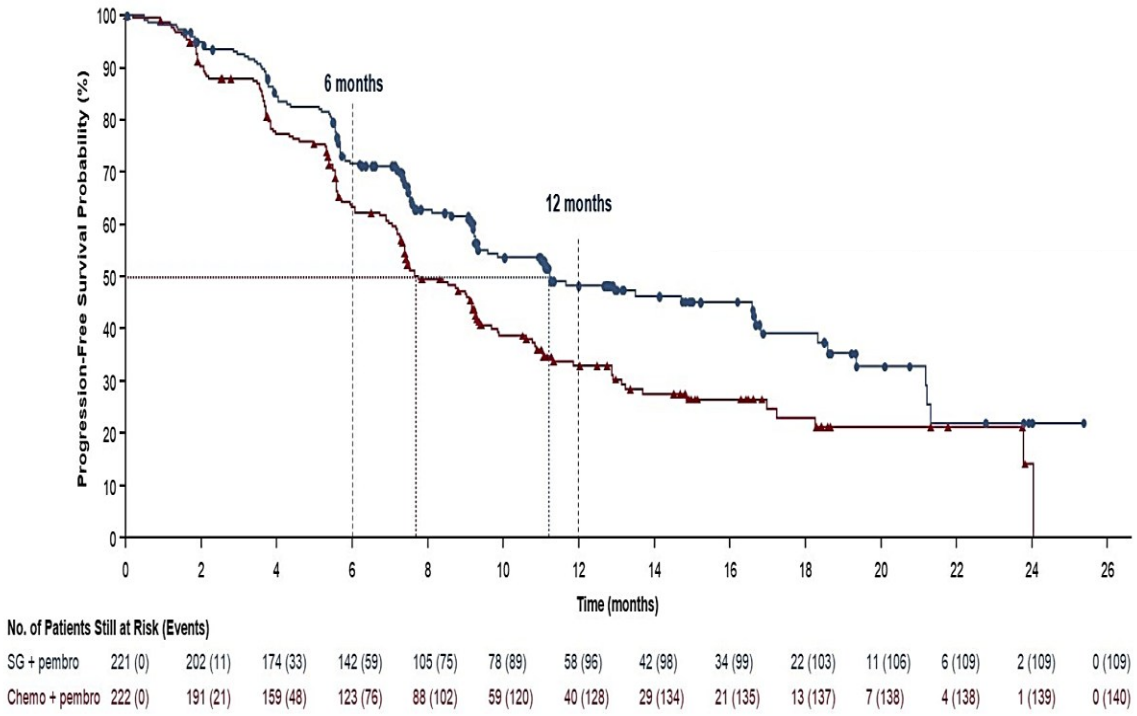
KEY DATA

ASCENT-04: 1L SG or chemo + pembro in PD-L1+ mTNBC

Primary Endpoint: Progression-Free Survival (PFS) by BICR - *first presented at ASCO 2025*

Data led to the FDA approved on June 24, 2026



	SG + Pembro (n = 221)	CT + Pembro (n = 222)
Median PFS, months (95% CI) • Stratified HR (95% CI) • P value	**11.2** (9.3-16.7) **0.65** (0.51-0.84) < 0.001	7.8 (7.3-9.3)
6-month PFS rate, % (95% CI)	**71.6** (64.9-77.3)	63.2 (56.2-69.4)
12-month PFS rate, % (95% CI)	**48.3** (40.6-55.6)	32.9 (26.0-40.0)

- **3.6-month** absolute improvement in mPFS
- **16%** improvement in pts without tumor progression at 12 months

Data cut off: 3 March 2025
Median follow-up: 14.0 months

N Engl J Med 2026;394:354-366
ASCO 2026. LBA1000.

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KEY DATA

ASCENT-04: 1L SG or chemo + pembro in PD-L1+ mTNBC

Exploratory Endpoint: Improved PFS shown in various biomarker subgroups evaluated

Subgroup	SG + Pembro		CT + Pembro		HR (95% CI)
	n	mPFS, mo	n	mPFS, mo	
ITT population	221	**11.2 (9.3-16.7)**	222	**7.8 (7.3-9.3)**	0.65 (0.51-0.84)
Trop-2 results (Trop-2 expression quartile)	204	**11.7 (9.3-16.8)**	196	**7.8 (7.3-9.3)**	**0.63 (0.48-0.82)**
• Q1	48	9.3 (7.4-19.4)	47	9.0 (6.0-10.9)	0.81 (0.48-1.36)
• Q2	50	9.6 (7.3-16.7)	50	7.4 (6.9-9.7)	0.73 (0.44-1.22)
• Q3	55	13.5 (9.3-NE)	50	8.4 (5.6-10.8)	0.46 (0.27-0.80)
• Q4	51	16.6 (8.1-NE)	49	9.2 (5.5-11.3)	0.57 (0.33-0.99)
tBRCA results	169	**11.1 (9.2-16.7)**	163	**7.8 (7.2-9.3)**	**0.69 (0.52-0.91)**
• WT	130	9.6 (7.6-16.7)	131	7.4 (6.9-9.2)	0.67 (0.49-0.91)
• Mut (BRCA 1, 2, or both genes)	39	16.6 (7.5-NE)	32	12.9 (7.1-NE)	0.88 (0.45-1.74)
HER2 results	217	**11.3 (9.3-16.7)**	218	**7.8 (7.3-9.3)**	**0.66 (0.51-0.85)**
• HER2 IHC 0	84	16.6 (9.1-21.2)	82	9.0 (7.2-10.8)	0.69 (0.46-1.04)
• HER2 low (IHC1+ or 2+/ISH-)	133	11.2 (9.1-16.6)	136	7.7 (7.0-9.4)	0.67 (0.48-0.92)

ASCO 2026. Abstract 1013.

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KEY DATA

ASCENT-04: 1L SG or chemo + pembro in PD-L1+ mTNBC

- Almost twice as many participants in the **SG + pembro group (43%)** remained on study treatment compared with the **chemo + pembro group (23%)** at the time of data cutoff

Rates of ADC Use as Second-line Treatment

Participants who discontinued first-line treatment, n (%)	**SG + Pembro (n = 125)**	**Chemo + Pembro (n = 170)**
Received second-line or later therapy	69 (55)	119 (70)
• Received any subsequent ADC	13 (19)	97 (82)
• Received any subsequent SG	3 (4)	96 (81)
Received third-line therapy	18 (14)	29 (17)

Data cut off: 3 March 2025
Median follow-up: 14.0 months

N Engl J Med 2026;394:354-366
ASCO 2026. LBA1000.

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KEY DATA

ASCENT-04: 1L SG or chemo + pembro in PD-L1+ mTNBC

Exploratory Endpoint: Subsequent Therapy

Subsequent Therapies in the Second Line

n (%)	SG + Pembro (n = 221)	CT + Pembro (n = 222)
Any subsequent therapy, n	69	119
Any subsequent 2L therapy	**68 (99)**	**119 (100)**
• Taxanes	23 (33)	8 (7)
• Platinum agents	18 (26)	3 (3)
• Antibody Drug Conjugates	7 (10)	94 (79)
• Trastuzumab deruxtecan	5 (7)	2 (2)
• Sacituzumab govitecan	2 (3)	**92 (77)**
• PD-(L)1 inhibitors	6 (9)	7 (6)
• Anthracyclines	4 (6)	5 (4)
• PARPi	3 (1)	1 (1)
• Other	40 (58)	14 (12)
Median TFST, months (95% CI)	**17.3** (12.7-NR)	9.8 (8.7-10.9)
• Stratified HR (95% CI)	0.59 (0.49-0.76)	

TFST: time to first subsequent therapy

Subsequent Therapies in the Third Line

n (%)	SG + Pembro (n = 221)	CT + Pembro (n = 222)
Any subsequent therapy, n	69	119
Any subsequent 3L therapy	**18 (26)**	**29 (24)**
• Taxanes	5 (7)	3 (3)
• Anthracyclines	4 (6)	2 (2)
• Platinum agents	3 (4)	5 (4)
• Antibody Drug Conjugates	2 (3)	6 (5)
• Trastuzumab deruxtecan	2 (3)	3 (3)
• Sacituzumab govitecan	0 (0)	3 (3)
• PD-(L)1 inhibitors	1 (1)	2 (2)
• PARPi	0 (0)	1 (1)
• Other	11 (16)	18 (15)
Median TSST, months (95% CI)	**NR** (22.9-NR)	21.0 (16.6-NR)
• Stratified HR (95% CI)	0.82 (0.59-1.14)	

TSST: time to second subsequent therapy

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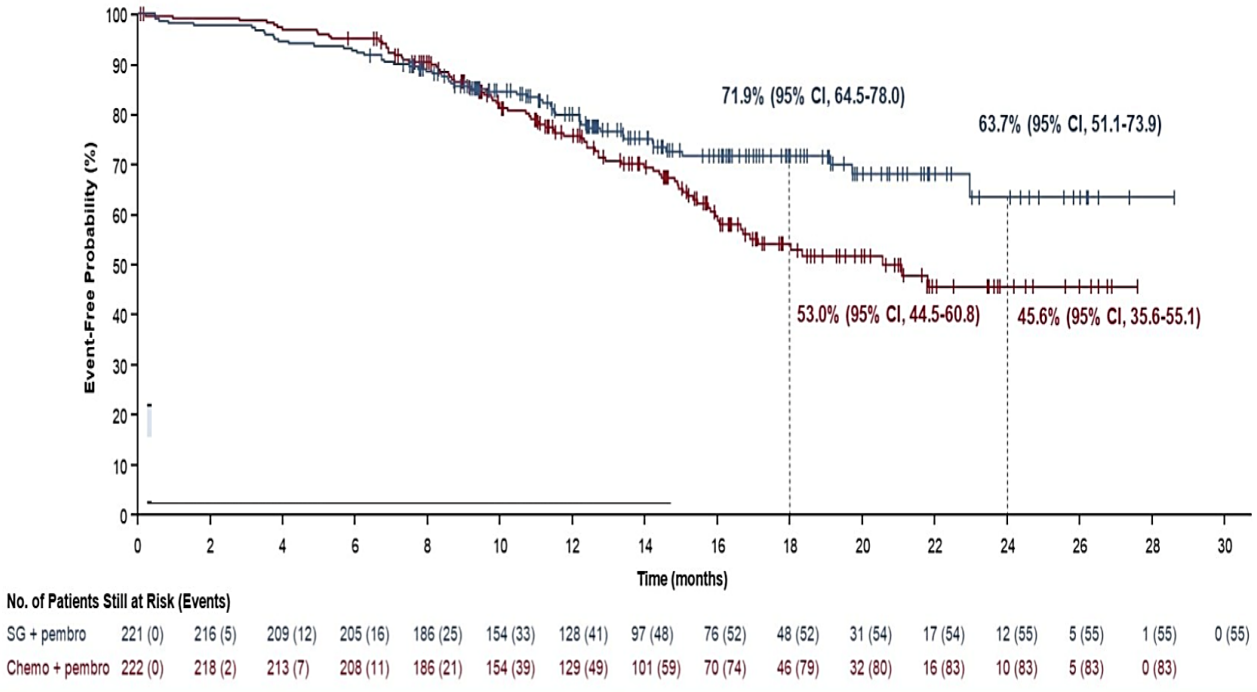
KEY DATA

ASCENT-04: 1L SG or chemo + pembro in PD-L1+ mTNBC

Exploratory Endpoint: PFS After Next Line of Treatment (PFS2)



	SG + Pembro (n = 221)	Chemo + Pembro (n = 222)
Median PFS2, months (95% CI)	**NR** (NR-NR)	21.0 (16.0-NR)
• Stratified HR (95% CI)	**0.67** (0.48-0.95)	

- **19% improvement at 1.5 years** in tumor progression to 2nd-line therapy for pts originally assigned to SG + pembro compared to those assigned to chemo + pembro

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SUMMARY

ASCENT-04

- PFS benefit for SG + pembro maintained across HER2 IHC 0 or HER2-low and BRCA wild-type or mutant
- Median time to first subsequent treatment after 1st line therapy:
  - 17.3 mo for SG/pembro vs 9.8 mo for chemo/pembro
  - Most frequent 2L+ subsequent therapy: chemotherapy in the SG + pembro group (88%) and SG in the chemo + pembro group (81%)

- Sacituzumab govitecan + pembrolizumab demonstrated a sustained benefit beyond first progression (PFS2) - despite high crossover to SG in the control arm
  - Median PFS2: NR vs 21.0 months
    - HR: **0.67** (95% CI, 0.48-0.95)

IMPACT

Sacituzumab govitecan + pembro is an effective 1L treatment option for patients with previously untreated PD-L1 positive metastatic TNBC, with benefits extending beyond first disease progression

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Will the presented data of PFS2 increase your conviction of the benefit for starting SG + pembro in the 1L setting versus chemo + pembro?

1. Yes
2. No

Key Studies

Breast

- ASCENT-04
- ASCENT-03
- TROPION-Breast02
- DESTINY-Breast05

Rapid Reviews

- SERENA-6
- persevERA
- KEYNOTE-522

GU/GI

- RASolute 302*
- EMERALD-3
- PROTEUS*
- TALAPRO-3

Other Notable Studies

- frontMIND
- MajesTEC-9
- HARMONi-6*
- LIBERTTO-432*

Rapid Reviews

- SARC041*

*Plenary Session

CLINICAL QUESTION

ASCENT-03

Does treatment with sacituzumab govitecan continue to improve progression-free survival after the next (PFS2) and deliver consistent efficacy across biomarker-defined subgroups compared with chemotherapy in previously untreated PD-L1 negative metastatic TNBC?

Exploratory analysis

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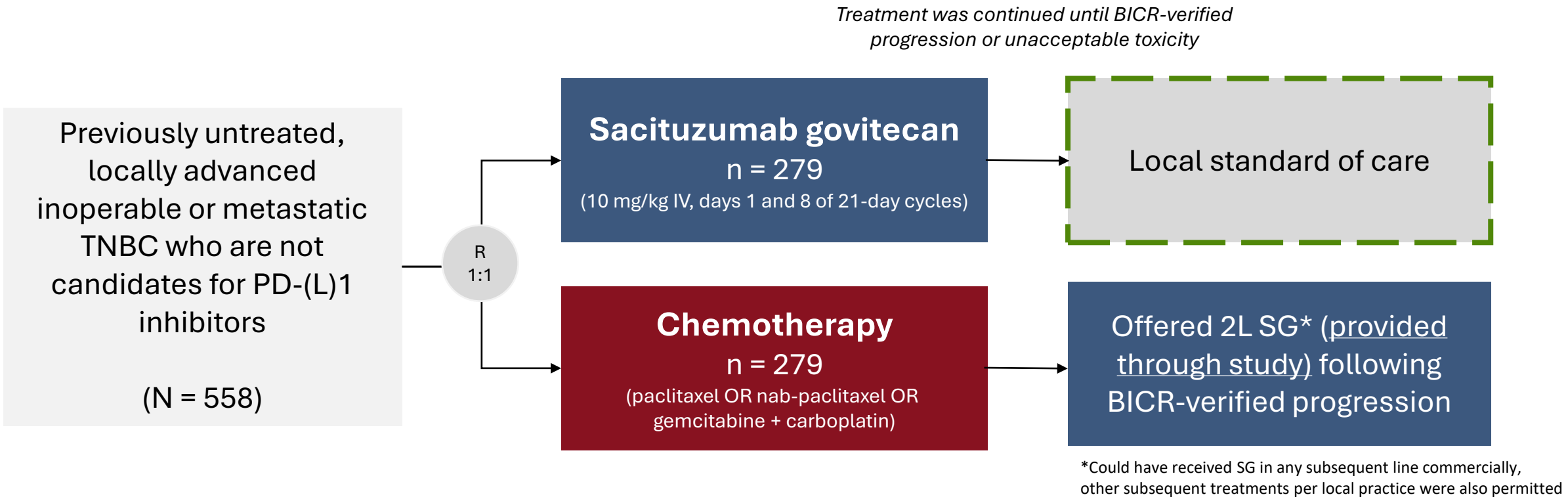
KEY DATA

ASCENT-03: 1L SG vs chemo in 1L mTNBC with PD-L1 negative or previously treated with anti-PD-L1

Study Design: Randomized phase III study



Primary endpoint: Progression-free survival by blinded independent clinical review (BICR)
Secondary endpoints: Overall survival (OS), overall response rate (ORR), and duration of response (DOR) by BICR, safety, and quality of life (QOL)
Exploratory endpoints: Progression-free survival after next line of treatment (PFS2), time to first subsequent therapy (TFST), and time to second subsequent therapy (TSST)

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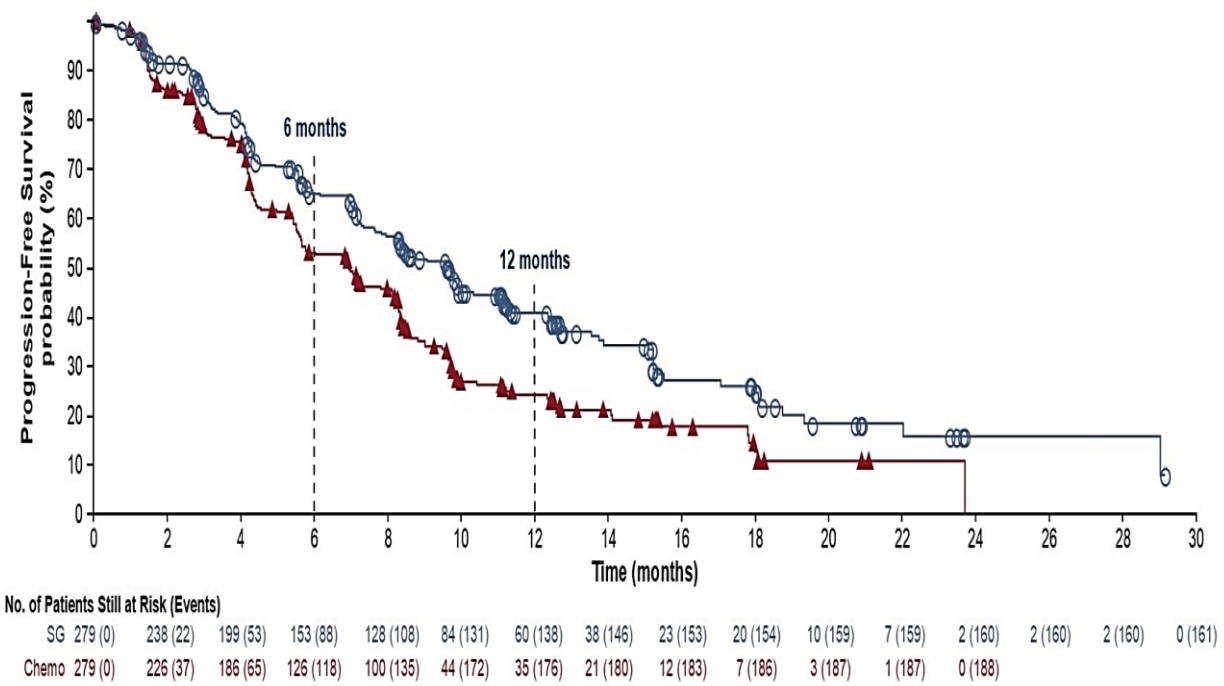
KEY DATA

ASCENT-03: 1L SG vs chemo in 1L mTNBC with PD-L1 negative or previously treated with anti-PD-L1

Primary Endpoint: Progression-free survival (PFS) by BICR - *first presented at ESMO 2025*

Data led to FDA approval on June 24, 2026



	SG (n = 279)	Chemo (n = 279)
Median PFS, months (95% CI)	**9.7** (8.1-11.1)	**6.9** (5.6-8.2)
• Stratified HR (95% CI)	**0.62** (0.50-0.77)	
• P value	< 0.0001	
6-month PFS rate, % (95% CI)	**65** (59-71)	53 (47-59)
12-month PFS rate, % (95% CI)	**41** (34-47)	24 (19-30)

- **2.8-month** absolute improvement in mPFS
- **17%** improvement in pts without tumor progression at 12 months

Data cut off: 2 April 2025
Median follow-up: 13.2 months

N Engl J Med. 2025 Nov 13;393(19):1912-1925
ASCO 2026. Abstract 1001.

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KEY DATA

ASCENT-03: 1L SG vs chemo in 1L mTNBC with PD-L1 negative or previously treated with anti-PD-L1

Exploratory Endpoint: Improved PFS shown in various biomarker subgroups evaluated

Subgroup	SG		CT		HR (95% CI)
	n	mPFS, mo	n	mPFS, mo	
ITT population	279	**9.7 (8.1-11.1)**	279	**6.9 (5.6-8.2)**	**0.62 (0.50-0.77)**
Trop-2 results (Trop-2 expression quartile)	252	**9.7 (7.8-11.1)**	247	**6.8 (5.4-8.1)**	**0.64 (0.51-0.80)**
• Q1	68	8.5 (5.6-12.7)	55	5.5 (4.2-8.1)	0.54 (0.35-0.84)
• Q2	60	8.3 (5.6-12.4)	62	6.8 (4.2-9.0)	0.62 (0.40-0.97)
• Q3	50	9.7 (7.6-11.3)	74	7.0 (5.3-8.5)	0.84 (0.54-1.31)
• Q4	74	9.9 (6.9-NE)	56	8.1 (4.4-8.5)	0.60 (0.38-0.95)
tBRCA results	217	**9.6 (8.0-11.1)**	206	**7.2 (5.6-8.3)**	**0.68 (0.54-0.87)**
• WT	177	8.8 (7.2-9.9)	169	6.9 (5.4-8.3)	0.70 (0.54-0.92)
• Mut (BRCA 1, 2, or both genes)	40	12.7 (7.2-18.7)	37	8.3 (5.6-11.2)	0.59 (0.32-1.09)
HER2 results	274	**9.7 (8.0-11.1)**	277	**6.9 (5.6-8.2)**	**0.67 (0.54-0.83)**
• HER2 IHC 0	115	8.3 (6.9-10.3)	138	5.6 (4.3-7.0)	0.63 (0.46-0.85)
• HER2 low (IHC1+ or 2+/ISH-)	159	9.8 (8.3-12.4)	139	8.3 (5.7-9.7)	0.74 (0.55-1.01)

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KEY DATA

ASCENT-03: 1L SG vs chemo in 1L mTNBC with PD-L1 negative or previously treated with anti-PD-L1

- Almost twice as many participants in the **SG group (27%)** remained on study treatment compared with the **chemo group (14%)** at the time of data cutoff

Rates of ADC use as Second-line Treatment

Participants who discontinued first-line treatment, n (%)	SG (n = 204)	Chemo (n = 240)
Received second-line or later therapy	126 (62)	179 (75)
• Received any subsequent ADC	19 (15)	153 (85)
• Received any subsequent SG	2 (2)	147 (82)
Received third-line therapy	31 (15)	55 (23)

Data cut off: 2 April 2025
Median follow-up: 13.2 months

N Engl J Med 2026;394:354-366
ASCO 2026. LBA1000.

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KEY DATA

ASCENT-03: 1L SG vs chemo in 1L mTNBC with PD-L1 negative or previously treated with anti-PD-L1

Exploratory Endpoint: Subsequent Therapy

Subsequent Therapies in the Second Line

n (%)	SG (n = 279)	Chemo (n = 279)
Any subsequent therapy, n	126	179
Any subsequent 2L therapy	**126 (100)**	**179 (100)**
• Platinum agents	43 (34)	4 (2)
• Taxanes	32 (25)	5 (3)
• Anthracyclines	14 (11)	3 (2)
• Antibody Drug Conjugates	13 (10)	149 (83)
• Trastuzumab deruxtecan	12 (10)	7 (4)
• Sacituzumab govitecan	1 (1)	142 (79)
• PD-(L)1 inhibitors	5 (4)	2 (1)
• PARPi	2 (2)	1 (1)
• Other	85 (67)	25 (14)
Median TFST, months (95% CI)	**11.2** (10.0-13.0)	**7.9** (7.2-9.0)
• Stratified HR (95% CI)	**0.61** (0.50-0.75)	

TFST: time to first subsequent therapy

Subsequent Therapies in the Third Line

n (%)	SG (n = 279)	Chemo (n = 279)
Any subsequent therapy, n	126	179
Any subsequent 3L therapy	**31 (25)**	**55 (31)**
• Platinum agents	6 (5)	7 (4)
• Taxanes	5 (4)	10 (6)
• Antibody Drug Conjugates	4 (3)	6 (3)
• Trastuzumab deruxtecan	1 (1)	4 (2)
• Sacituzumab govitecan	5 (4)	7 (4)
• Platinum agents	3 (2)	8 (4)
• Anthracyclines	3 (2)	2 (1)
• PD-(L)1 inhibitors	2 (2)	2 (1)
• PARPi	16 (13)	36 (20)
• Other		
Median TSST, months (95% CI)	**17.3** (15.2-NR)	**16.6** (13.6-18.5)
• Stratified HR (95% CI)	**0.82** (0.64-1.05)	

TSST: time to second subsequent therapy

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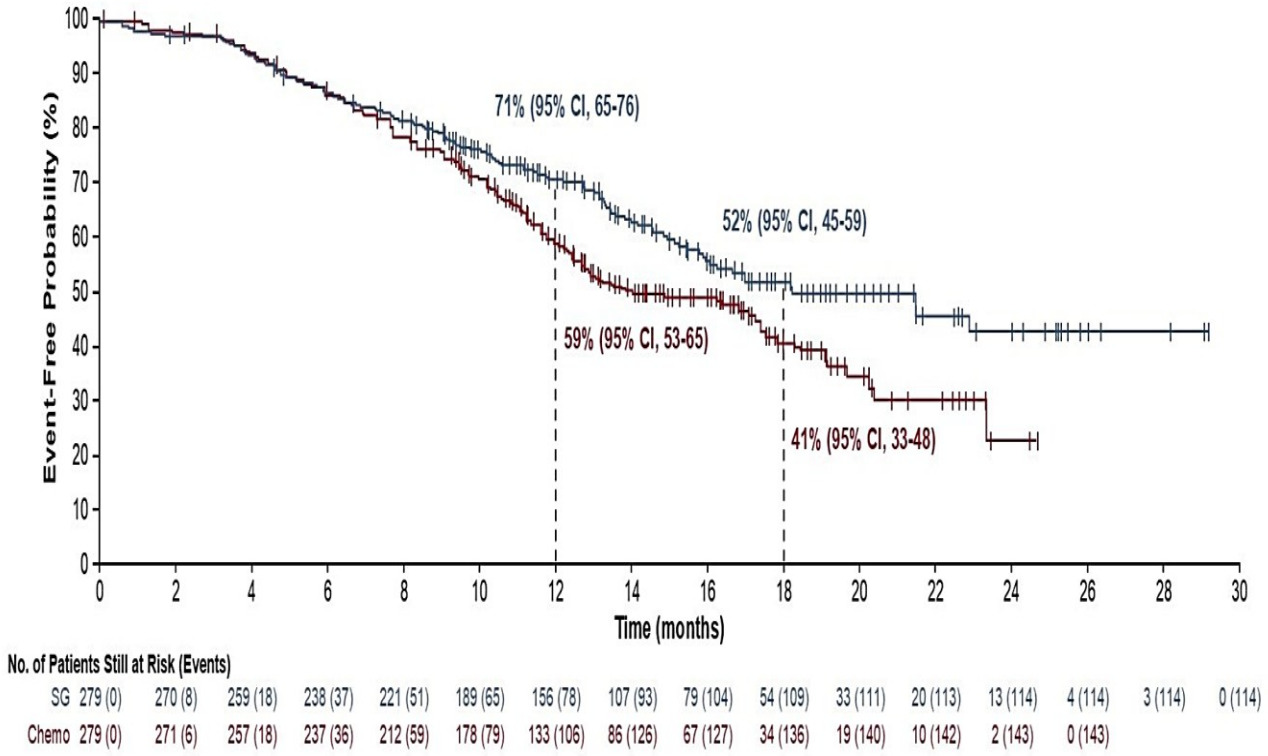
KEY DATA

ASCENT-03: 1L SG vs chemo in 1L mTNBC with PD-L1 negative or previously treated with anti-PD-L1

Exploratory Endpoint: PFS After Next Line of Treatment (PFS2*)



	SG (n = 279)	Chemo (n = 279)
Median PFS2, months (95% CI)	**18.2** (15.9-NR)	**14.0** (12.5-17.4)
• Stratified HR (95% CI)	**0.70** (0.55-0.90)	

- **4.2-month** absolute improvement in mPFS2

*PFS2 is defined as time from randomization to first documented progression on next-line therapy per investigator assessment, or death due to any cause, whichever occurred first

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SUMMARY

ASCENT-03

- Benefit for SG maintained across HER2 IHC 0 or HER2-low and BRCA wild-type or mutant
- The most frequent 2L+ subsequent therapy was chemotherapy in the SG group (85%) and SG in the chemo group (82%)
- Sacituzumab govitecan demonstrated a sustained long-term benefit beyond first progression
  - Median PFS2: 18.2 vs 14.0 months
    - HR: 0.70 (95% CI, 0.55-0.90)
  - Median time to first subsequent treatment (TFST):
    - 11.2 vs 7.9 months

IMPACT

Sacituzumab govitecan is an effective 1st-line treatment option for patients with PD-L1 negative metastatic TNBC, with benefits extending beyond first disease progression

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Key Studies

Breast

- ASCENT-04
- ASCENT-03
- TROPION-Breast02
- DESTINY-Breast05

Rapid Reviews

- SERENA-6
- persevERA
- KEYNOTE-522

GU/GI

- RASolute 302*
- EMERALD-3
- PROTEUS*
- TALAPRO-3

Other Notable Studies

- frontMIND
- MajesTEC-9
- HARMONi-6*
- LIBERTTO-432*

Rapid Reviews

- SARC041*

*Plenary Session

CLINICAL QUESTION

TROPION-Breast02

Does treatment with datopotamab deruxtecan (Dato-DXd) continue to improve survival after the next (PFS2) and subsequent lines of therapy compared with chemotherapy for patients with metastatic TNBC unable to receive immunotherapy?

Additional efficacy endpoints: time to first subsequent therapy or death (TFST), time to second progression or death (PFS2), and time to second subsequent therapy or death (TSST)

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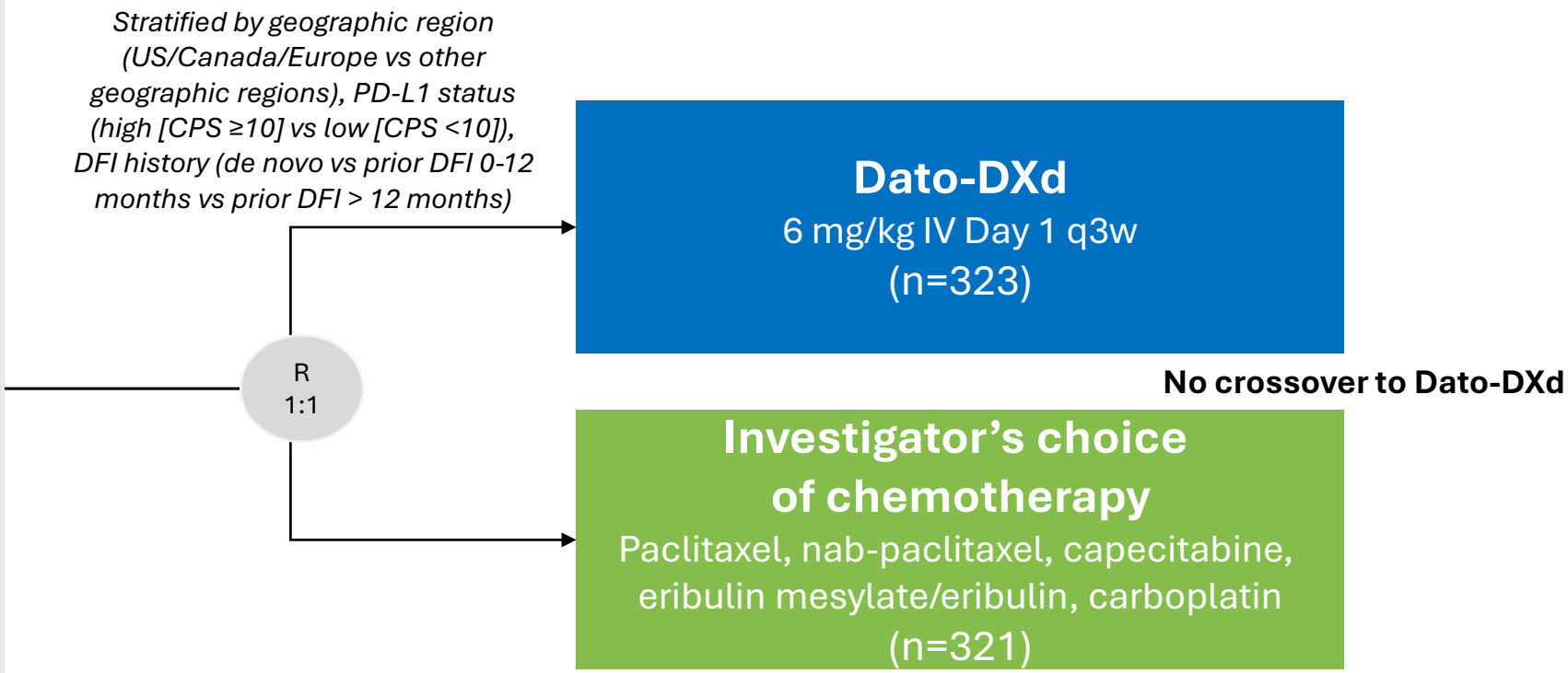
KEY DATA

TROPION-Breast02: 1L Dato-DXd vs chemo in untreated mTNBC with PD-L1 negative or previously treated with anti-PD-L1

Study Design: Randomized phase III study

- Locally recurrent inoperable or metastatic TNBC
- No prior chemotherapy or targeted systemic therapy in the locally recurrent inoperable or metastatic setting
- Immunotherapy not an option
- ECOG PS 0 or 1
- No minimum disease-free interval (DFI)
- Not eligible for PD-L1 therapy (almost all cases enrolled had PD-L1 neg tumor)

(N = 443)



Treatment continued until investigator-assessed RECIST v1.1 progression disease, unacceptable toxicity, or another discontinuation criterion was met; following progression or discontinuation of study treatment, patients could receive subsequent therapies, including approved ADCs or chemotherapy, at the investigator's discretion.

Dual primary endpoints: Progression-free survival (PFS) by BICR per RECIST v1.1 and overall survival (OS)
Secondary endpoints: Progression-free survival (PFS) investigator-assessed, overall response rate (ORR), duration of response (DoR), disease control rate (DCR) at 12 weeks, safety, PROs, time to first subsequent therapy or death (TFST), time to second progression or death (PFS2), and time to second subsequent therapy or death (TSST)

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KEY DATA

TROPION-Breast02: 1L Dato-DXd vs chemo in untreated mTNBC with PD-L1 negative or previously treated with anti-PD-L1

Subsequent ADC therapy

n (%)	Dato-DXd (n=278)	ICC (n=313)
Any subsequent therapy*	210 (76)	232 (74)
Received 3L+ therapy	100 (36)	112 (36)
Any ADC	44 (21)	95 (41)
• Sacituzumab govitecan	33 (16)	76 (33)
• Sacituzumab tirumotecan	0	1 (<1)
• Trastuzumab deruxtecan	16 (8)	34 (15)

ICC: Investigator's choice of chemotherapy

*~25% of pts did not receive any subsequent line therapy

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KEY DATA

TROPION-Breast02: 1L Dato-DXd vs chemo in untreated mTNBC with PD-L1 negative or previously treated with anti-PD-L1

Primary and Secondary Endpoints

	Dato-DXd Median (months)		Chemotherapy (ICC) Median (months)	Hazard Ratio (95% CI)
PFS (by BICR), Progression-free survival	**10.8**	Δ 5.3	5.6	0.57 (0.44–0.73)
OS, Overall Survival	**23.7**	Δ 5.0	18.7	0.79 (0.64–0.98)
TFST, Time to first subsequent therapy or death	**10.9**	Δ 5.3	5.6	0.49 (0.41–0.59)
PFS2, time to second progression or death	**15.6**	Δ 3.8	11.8	0.61 (0.50–0.74)
TSST, time to second subsequent therapy or death	**16.7**	Δ 4.1	12.6	0.67 (0.55–0.81)

ICC: Investigator's choice of chemotherapy
BICR: Blinded Independent Central Review

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SUMMARY

TROPION-Breast02

- Dato-DXd demonstrated improvements in time to first subsequent therapy or death, time to second progression or death, and time to second subsequent therapy or death compared with investigator's choice chemotherapy for patients in whom immunotherapy is not an option
- Absolute improvement in PFS2: Δ 3.8 months
- No crossover

IMPACT

Datopotomab deruxtecan is an effective new 1st-line treatment option for patients with locally recurrent inoperable or metastatic PD-L1 negative TNBC, with benefits extending beyond first disease progression

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Cross study comparison of approved 1L ADCs for PD-L1-negative TNBC

	TROPION-Breast02 (N=644)	ASCENT-03 (N=558)
Study Design	Metastatic TNBC -- PD-L1-negative, previous IO in adjuvant setting, or no access to IO, no prior chemo or targeted therapy, ECOG PS 0 or 1 (no crossover)	Metastatic TNBC -- PD-L1-negative or treated with IO in early setting (crossover)
	For TROPION-Breast02 and Ascent03 only 5% of patients had prior IO therapy	
Efficacy	**Dato-DXd** (n=323) vs ICC† (n=321)	**SG** (n=279) vs Chemotherapy‡ (n=279)
• **mPFS (mo)**	HR=0.57	HR=0.62
• **mOS (mo)**	2-year (23.7 mos) vs 1.5-year for chemo HR=0.79	Almost 2-year (*data not mature*)
• **ORR**	**62.5% vs 29.3%**	**48.4% vs 45.5%**
• **mDOR (mo)**	**12.3** vs 7.1	**12.2** vs 7.2
• **PFS2**	HR 0.61	HR 0.70
• **TFST**	HR 0.49	HR 0.61
• **TSST**	HR 0.67	HR 0.82
• **Grade ≥3 TRAEs**	**33% vs 29%**	**66% vs 62%**
• **Schedule**	Once every 3 weeks (21-day cycle)	Days 1 and 8 (21-day cycle)

†Investigators choice chemotherapy: Paclitaxel, nab-paclitaxel, capecitabine, carboplatin, eribulin mesylate/eribulin

Ann Oncol . 2026 Apr 3:S0923-7534(26)00130-4.

‡ Chemotherapy: Paclitaxel, nab-paclitaxel, gemcitabine + carboplatin

N Engl J Med . 2025 Nov 13;393(19):1912-1925.

PFS2, time to second progression or death; **TFST,** Time to first subsequent therapy or death; **TSST,** time to second subsequent therapy or death

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What will be your preference for 1L PD-L1-negative mTNBC now that both the ASCENT-03 regimen and TROPION-Breast02 regimen are approved by the FDA?

1. Datopotomab DXd (TROPION-Breast02)
2. Sacituzumab govitecan (ASCENT-03)
3. Both equally on a patient-by-patient basis

Key Studies

Breast

- ASCENT-04
- ASCENT-03
- TROPION-Breast02
- DESTINY-Breast05

Rapid Reviews

- SERENA-6
- persevERA
- KEYNOTE-522

GU/GI

- RASolute 302*
- EMERALD-3
- PROTEUS*
- TALAPRO-3

Other Notable Studies

- frontMIND
- MajesTEC-9
- HARMONi-6*
- LIBERTTO-432*

Rapid Reviews

- SARC041*

*Plenary Session

CLINICAL QUESTION

DESTINY-Breast05

How does trastuzumab deruxtecan (T-DXd) compare with trastuzumab emtansine (T-DM1) in clinical and demographic risk factors of lung disease and radiation pneumonitis?

Secondary safety analysis

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NEW KEY DATA

DESTINY-Breast05: post-neoadjuvant T-DXd vs T-DM1

Study Design: global, multicenter, randomized, open-label, phase 3 study

Stratified by extent of disease at presentation (inoperable, operable), HER2-targeted NAT (single, dual), hormone receptor status (positive, negative), and post-NAT pathologic nodal status (positive, negative)

- Residual invasive disease in breast and/or axillary lymph nodes after neoadjuvant chemo with HER2-directed therapy (NAT*)
- HER2+ (IHC 3+ or ISH+)
- ECOG PS 0-1

*NAT=neoadjuvant therapy

R
1:1

T-DXd
5.4 mg/kg IV q3w
(x14 cycles, ~8 months) (N=818)

Concurrent endocrine therapy (ET) allowed. Radiotherapy allowed if concurrent with T-DXd or completed prior to T-DXd (sequential).

T-DM1
3.6 mg/kg IV q3w
(x14 cycles, ~8 months) (N=817)

40-day safety follow-up

Interim analysis timeline
Data cutoff: 2 July 2025

Primary endpoint: Invasive disease–free survival
Key secondary endpoint: Disease-free survival
Other secondary endpoints: Overall survival, distant recurrence–free interval, brain metastasis–free interval, and safety

ASCO 2026. Abstract 516.
New Eng J Med 2026;394:845-857

KEY DATA

DESTINY-Breast05: post-neoadjuvant T-DXd vs T-DM1

>72% of patients in each arm completed the planned 14 cycles of therapy

Efficacy Endpoints	T-DXd x14 cycles (N=818)		T-DM1 x14 cycles (N=817)
Primary endpoint: 3-yr invasive disease-free survival*	**92.4%**	**Δ 8.7%**	**83.7%**
	HR 0.47 (95% CI 0.34-0.66), **P <0.0001**		
Key secondary endpoints: 3-yr disease-free survival	92.3%		83.5%
	HR 0.47 (95% CI 0.34-0.66), P <0.0001		
3-yr distant recurrence-free interval	93.9%		86.1%
	HR 0.49 (95% CI 0.34-0.71)		
3-yr brain metastasis-free interval	97.6%		95.8%
	HR 0.64 (95% CI 0.35-1.17)		
Patients with recurrence in CNS	n=17 (2.1%)		n=26 (3.2%)
3-yr overall survival	97.4%		95.7%
	HR 0.61 (95% CI 0.34-1.10)		

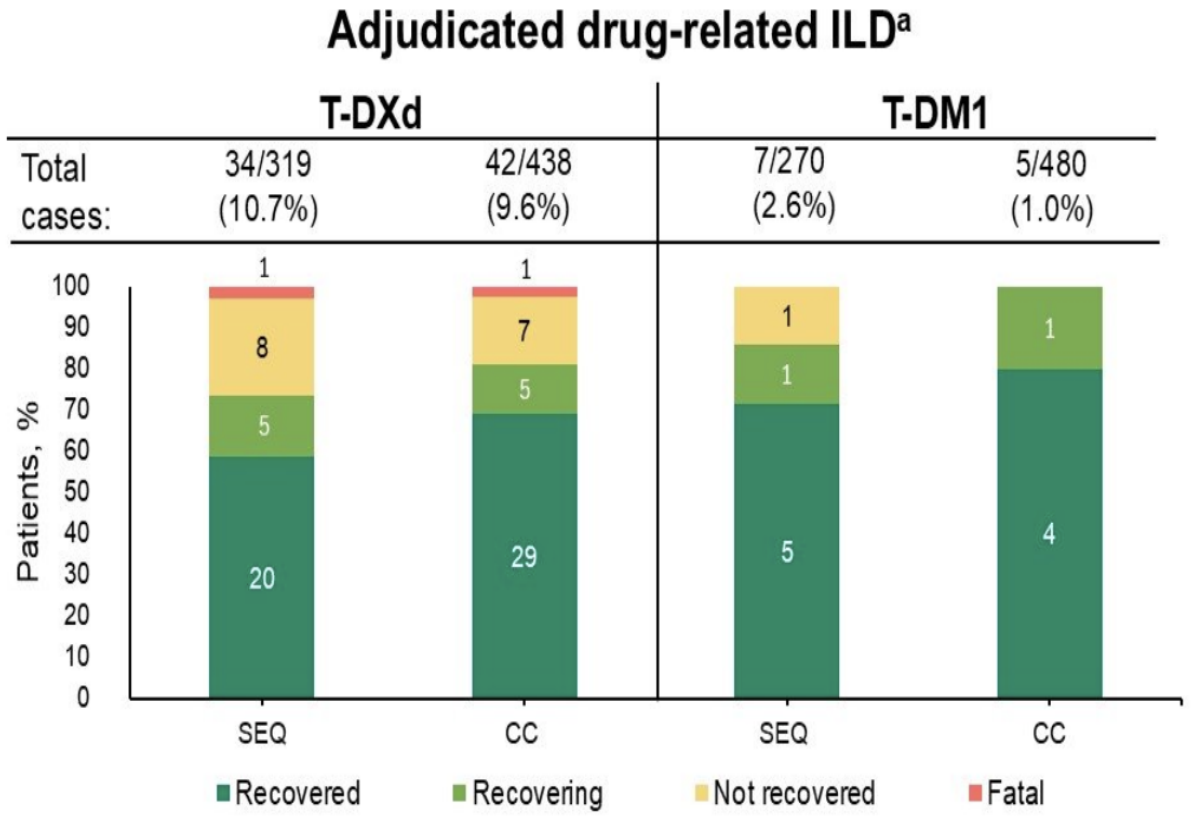
*Invasive disease-free survival: Time from randomization until recurrence of ipsilateral invasive breast tumor, recurrence of ipsilateral locoregional invasive breast cancer, contralateral invasive breast cancer, distant disease recurrence, or death from any cause

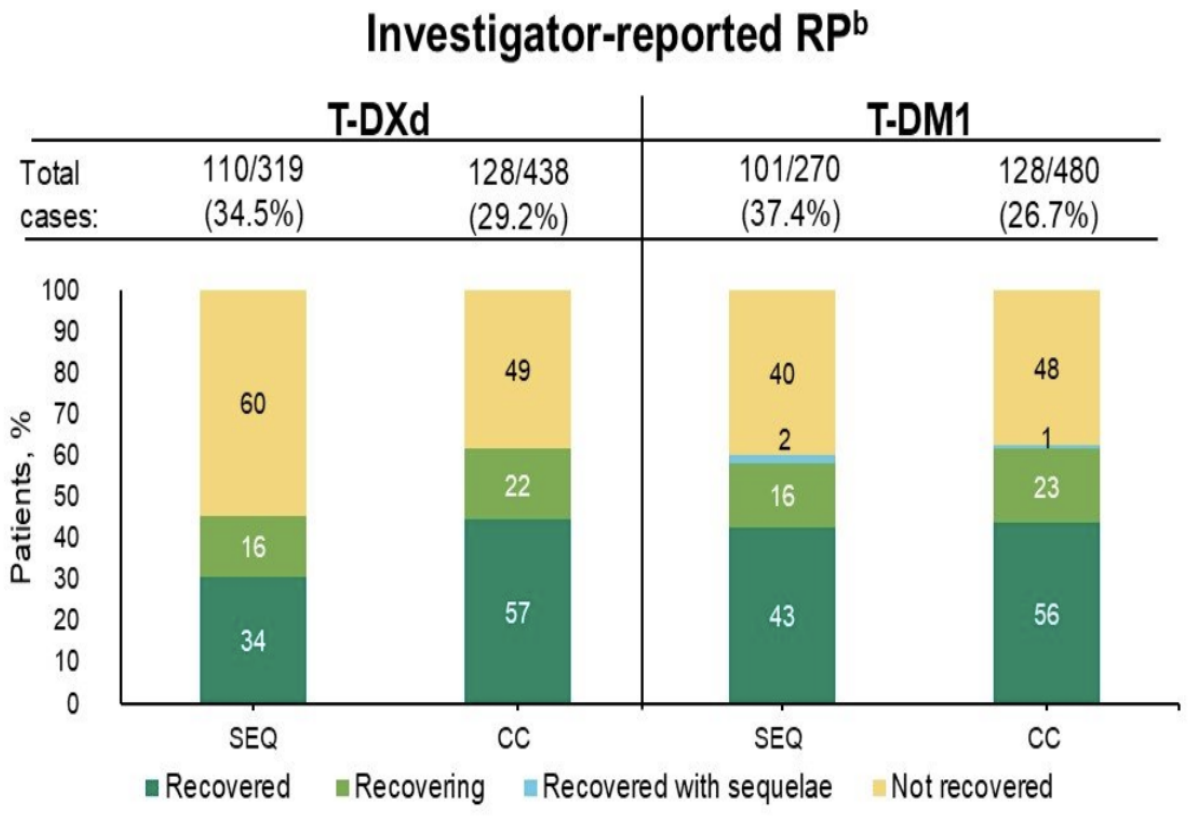
New Eng J Med 2026;394:845-857

DESTINY-Breast05: post-neoadjuvant T-DXd vs T-DM1

Rate and outcome of adjudicated drug-related ILD and investigator-reported Radiation Pneumonitis (RP)

Radiotherapy could be concurrent (CC) or sequential (SEQ) to the ADC





SEQ: sequential, **CC:** concurrent, **ILD:** interstitial lung disease, **RP**: Radiation pneumonitis

ASCO 2026. Abstract 516.
New Eng J Med 2026;394:845-857

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KEY DATA

DESTINY-Breast05: post-neoadjuvant T-DXd vs T-DM1

ILD and radiation pneumonitis rates by region and baseline renal function

Higher risk of ILD and radiation pneumonitis in patients from Japan and in patients with an impaired renal function

Japan vs non-Japan

n (%)	T-DXd			T-DM1		
	Japan (n = 87)	Asia (n = 301)	Global (n = 719)	Japan (n = 60)	Asia (n = 315)	Global (n = 741)
Adjudicated drug-related ILD	**13 (14.9)**	25 (8.3)	64 (8.9)	**4 (6.7)**	4 (1.3)	9 (1.2)
Investigator-reported RP	**41 (47.1)**	116 (38.5)	197 (27.4)	**27 (45.0)**	122 (38.7)	202 (27.3)

Baseline renal function

n (%)	T-DXd (n = 806)			T-DM1 (n = 801)		
	Normal (n = 506)	Mild Impairment (n = 258)	Moderate Impairment (n = 42)	Normal (n = 486)	Mild Impairment (n = 274)	Moderate Impairment (n = 40)
Adjudicated drug-related ILD	49 (9.7)	22 (8.5)	**6 (14.3)***	5 (1.0)	6 (2.2)	2 (5.0)†
Investigator-reported RP	133 (26.3)	**95 (36.8)**	10 (23.8)	131 (27.0)	**86 (31.4)**	11 (27.5)

*Patients with baseline moderate renal impairment who developed adjudicated drug-related ILD in the T-DXd arm, 5 out of 6 had grade 2 ILD (all recovered at DCO) and 1 of 6 had grade 3 ILD (not recovered at DCO).
†Both patients with baseline moderate renal impairment who developed adjudicated drug-related ILD in the T-DM1 arm had grade 2 ILD and had recovered at DCO.

ASCO 2026. Abstract 516.
New Eng J Med 2026;394:845-857

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SUMMARY

DESTINY-Breast05

- Adjudicated drug-related ILD cases were mostly low grade and reversible with treatment management guidelines
- Drug-related ILD and radiation pneumonitis risk increased with impaired renal function at baseline and in patients from Japan, consistent with prior data
- Grade 1 or 2 radiation pneumonitis (RP) had similar median duration in both treatment arms and at the time of the analysis had resolved or were resolving in 54.2% of T-DXd patients and 61.6% of T-DM1 patients
- Prior ILD or RP did not increase risk or severity of subsequent events, supporting T-DXd use with adjuvant radiotherapy

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IMPACT

Trastuzumab deruxtecan is a novel effective treatment option for patients with high risk HER2+ early breast cancer with residual disease after neoadjuvant Rx

T-DXd has an overall better efficacy / risk ratio compared to T-DM1 in the post-neoadjuvant HER2+ setting

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Key Studies

Breast

- ASCENT-04
- ASCENT-03
- TROPION-Breast02
- DESTINY-Breast05

Rapid Reviews

- SERENA-6
- persevERA
- KEYNOTE-522

GU/GI

- RASolute 302*
- EMERALD-3
- PROTEUS*
- TALAPRO-3

Other Notable Studies

- frontMIND
- MajesTEC-9
- HARMONi-6*
- LIBERTTO-432*

Rapid Reviews

- SARC041*

*Plenary Session

DESTINY-Breast09

How do treatment duration and clinical outcomes vary by best response to trastuzumab deruxtecan (T-DXd) plus pertuzumab in 1L HER2+ metastatic breast cancer?

Exploratory Analysis

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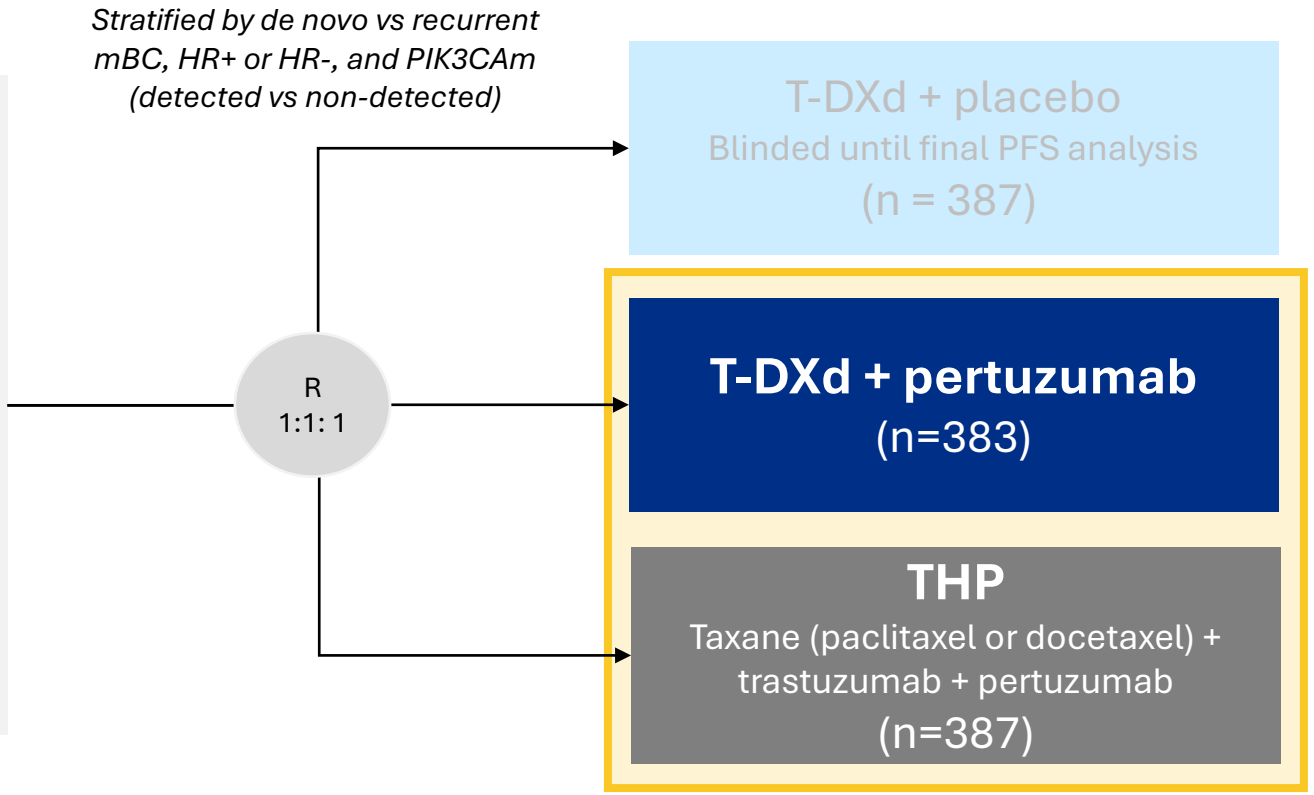
KEY DATA

DESTINY-Breast09: 1L T-DXd + pertuzumab vs pertuzumab + trastuzumab + taxane in HER2+ metastatic breast cancer (mBC)

Study Design: Randomized, multicenter, open-label, Phase III study

- 1L HER2-positive mBC
- Asymptomatic/inactive brain mets allowed
- Disease-free interval >6 mo from last chemotherapy or HER2-targeted therapy in neoadjuvant/adjuvant setting
- One prior line of endocrine therapy for mBC permitted



Primary endpoint: Progression-free survival (PFS) by BICR
Key secondary endpoints: Overall survival (OS)
Other secondary endpoints: PFS (INV), ORR (BICR/INV), DOR (BICR/INV), PFS2 (INV), safety/tolerability

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KEY DATA

DESTINY-Breast09: 1L T-DXd + pertuzumab vs pertuzumab + trastuzumab + taxane in HER2+ metastatic breast cancer (mBC)

Primary Endpoint: Progression-free survival
Previously reported - ESMO 2025

	T-DXd + Pertuzumab (n=383)	THP (n=387)
Median PFS	**40.7** (36.5 – NC)	26.9 (21.8 – NC)
	Δ 13.8 months	
HR (95% CI)	**0.56** (0.44 – 0.71)	
P-value	<0.00001	

Subgroup analysis:

- Benefit regardless of treatment status
  - De novo disease or recurrent
- Benefit regardless of HR status
  - HR-positive or HR-negative
- Benefit regardless of PIK3CA mutation status
  - Mutation or wild-type

New data at ASCO 2026

Endpoints evaluated in response subgroups:

- Time to best response
- Duration of response
- Progression-free survival

Response groups:

- CR by RECIST1.1.
- Deep PR (≥80%) PR with ≥80% to <100% reduction in target lesion (TL) sum
- PR (<80%) Remaining patients with confirmed PR after excluding patients with deep PR (i.e. PR with ≥30% to <80% reduction in TL sum)
- SD/PD by RECIST1.1

N Engl J Med 2026;394:551-562.

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KEY DATA

DESTINY-Breast09: 1L T-DXd + pertuzumab vs pertuzumab + trastuzumab + taxane in HER2+ metastatic breast cancer (mBC)

Response characteristics and PFS outcome : T-DXd + P vs THP

	CR	Deep PR[a]	PR (<80%)	SD/PD
T-DXd + P **PFS at 24 mo, % (95% CI)**	**85.1** (72.2 - 92.3) (n=58)	**80.0** (71.7 - 86.1) (n=141)	**64.3** (54.3 - 72.8) (n=127)	**35.5** (21.1 - 50.2) (n=51)
THP **PFS at 24 mo, % (95% CI)**	**76.7** (56.9 - 88.2) (n=33)	**60.7** (50.3 - 69.6) (n=110)	**48.5** (39.8 - 56.6) (n=161)	**31.7** (18.6, 45.5) (n=68)

80% of patients (ITT) achieved **maximal tumor reduction** by **24 months**

[a]PR with ≥80% to <100% reduction in target lesion (TL) sum and CR or non-CR/non-PD in non-TLs, or CR in TL and non-CR/non-PD in non-TLs

Note, time to best response: T-DXd + P CR **8.4** mos and Deep PR **9.6** mos
THP CR **5.6** mos and Deep PR **8.2** mos

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SUMMARY

DESTINY-Breast09

- T-DXd + pertuzumab was superior to taxane + trastuzumab + pertuzumab (THP) in first-line HER2+ metastatic breast cancer
  - mPFS ~40.7 months vs 26.9 months, HR 0.56
- PFS rate at 24 mos:
  - T-DXd + P: CR 85.1% and Deep PR 80%
  - THP: CR 76.7% and Deep PR 60.7%
- Overall PFS rate better for CR and deep PR compared to PR and SD/PD

IMPACT

Trastuzumab deruxtecan is an effective treatment option for patients with HER2+ metastatic breast cancer in the 1L setting

Depth of response translates into better PFS and treatment duration

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Among the T-DXd datasets in HER2+ breast cancer, which most strongly influences your preference to first incorporate T-DXd in your community practice?

1. T-DXd based on DESTINY-Breast11 (neoadjuvant)
2. T-DXd based on DESTINY-Breast05 (post-neoadjuvant)
3. T-DXd based on DESTINY-Breast09 (1L)
4. T-DXd based on DESTINY-Breast03 (2L)

ASCO 2026: RAPID REVIEW

SERENA-6

persevERA

KEYNOTE-522

SERENA-6

Switching to camizestrant upon detection of an ESR1 mutation in HR+/HER2– advanced breast cancer receiving 1L AI + CDK4/6 inhibitor

- **Design**
  - N= 315
  - All patients had received AI + CDK4/6i (palbociclib, ribociclib, or abemaciclib) as initial endocrine-based therapy for mBC for at least 6 months
  - Primary endpoint: Investigator-assessed progression-free survival (INV-PFS)
  - Main focus of ASCO 2026 presentation: update on PFS; PFS2 (progression after subsequent treatment), etc. for those switched to camizestrant based on asymptomatic ct-DNA testing
  - Median follow-up: 2 years

- **New Data at ASCO 2026**
  - Reduction of ctDNA noted by switching to SERD + the CDK4/6i
  - Switching from the AI to the SERD camizestrant, and continuing the CDK4/6i, after asymptomatic molecular evidence of developing mESR1 led to improvement in PFS, PFS2, time to chemotherapy, cancer-related symptoms
  - No mOS improvement at this timepoint; neutropenia
  - Regimen approved by the EU, not yet by the FDA

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ASCO 2026. Abstract LBA1007; Lancel Oncol; accepted for publication (in press)

persevERA

First-line giredestrant vs letrozole + palbociclib in ER-positive, HER2-negative locally advanced or metastatic breast cancer

Design

- N= 992; 1st-line mBC; HR+ HER2 neg
- Main endpoint: Investigator-assessed progression-free survival (INV-PFS)
- Median follow-up: 4.6 years

New Data at ASCO 2026

- Negative trial of the SERD giredestrant vs letrozole (given in combination with palbo)
- Trend for better mPFS in the giredestrant arm; no difference in mOS
- Safety: 80% TRAEs; 2% deaths due to AEs
- Negative result challenging to put in context with giredestrant's statistically positive trials in adjuvant and 2nd-line mBC

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ASCO 2026. Abstract LBA1006

KEYNOTE-522

Neoadjuvant pembrolizumab plus chemotherapy (TC followed by AC) followed by adjuvant pembrolizumab in high-risk early-stage TNBC

Design

- N= 1174; 1st line high-risk early-stage TNBC
- Dual primary endpoints: Pathologic complete response (pCR) and event-free survival (EFS)
- Median follow-up: 7.8 years (Data cutoff: Oct 14, 2025)

New Data at ASCO 2026

- Final ~8-year follow-up confirmed survival benefit of neoadjuvant pembrolizumab + chemotherapy followed by adjuvant pembrolizumab in high-risk early-stage TNBC
- Long-term improvements in EFS and OS maintained across key patient subgroups and regardless of pCR status
  - 7-year EFS 78.3% vs 69.8% (HR 0.68)
  - 7-year OS 85.1% vs 77.2% (HR 0.64)
  - Safety: 99% TRAEs; 0.5% deaths due to AEs

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ASCO 2026. Abstract 507.

ASCO 2026:
Breast Cancer

Key Takeaways

Q&A
@EdithPerezMD

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ASCENT-04: In first-line PD-L1 + mTNBC, sacituzumab govitecan plus pembrolizumab showed sustained benefit beyond first progression despite crossover to SG

Now FDA approved

ASCENT-03: In first-line mTNBC patients ineligible for PD-1/PD-L1 inhibitors, sacituzumab govitecan demonstrated long-term benefit until the next line of therapy despite crossover to SG

Now FDA approved

TROPION-Breast02: In first-line mTNBC, patients ineligible for PD-1/PD-L1 inhibitors, datopotamab deruxtecan improved PFS2, TFST, and TSST, alongside a manageable safety profile

Now FDA approved

DESTINY-Breast05: Post-neoadjuvant T-DXd was associated with mostly low-grade, reversible ILD/RP events, though higher ILD rates vs T-DM1 and influenced by region and baseline renal function in HER2+ early breast cancer

Now FDA approved

DESTINY-Breast09: In first-line HER2+ mBC, T-DXd plus pertuzumab achieving a durable CR or PR was associated with favorable PFS outcomes and prolonged treatment duration

Now FDA approved

SERENA-6: No OS yet by switching to camizestrant

PersevERA: No benefit for giredestrant vs letrozole in combo with palbo as 1L for HR+HER2- mBC

Keynote-522: Long-term OS benefit in pembro groups vs placebo group for early-stage TNBC

RECENT FDA APPROVALS

PROSTATE CANCER

On **June 12, 2026**

- **CAPItello-281** – capivasertib in combination with abiraterone and prednisone for metastatic androgen pathway modulation-naïve or -sensitive (mAPMN/S) prostate cancer (previously referred to as metastatic hormone-sensitive prostate cancer) that is PTEN-deficient

RENAL CELL CARCINOMA

On **June 12, 2026**

- **LITESPARK-022** – belzutifan in combination with pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph (subQ formulation) for the adjuvant treatment of renal cell carcinoma with a clear cell component (ccRCC) at intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions

BLADDER CANCER

On **May 28, 2026**

- **POTOMAC** - durvalumab in combination with Bacillus Calmette-Guerin (BCG) for BCG-naïve, high-risk non-muscle invasive bladder cancer (NMIBC)

On **July 10, 2026**

- **KEYNOTE-B15/EV-304** – pembrolizumab in combination with enfortumab vedotin-ejfv as neoadjuvant treatment (before surgery) followed by adjuvant treatment after cystectomy (surgery to remove the bladder) for muscle invasive bladder cancer (MIBC)

Key Studies

Breast

- ASCENT-04
- ASCENT-03
- TROPION-Breast02
- DESTINY-Breast05

Rapid Reviews

- SERENA-6
- persevERA
- KEYNOTE-522

GU/GI

- RASolute 302*
- EMERALD-3
- PROTEUS*
- TALAPRO-3

Other Notable Studies

- frontMIND
- MajesTEC-9
- HARMONi-6*
- LIBERTTO-432*

Rapid Reviews

- SARC041*

*Plenary Session

CLINICAL QUESTION

RASolute 302*

*Plenary Session

Is targeting RAS the new standard of care in patients with previously treated metastatic pancreatic adenocarcinoma?

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KEY DATA

RASolute 302: Daraxonrasib vs Chemotherapy in Metastatic Pancreatic Adenocarcinoma (mPDAC)

Study Design: Phase 3, randomized study

- Adults with mPDAC
- One prior fluoropyrimidine- or gemcitabine-based regimen in the metastatic setting
- ECOG PS 0-1
- Documented tumor RAS mutational status by local testing:
  - Mutant, defined as nonsynonymous mutations in KRAS, NRAS, or HRAS at codons 12, 13, or 61 (G12, G13, or G61)
  - No RAS mutation identified

R 1:1

Daraxonrasib
300 mg, PO QD

Investigator's choice chemotherapy (1 of 4)
GnP, mFOLFIRINOX,
Nal-IRI + 5-FU/LV, FOLFOX

Stratification
- ECOG PS (0, 1)
- Metastatic disease at diagnosis (yes, no)
- Liver metastases at baseline (yes, no)
- Tumor RAS mutational status (RAS G12D/V, other RAS G12, RAS G13 or Q61, no RAS mutation identified)

Dual primary endpoints:
- Overall survival (OS) by BICR per RECIST v1.1, RAS G12 population
- Progression-free survival (PFS) by BICR per RECIST v1.1, RAS G12 population

Key secondary endpoints:
- OS and PFS in overall population, overall response rate (ORR), time to deterioration in patient-reported outcomes

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KEY DATA

RASolute 302: Daraxonrasib vs Chemotherapy in Metastatic Pancreatic Adenocarcinoma (mPDAC)

Baseline Characteristics

	Daraxonrasib (n=248)	Chemotherapy (n=252)
Age, median (range), years	66 (30-88)	65 (36-86)
Metastatic disease at initial diagnosis, n (%)	154 (62)	154 (61)
Prior chemotherapy regimens in metastatic setting, n (%)		
• (m)FOLFIRINOX	98 (40)	105 (42)
• Gemcitabine + nab-paclitaxel	94 (38)	94 (37)
• Other	56 (23)	53 (21)
Prior pancreatectomy, n (%)	83 (33)	92 (37)
Liver metastases at baseline, n (%)	174 (70)	176 (70)
Tumor RAS mutational status, n (%)		
• RAS G12 D/V	197 (79)	197 (78)
• Other RAS G12	31 (13)	34 (13)
• RAS G13 or Q61, or no RAS mutation identified	20 (8)	21 (8)

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KEY DATA

RASolute 302: Daraxonrasib vs Chemotherapy in Metastatic Pancreatic Adenocarcinoma (mPDAC)

Dual Primary Endpoints:

Progression-free Survival (PFS) in the RAS G12 Population

	Daraxonrasib (n=228)	Chemotherapy (n=231)
Median PFS, months (95% CI)	**7.3** (6.3–8.1)	3.5 (2.9–3.8)
HR (95% CI)	**0.45** (0.34–0.59); P =3.2×10^{-9}	
6-mo PFS rate	**58.7%**	31.7%

Median follow-up (range): 8.5 (3.2-15.9) months

Overall survival (OS) in the RAS G12 Population

	Daraxonrasib (n=228)	Chemotherapy (n=231)
Median OS, months (95% CI)	**13.2** (10.0–NE)	6.6 (5.4–8.2)
HR (95% CI)	**0.40** (0.30–0.54); P =5.9×10^{-10}	
12-mo OS rate	**53.3%**	18.7%

Median follow-up (range): 8.5 (3.2-15.9) months

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KEY DATA

RASolute 302: Daraxonrasib vs Chemotherapy in Metastatic Pancreatic Adenocarcinoma (mPDAC)

Secondary Endpoints: Overall Population

	Daraxonrasib (n=248)	Chemotherapy (n=252)
Median overall survival, overall population	**13.2** months	6.7 months
	HR 0.40 (95% CI, 0.30-0.53); **P =4.6×10^{-11}**	
3-y overall survival rate	**53.2%**	17.3%
Median progression-free survival, overall population	**7.2** months	3.6 months
	HR 0.49 (95% CI, 0.38-0.64); **P =5.2×10^{-8}**	
3-y progression-free survival rate	**56.0%**	32.9%
Objective response rate, overall population	**31.6%**	11.2%
	P <0.0001	
RAS G12 population	**33.2%**	11.8%

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KEY DATA

RASolute 302: Daraxonrasib vs Chemotherapy in Metastatic Pancreatic Adenocarcinoma (mPDAC)

Safety

	Daraxonrasib (n=248)	Chemotherapy* (n=252)
Median time on treatment, mo	**6.2**	1.5-3.2 across regimens
Median dose intensity	**93.1%**	65.3-95.0% across regimens
Treatment-emergent AE, n (%)	241 (100)	209 (97.7)
Treatment-related AE, n (%)	236 (97.9)	200 (93.5)
• Leading to dose reduction	**87 (36.1)**	**123 (57.5)**
• Leading to dose interruption	135 (56.0)	118 (55.1)
• Leading to discontinuation	**3 (1.2)**	**24 (11.2)**
• Grade ≥3	**105 (43.6)**	**123 (57.5)**
• Serious	**26 (10.8)**	**40 (18.7)**
• Grade 5	1 (0.4) Pneumonitis	0

Most common treatment-related AEs with daraxonrasib

- **Rash: 85%** (Grade ≥3, 14%)
- **Diarrhea: 58%** (Grade ≥3, 5%)
- **Stomatitis: 53%** (Grade ≥3, 12%)
- **Nausea: 46%** (Grade ≥3, 12%)

*Investigator's choice chemotherapy: GnP, mFOLFIRINOX, Nal-IRI + 5-FU/LV, FOLFOX

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SUMMARY

RASolute 302

- Daraxonrasib demonstrated statistically significant and clinically meaningful improvements in OS, PFS, and ORR in patients with previously treated metastatic PDAC

- Daraxonrasib mOS: 13.2 months
- Chemotherapy mOS: 6.7 months
  - HR, 0.40 (95% CI: 0.30–0.53); $p=4.6\times10^{-11}$ in the overall population (patients with and without an identified tumor RAS mutation)

- Monitor and manage treatment-related AEs: rash, diarrhea, nausea and stomatitis

IMPACT

Daraxonrasib is a new standard of care for patients with previously treated metastatic PDAC

May 1, 2026: FDA approved expanded access

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What is your biggest barrier to implementing daraxonrasib in your practice?

1. Timely KRAS G12D testing
2. Access/coverage and reimbursement
3. AE monitoring and management
4. Patient selection and sequencing guidance
5. Waiting on FDA approval
6. No major barriers – already using

Key Studies

Breast

- ASCENT-04
- ASCENT-03
- TROPION-Breast02
- DESTINY-Breast05

Rapid Reviews

- SERENA-6
- persevERA
- KEYNOTE-522

GU/GI

- RASolute 302*
- EMERALD-3
- PROTEUS*
- TALAPRO-3

Other Notable Studies

- frontMIND
- MajesTEC-9
- HARMONi-6*
- LIBERTTO-432*

Rapid Reviews

- SARC041*

*Plenary Session

CLINICAL QUESTION

EMERALD-3

Can adding immunotherapy and anti-angiogenic therapy to transarterial chemoembolization (TACE) improve outcomes in hepatocellular carcinoma?

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KEY DATA

EMERALD-3: Tremelimumab + Durvalumab (STRIDE) ± Lenvatinib (L) + Transarterial Chemoembolization (TACE) vs TACE Alone in Hepatocellular Carcinoma (HCC)

Study Design: Phase 3, randomized, open-label, sponsor-blinded, multicenter study

- Unresectable HCC amenable to embolization
- Child-Pugh A
- ECOG PS 0-1
- No extrahepatic disease
- Excludes Vp3 and Vp4
- No prior systemic therapy

(N=760)

R

1:1:1 until each arm reached 175 participants → then 1:1 to Arms A and C

- **Arm A: STRIDE* + Lenvatinib + TACE† (n=293)**
- **Arm B: STRIDE* + TACE† (n=175)**
- **Arm C: TACE† (n=292)**

Stratification
- Geographical region (Japan vs Asia [excluding Japan] vs rest of world
- Prior palliative locoregional therapy (>6 months vs ≤6 months vs none)
- Baseline tumor burden (>up-to-7 vs ≤up-to-7)

***STRIDE:** Single Tremelimumab Regular Interval Durvalumab
- Tremelimumab 300 mg day 1
- Durvalumab 1500 mg IV day 1 then q4w

Lenvatinib: Daily

†**TACE:** Conventional (cTACE) or with drug eluting beads (DEB-TACE), starting at least 7 days after tremelimumab + durvalumab ± lenvatinib for Arms A and B, or within 7 days of randomization for Arm C, followed by additional procedures per investigator

Primary endpoint: Progression-free survival (PFS) for Arm A vs C using BICR per RECIST v1.1
Key secondary endpoints: Overall survival (OS) for Arm A vs C, PFS and OS for Arm A vs C

Other secondary endpoints: Objective response rate, disease control rate, duration of response, time to progression, time to second progression, patient-reported outcomes, safety, qualify of life

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KEY DATA

EMERALD-3: Tremelimumab + Durvalumab (STRIDE) ± Lenvatinib (L) + Transarterial Chemoembolization (TACE) vs TACE Alone in Hepatocellular Carcinoma (HCC)

Baseline Characteristics

		STRIDE + L + TACE (n=293)	STRIDE + TACE (n=175)	TACE (n=292)
Median age, years (range)		67 (25-86)	65 (32-85)	65 (34-85)
Virology status, n (%)	Hepatitis B virus	**131 (44.7)**	**99 (56.6)**	**138 (47.3)**
	Hepatitis C virus	39 (13.3)	19 (10.9)	37 (12.7)
	None / neither	120 (41.0)	56 (32.0)	109 (37.3)
Barcelona Clinic Liver Center Stage, n (%)	**A**	**51 (17.4)**	**33 (18.9)**	**69 (23.6)**
	B	**187 (63.8)**	**114 (65.1)**	**171 (58.6)**
	C	55 (18.8)	28 (16.0)	50 (17.1)
Albumin-bilirubin grade, n (%)	1	188 (64.2)	105 (60.0)	183 (62.7)
	≥2	105 (35.8)	70 (40.0)	109 (37.3)
Tumor burden (Up-to-7 criteria), n (%) Size of largest tumor (in cm) + number of tumors	≤7	115 (39.2)	60 (34.3)	115 (39.4)
	>7	178 (60.8)	115 (65.7)	177 (60.6)
Portal vein invasion, n (%)	**Vp1 or Vp2**	**29 (9.9)**	**19 (10.9)**	**28 (9.6)**
Prior palliative embolization before randomization, n (%)		**51 (17.4)**	**29 (16.6)**	**50 (17.1)**

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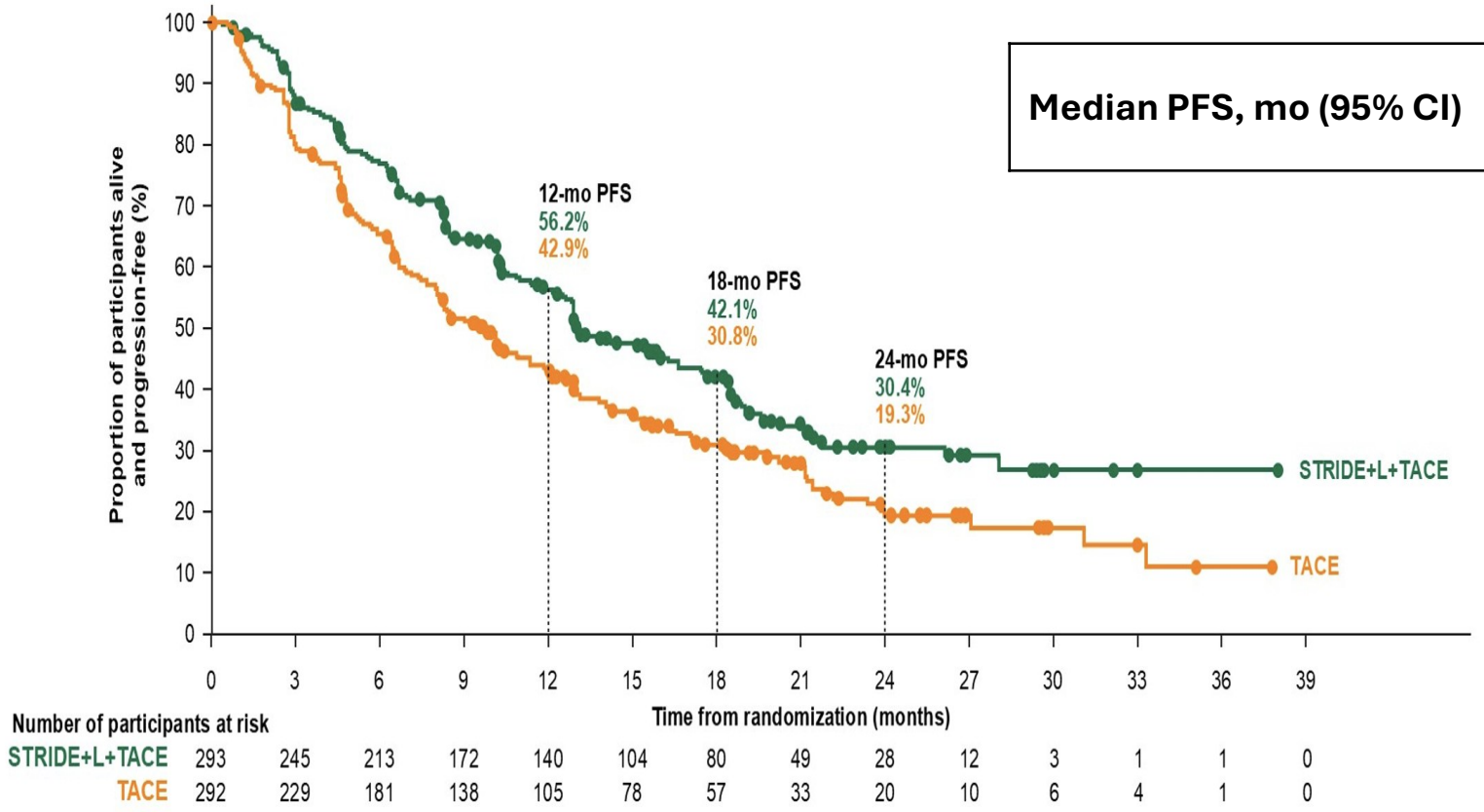
KEY DATA

EMERALD-3: Tremelimumab + Durvalumab (STRIDE) ± Lenvatinib (L) + Transarterial Chemoembolization (TACE) vs TACE Alone in Hepatocellular Carcinoma (HCC)

Primary Endpoint: Progression-free survival (PFS), STRIDE + L + TACE vs TACE



	STRIDE + L + TACE (n=293)	TACE (n=292)
Median PFS, mo (95% CI)	**13.0** (12.2-16.7)	9.8 (8.0-11.4)
	HR 0.70 (0.57–0.86); **P=0.0007**	

PFS maturity: 63.8%
Median follow-up: 11.0 vs 8.2 mo

mPFS, **STRIDE + TACE** vs **TACE:**

- Key secondary endpoint
- **Median: 12.9** vs 8.1 months
- **HR 0.71** (95% CI, 0.56-0.91)
- Nominal P=0.0062
- Formal statistical testing not yet done

PFS maturity: 75.1%

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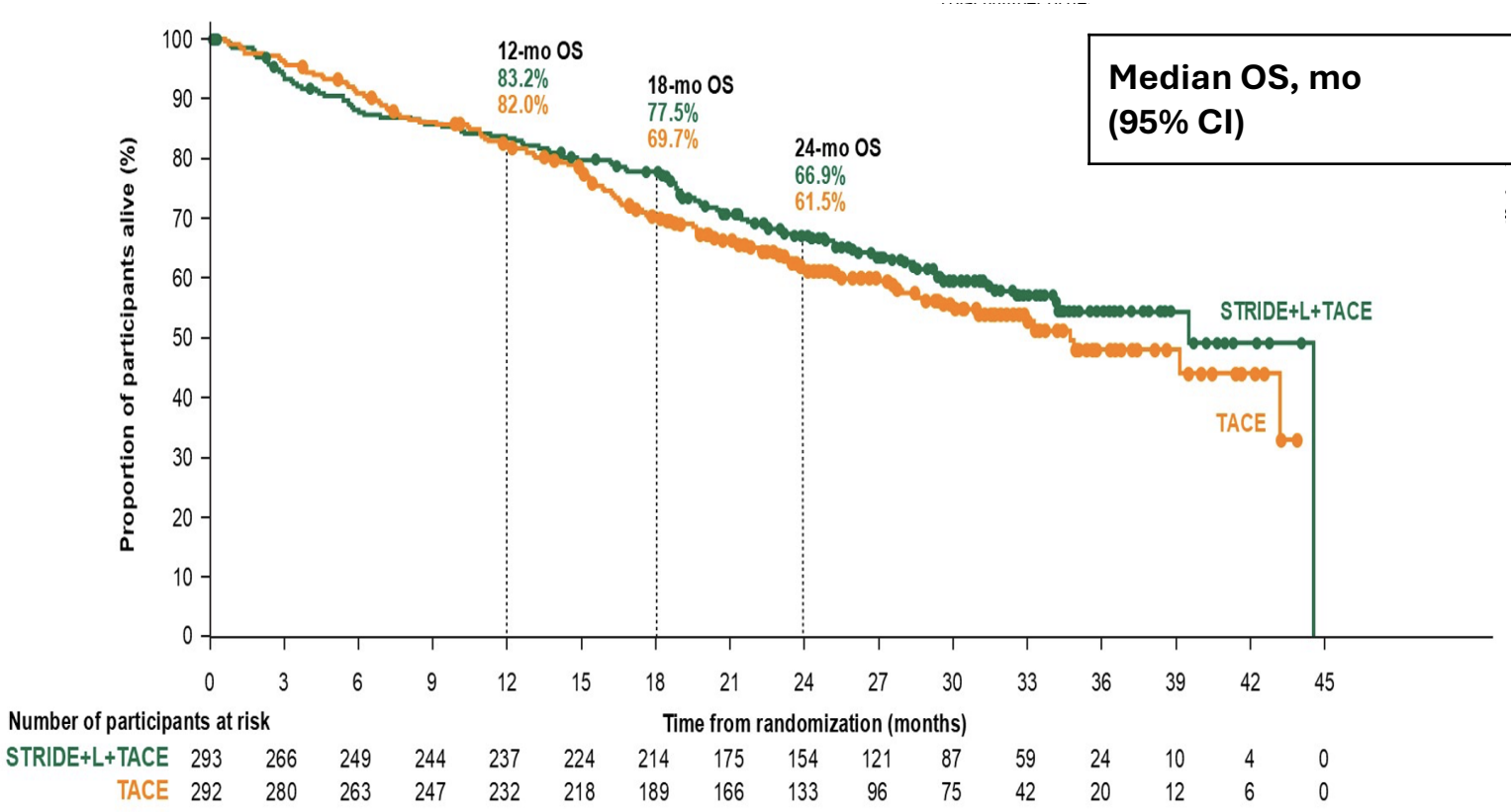
KEY DATA

EMERALD-3: Tremelimumab + Durvalumab (STRIDE) ± Lenvatinib (L) + Transarterial Chemoembolization (TACE) vs TACE Alone in Hepatocellular Carcinoma (HCC)

Key secondary endpoint: Overall survival (OS), STRIDE + L + TACE vs TACE



	STRIDE + L + TACE (n=293)	TACE (n=292)
Median OS, mo (95% CI)	**39.5** (34.1-not calculable)	34.7 (28.8-not calculable)
	HR 0.84 (0.65–1.09); P=0.1814	

OS maturity: 40.3%
Median follow-up: 24.6 vs 22.9 mo

OS, **STRIDE + TACE** vs **TACE:**

- **median: not calculable** vs 32.9 months
- **HR 0.70** (95% CI, 0.51-0.95)
- Nominal P=0.0233
- Formal statistical testing not yet done
- **24-mo rate: 68.0%** vs 57.8%

OS maturity: 45.4%

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SUMMARY

EMERALD-3

- Tremelimumab + durvalumab + lenvatinib + TACE improved progression-free survival (PFS) vs TACE alone in patients with embolization-eligible hepatocellular carcinoma
  - Favorable overall survival (OS) trend was observed at interim analysis
- Improvements in PFS and OS suggest tremelimumab + durvalumab as driver of efficacy; formal statistical analysis vs TACE alone has not yet been done
- Safety profile was consistent with that of individual drugs

IMPACT

A STRIDE-based regimen improves clinical outcomes when combined with TACE, supporting movement of systemic therapies earlier in the treatment paradigm for hepatocellular carcinoma

Builds on the HIMALAYA Phase III trial – different patient population

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Do you have an interventional radiologist and are you likely to consider the EMERALD-3 regimen?

1. Yes – have access to an interventional radiologist and would you consider the EMERALD-3 regimen
2. No – do not have access to an interventional radiologist
3. No – would not consider the EMERALD-3 regimen

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Key Studies

Breast

- ASCENT-04
- ASCENT-03
- TROPION-Breast02
- DESTINY-Breast05

Rapid Reviews

- SERENA-6
- persevERA
- KEYNOTE-522

GU/GI

- RASolute 302*
- EMERALD-3
- PROTEUS*
- TALAPRO-3

Other Notable Studies

- frontMIND
- MajesTEC-9
- HARMONi-6*
- LIBERTTO-432*

Rapid Reviews

- SARC041*

*Plenary Session

CLINICAL QUESTION

PROTEUS*

*Plenary Session

Can perioperative treatment with the androgen receptor pathway inhibitor apalutamide (APA) and androgen deprivation therapy become a new standard of care in high-risk localized prostate cancer?

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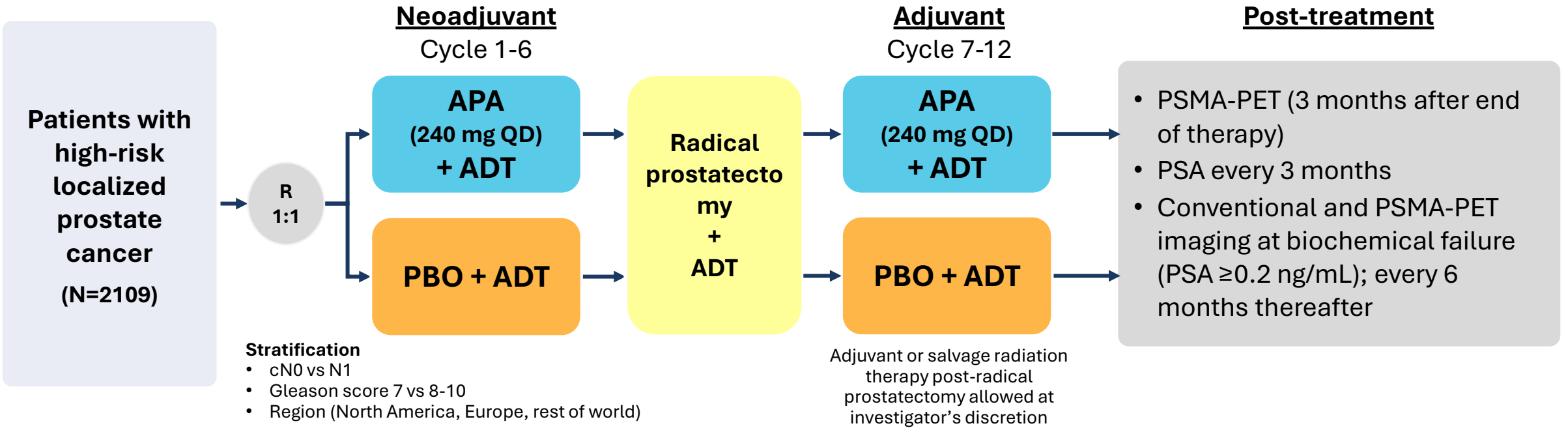
KEY DATA

PROTEUS: Neoadjuvant and Adjuvant Apalutamide (APA) + Androgen Deprivation Therapy (ADT) vs Placebo (PBO) + ADT in High-Risk Localized Prostate Cancer

Study Design: Phase 3, randomized, double-blind, placebo-controlled study



Dual primary endpoints:
- Pathological complete response (pCR)/Minimal residual disease (MRD) (ypT0 or ≤ypT2; ≤5 mm tumor)
- Metastasis-free survival (MFS) (by conventional or PSMA-PET imaging or histopathology, or death)

Secondary endpoints (in hierarchical testing order):
- Event Free Survival (EFS), time to subsequent therapy, time to distant metastasis by conventional or PSMA-PET imaging, no evidence of disease at 4 years, MFS by conventional imaging, time to PSA-free survival with testosterone recovery

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KEY DATA

PROTEUS: Neoadjuvant and Adjuvant Apalutamide (APA) + Androgen Deprivation Therapy (ADT) vs Placebo (PBO) + ADT in High-Risk Localized Prostate Cancer

Baseline Characteristics

		APA + ADT (n=1057)	PBO + ADT (n=1052)
Median age, years (IQR)		66.0 (62-71)	66.0 (61-70)
≥75, n (%)		106 (10.0)	94 (8.9)
Gleason score at initial diagnosis, n (%)	7	45 (4.3)	44 (4.2)
	≥8	1012 (95.7)	1008 (95.8)
Baseline prostate-specific antigen (PSA) PSA before first dose was the closest value assessment on or prior to ADT or APA start date	Median (IQR), ng/mL	14.4 (8.3-29.2)	15.1 (8.1-33.7)[c]
	<20, n (%)	630 (61.5)	604 (58.5)
	≥20, n (%)	395 (38.5)	429 (41.5)
Tumor stage at diagnosis, n (%)	≤T2	684 (64.7)	667 (63.4)
	≥T3	371 (35.1)	377 (35.8)
Regional lymph node stage at diagnosis, n (%)	N0	928 (87.8)	922 (87.6)
	N1	129 (12.2)	130 (12.4)

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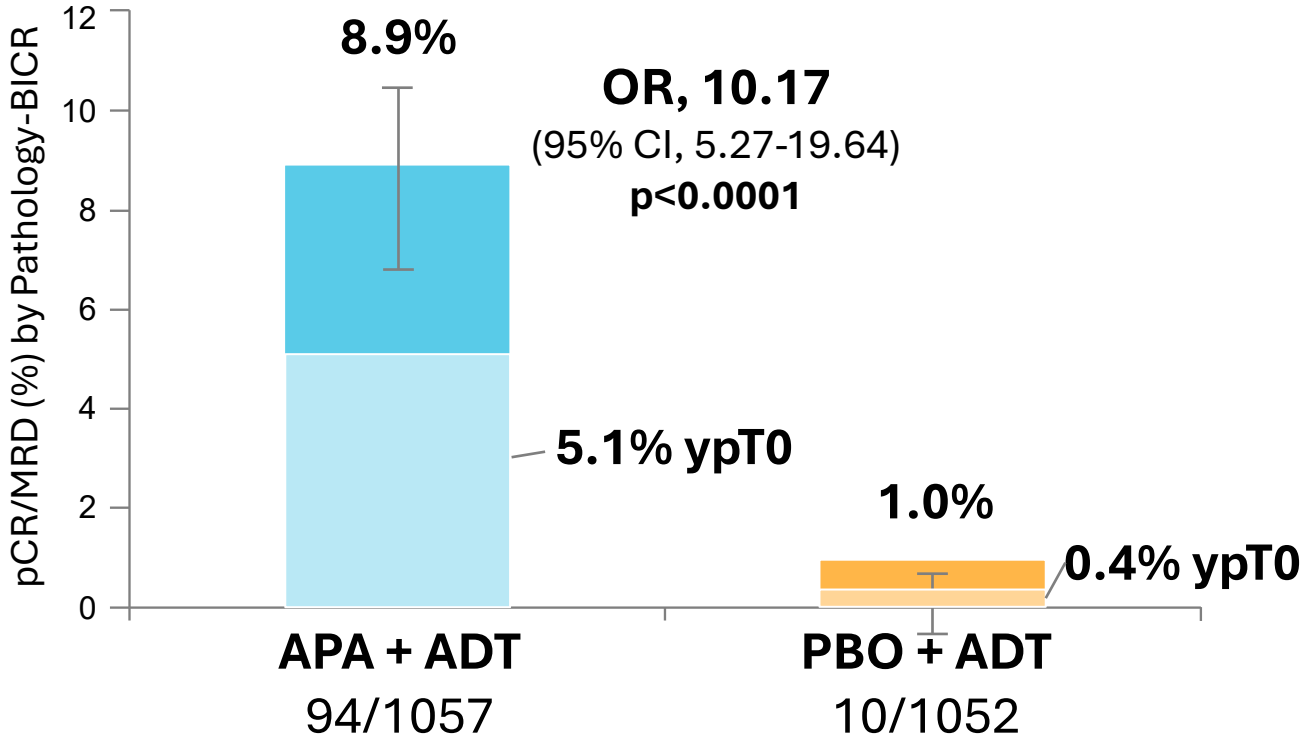
KEY DATA

PROTEUS: Neoadjuvant and Adjuvant Apalutamide (APA) + Androgen Deprivation Therapy (ADT) vs Placebo (PBO) + ADT in High-Risk Localized Prostate Cancer

Dual Primary Endpoint: Pathological complete response (pCR)/Minimal residual disease (MRD)



9-fold improvement in pCR/MRD at radical prostatectomy after 6 cycles of neoadjuvant APA + ADT vs PBO + ADT

Corroborated by exploratory endpoint of **residual cancer burden (RCB)** (≤ypT2, N0, ≤0.25 cm^3):

- APA + ADT vs PBO + ADT, 30.6% vs 11.7%
- OR 3.36 (95% CI, 2.67-4.23), P <0.0001

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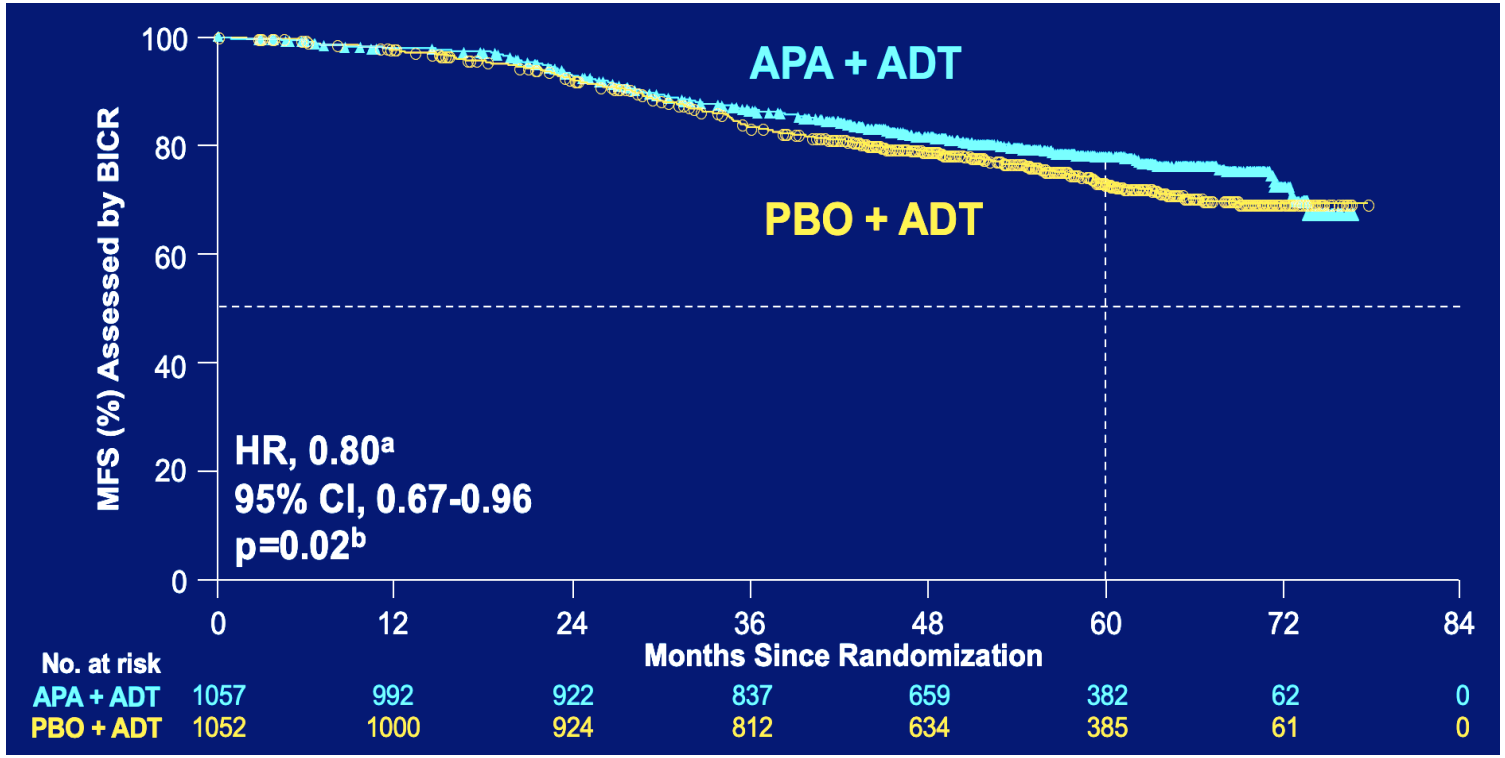
KEY DATA

PROTEUS: Neoadjuvant and Adjuvant Apalutamide (APA) + Androgen Deprivation Therapy (ADT) vs Placebo (PBO) + ADT in High-Risk Localized Prostate Cancer

Dual Primary Endpoint: Metastasis-free survival (MFS) by conventional or PSMA-PET imaging



20% reduction in risk of metastasis or death after 1 year of perioperative APA + ADT with radical prostatectomy by BICR

Consistent with investigator-assessed MFS:

- HR 0.74 (95% CI, 0.62-0.87), P=0.0004

MFS: Time to first occurrence of radiographic distant metastasis based on conventional imaging or PSMA-PET imaging, pathologic finding of distant metastasis, or death from any cause

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KEY DATA

PROTEUS: Neoadjuvant and Adjuvant Apalutamide (APA) + Androgen Deprivation Therapy (ADT) vs Placebo (PBO) + ADT in High-Risk Localized Prostate Cancer

Secondary Endpoints

	APA + ADT	PBO + ENZA
Event-free survival Time to first biochemical failure (PSA progression) or local or regional recurrences or distant metastasis, or death by any cause	**57.1 mo**	38.4 mo
	HR 0.71 (95% CI, 0.63-0.80); **P<0.0001**	
Time to first subsequent therapy Time to local, regional, or systemic therapy, including reinitiation of ADT	**74.2 mo**	41.5 mo
	HR 0.65 (95% CI, 0.57-0.73); **P<0.0001**	
Patients without distant metastasis on conventional or PSMA-PET imaging at 3 y	**82.8%** (95% CI, 80.0-85.2%)	76.2% (95% CI, 73.2-79.0%)
	HR 0.68 (95% CI, 0.55-0.83); **P=0.0002**	
Metastasis-free survival by conventional imaging, 3-y rate Patients progressing on PSMA-PET and receiving subsequent treatments are included in this analysis which may delay onset of metastasis on conventional imaging	**87.1%** (95% CI, 84.8-89.2%)	83.9% (95% CI, 81.2-86.2%)
	HR 0.84 (95% CI, 0.67-1.07); P=0.15	

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KEY DATA

PROTEUS: Neoadjuvant and Adjuvant Apalutamide (APA) + Androgen Deprivation Therapy (ADT) vs Placebo (PBO) + ADT in High-Risk Localized Prostate Cancer

Safety

Summary of adverse events (AEs)		APA + ADT (n=1050)	PBO + ADT (n=1050)
All grades	**Treatment-related AE**	1000 (95.2)	985 (93.8)
Grade 3/4	Treatment-related AEs	**289 (27.5)**	198 (18.9)
	Treatment-related AEs leading to dose reduction	**118 (11.2)**	24 (2.3)
	Treatment-related AEs leading to dose interruption	**126 (12.0)**	46 (4.4)
All grades	**Treatment-related AEs leading to death*** *Includes grade 5 events; AEs leading to death are based on AE outcome of fatal	7 (0.7)	1 (0.1)

Select treatment-emergent AEs (TEAEs) of special interest, n (%)	APA + ADT (n=1050)		PBO + ADT (n=1050)	
	All Grades	Grade ≥3	All Grades	Grade ≥3
≥1 TEAE of special interest	398 (37.9)	90 (8.6)	214 (20.4)	23 (2.2)
• Skin rash	**346 (33.0)**	**62 (5.9)**	161 (15.3)	3 (0.3)
• Ischemic heart disease	25 (2.4)	**13 (1.2)**	22 (2.1)	9 (0.9)
• Fatigue	**291 (27.7)**	4 (0.4)	**281 (26.8)**	1 (0.1)

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SUMMARY

PROTEUS

- In high-risk localized prostate cancer, 1 year of neoadjuvant/adjuvant apalutamide + ADT improved outcomes compared to placebo + ADT, including:
  - Significantly improved metastasis-free survival
  - Significant improvement in major pathological response at prostatectomy
  - Significant improvement in event-free survival, and delayed time to subsequent therapy
- Tolerability of apalutamide + ADT was consistent with prior studies

IMPACT

Apalutamide + ADT as a perioperative therapy is a potential new standard of care in high-risk localized prostate cancer

Not approved for perioperative treatment around prostatectomy

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How likely are you to incorporate perioperative apalutamide + ADT (PROTEUS) for patients with high-risk localized prostate cancer undergoing radical prostatectomy, if approved?

1. Very likely
2. Somewhat likely
3. Not likely

Care coordination with urologists?

***Question remains**: Is perioperative apalutamide plus ADT better than going straight to surgery without systemic therapy?*

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Key Studies

Breast

- ASCENT-04
- ASCENT-03
- TROPION-Breast02
- DESTINY-Breast05

Rapid Reviews

- SERENA-6
- persevERA
- KEYNOTE-522

GU/GI

- RASolute 302*
- EMERALD-3
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- TALAPRO-3

Other Notable Studies

- frontMIND
- MajesTEC-9
- HARMONi-6*
- LIBERTTO-432*

Rapid Reviews

- SARC041*

*Plenary Session

CLINICAL QUESTION

TALAPRO-3

Can PARP inhibition be moved earlier in the treatment of metastatic prostate cancer to benefit biomarker-selected (HRR+) patients?

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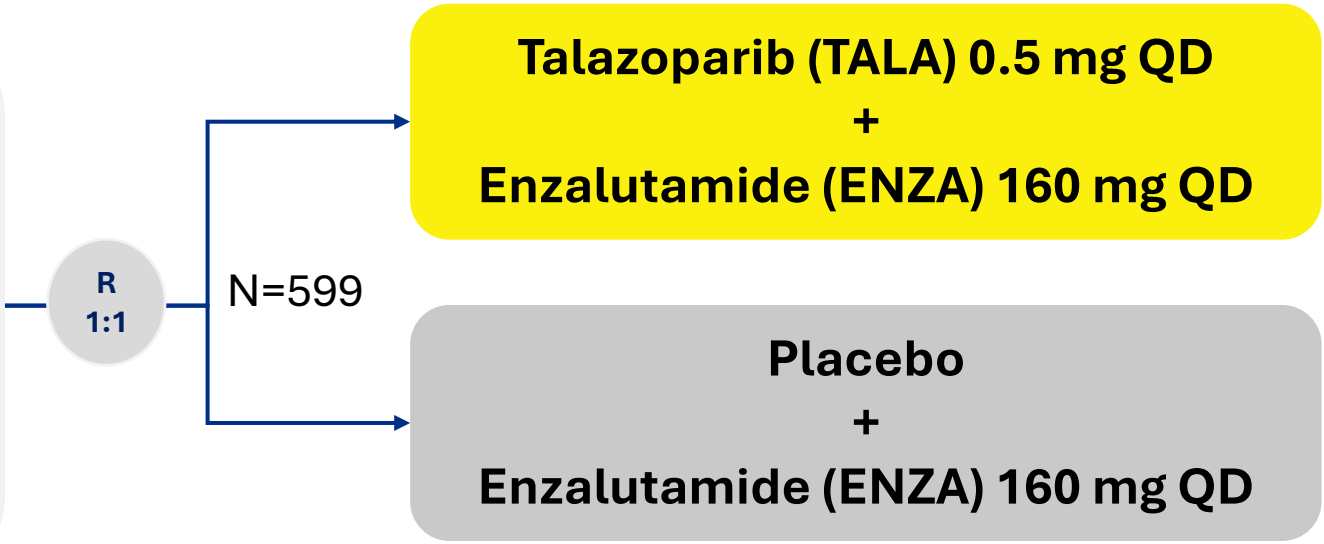
KEY DATA

TALAPRO-3: Talazoparib (TALA) + Enzalutamide (ENZA) vs Placebo (PBO) + Enzalutamide in HRR+ Metastatic Castration-Sensitive Prostate Cancer (mCSPC)

Study Design: Phase 3, randomized study

- HRR gene-altered mCSPC:
  - *ATM, ATR, BRCA1, CDK12, CHEK2, FANCA, MLH1, MRE11A, NBN, PALB2, RAD51C*
- ECOG PS 0-1
- Ongoing androgen deprivation therapy (ADT)
- ≤3 months of prior ADT ± androgen receptor pathway inhibitor (ARPI) for mCSPC
- Prior docetaxel for mCSPC not permitted



Data cutoff: February 18, 2026

Primary endpoint: Radiographic progression-free survival (rPFS) by investigator
Key secondary endpoint: Overall survival (OS; alpha-protected)
Other secondary endpoints: Overall response rate (ORR per RECIST v1.1), duration of soft tissue response, prostate specific antigen (PSA) response, time to PSA progression, time to subsequent antineoplastic therapy, time to first symptomatic skeletal event (SSE), safety, patient-reported outcomes (PROs)

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KEY DATA

TALAPRO-3: Talazoparib (TALA) + Enzalutamide (ENZA) vs Placebo (PBO) + Enzalutamide in HRR+ Metastatic Castration-Sensitive Prostate Cancer (mCSPC)

Baseline Characteristics

	TALA + ENZA (N=300)	PBO + ENZA (N=299)
Median age, y (range)	70 (45-89)	69 (44-86)
Median PSA level, ng/mL	3.6 (0-1483)	3.6 (0-2282)
Disease status, n (%)		
• *De novo*	252 (84)	254 (85)
Disease volume, n (%)		
• High	211 (70)	212 (71)
Gleason score, n (%)		
• ≥8	245 (82)	245 (82)
Disease site, n (%)		
• Bone only	86 (29)	96 (32)
• Soft tissue only	38 (13)	27 (9)
• Bone and soft tissue	176 (59)	173 (58)

Baseline HRR Alterations

	TALA + ENZA (N=300)	PBO + ENZA (N=299)
HRR gene alteration, n (%)		
• ***BRCA1/2***	**104 (35)**	**103 (34)**
• Other	196 (65)	196 (66)
Select ≥1 alteration in corresponding HRR gene, n (%)		
• ***ATM***	**87 (29)**	**80 (27)**
• *ATR*	23 (8)	18 (6)
• *BRCA1*	16 (5)	11 (4)
• ***BRCA2***	**86 (29)**	**92 (31)**
• ***CDK12***	**55 (18)**	**60 (20)**
• ***CHEK2***	**44 (15)**	**44 (15)**
• *FANCA*	10 (3)	6 (2)

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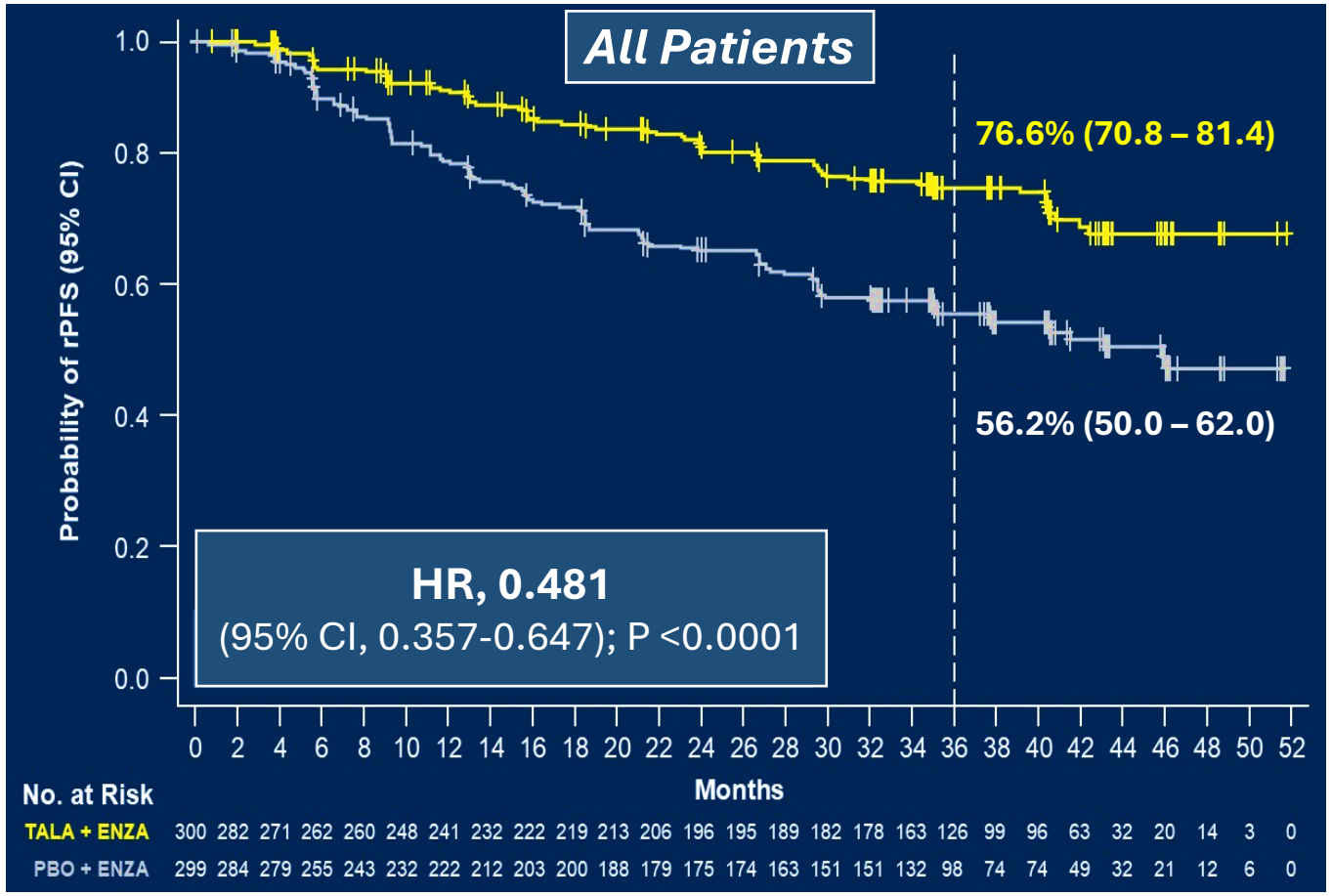
KEY DATA

TALAPRO-3: Talazoparib (TALA) + Enzalutamide (ENZA) vs Placebo (PBO) + Enzalutamide in HRR+ Metastatic Castration-Sensitive Prostate Cancer (mCSPC)

Primary Endpoint: Investigator-assessed radiographic progression-free survival (rPFS)



	TALA + ENZA (N=300)	PBO + ENZA (N=299)
Events, n	67	126
Median rPFS, mo (95% CI)	**NR** (NR-NR)	**45.8** (37.7-NR)

TALA + ENZA led to 52% reduction in risk of progression or death

Median follow-up, mo	**37.6**	**37.7**

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KEY DATA

TALAPRO-3: Talazoparib (TALA) + Enzalutamide (ENZA) vs Placebo (PBO) + Enzalutamide in HRR+ Metastatic Castration-Sensitive Prostate Cancer (mCSPC)

Radiographic progression-free survival (rPFS) across subgroups

	N of events/patients		
	TALA + ENZA	**PBO + ENZA**	**HR (95% CI)**
Disease stage			
• **De novo**	58/252	113/254	**0.464** (0.338-0.637)
• Relapsed	9/48	13/45	0.697 (0.289-1.594)
Disease volume			
• **High**	52/211	107/212	**0.422** (0.303-0.588)
• Low	15/89	19/87	0.808 (0.410-1.590)
Age			
• ≥70 years	37/156	64/147	0.502 (0.335-0.753)
• **<70 years**	30/144	62/152	0.460 (0.297-0.712)
Site of metastasis			
• Bone only	14/86	27/96	0.546 (0.286-1.042)
• **Soft tissue only**	6/38	12/27	**0.318** (0.118-0.852)
• Bone and soft tissue	47/176	87/173	0.474 (0.332-0.676)
Gleason score			
• <8	8/45	14/49	0.599 (0.251-1.429)
• **≥8**	56/245	111/245	**0.449** (0.326-0.620)
Baseline prostate specific antigen			
• ≤Median	29/150	51/149	0.527 (0.334-0.831)
• >Median	38/150	75/149	0.446 (0.302-0.660)

	N of events/patients		
	TALA + ENZA	**PBO + ENZA**	**HR (95% CI)**
***BRCA1/2* alterations**			
• **Yes**	22/104	49/103	**0.368** (0.222-0.609)
• No	45/196	77/196	0.567 (0.392-0.819)
HRR gene subgroups*			
• ***ATM***	16/80	33/77	**0.433** (0.238-0.786)
• *ATR*	3/19	2/14	0.786 (0.131-4.711)
• *BRCA1*	5/15	6/12	0.706 (0.215-2.321)
• ***BRCA2***	17/87	45/97	**0.353** (0.202-0.617)
• ***CDK12***	8/51	29/55	**0.275** (0.125-0.603)
• *CHEK2*	12/44	19/44	0.626 (0.304-1.290)
• ***FANCA***	6/10	1/6	**4.277** (0.512-35.752)

*Analyses included all available tumor and baseline ctDNA records. For non-*BRCA*m, those with co-occurring *BRCA1/2*m were excluded. For *BRCA1*m, those with co-occurring *BRCA2*m were excluded.
Note: MLH1, MRE11A, NBN, PALB2, RAD51C were not evaluable

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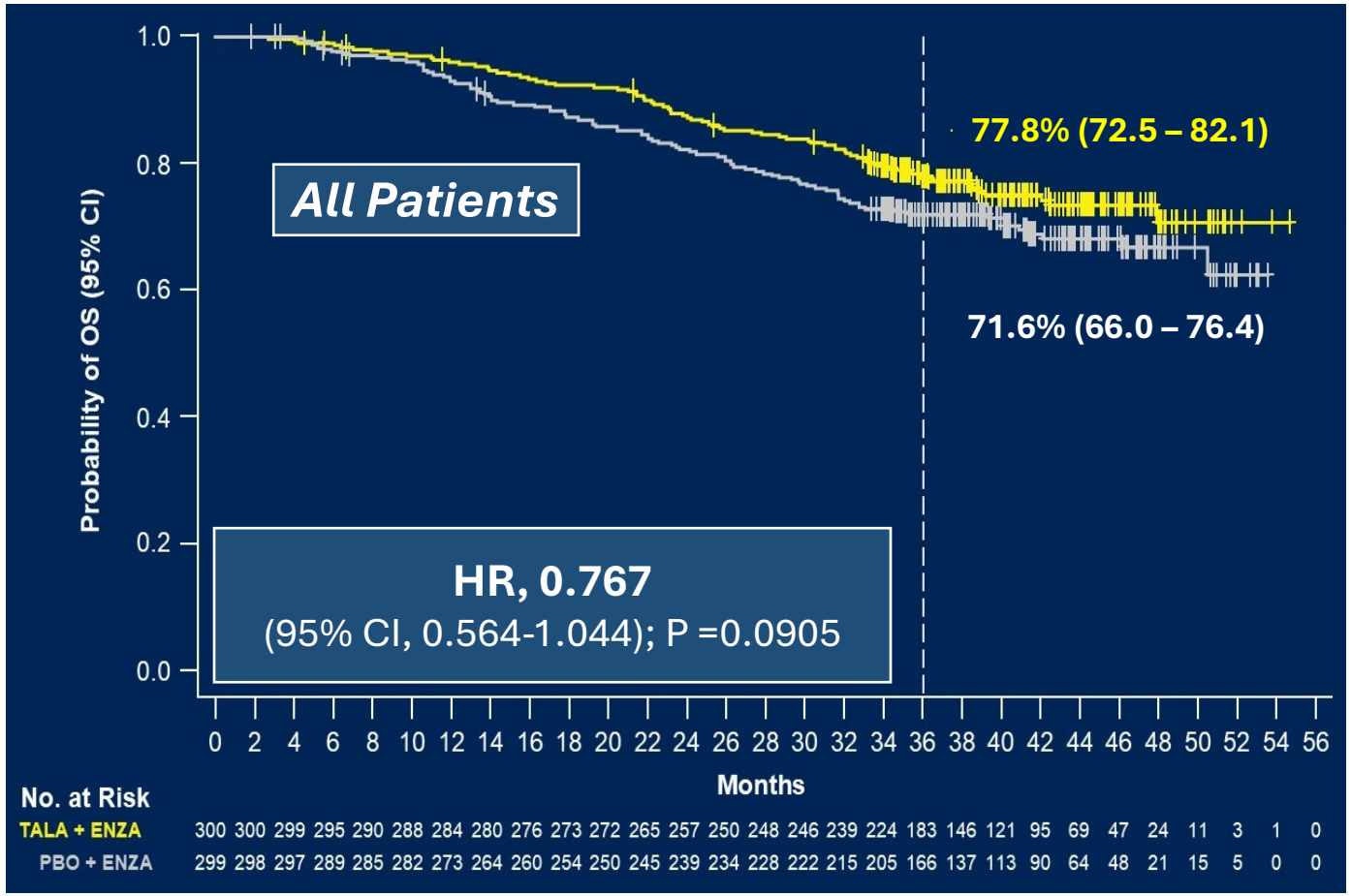
KEY DATA

TALAPRO-3: Talazoparib (TALA) + Enzalutamide (ENZA) vs Placebo (PBO) + Enzalutamide in HRR+ Metastatic Castration-Sensitive Prostate Cancer (mCSPC)

Key Secondary Endpoint: Overall survival (OS) (Interim Analysis)



	TALA + ENZA (N=300)	PBO + ENZA (N=299)
Events, n	74	91
Median OS, mo (95% CI)	**NR** (NR-NR)	**NR** (NR-NR)

Interim OS trend favors TALA + ENZA

Median follow-up, mo	40.5	41.1

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KEY DATA

TALAPRO-3: Talazoparib (TALA) + Enzalutamide (ENZA) vs Placebo (PBO) + Enzalutamide in HRR+ Metastatic Castration-Sensitive Prostate Cancer (mCSPC)

Secondary Endpoints

	TALA + ENZA	PBO + ENZA
Prostate specific antigen (PSA) response	(n=300)	(n=299)
PSA response rate, % (95% CI)	**90.5** (86.5-93.5)	86.5 (82.0-90.1)
Median time to PSA progression, mo (95% CI)	NR (NR-NR)	NR (NR-NR)
	HR 0.513 (95% CI, 0.370-0.712); **P<0.0001**	
3-y PSA progression, % (95% CI)	**78.3** (72.6-82.9)	62.7 (56.3-68.4)
Tumor response	(n=99)	(n=109)
Overall response rate, % (95% CI)	**74.7 (64.8-82.7)**	**67.0 (57.2-75.5)**
Complete response, n/N (%)	**23 (23)**	15 (14)
Partial response, n/N (%)	51 (52)	58 (53)
Stable disease, n/N (%)	22 (22)	29 (27)
Median duration of response (DoR), mo (95% CI)	**NR** (NR-NR)	27.2 (19.5-39.6)
3-y DoR, % (95% CI)	**71.7** (58.6-81.3)	42.6 (30.2-54.4)
Time to subsequent antineoplastic therapy	(n=300)	(n=299)
Median time to therapy initiation, mo (95% CI)	**NR** (NR-NR)	NR (46.9-NR)
	HR 0.514 (95% CI, 0.378-0.689); **P<0.0001**	
3-y therapy initiation rate, % (95% CI)	**78.6** (73.3-82.9)	62.0 (56.0-67.5)

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TALAPRO-3: Talazoparib (TALA) + Enzalutamide (ENZA) vs Placebo (PBO) + Enzalutamide in HRR+ Metastatic Castration-Sensitive Prostate Cancer (mCSPC)

Safety Summary

	TALA + ENZA (n=299)	PBO + ENZA (n=295)
Any TEAE, n (%)	297 (99)	286 (97)
Serious AEs, n (%)	126 (42)	93 (32)
Grade 3-4 TEAEs, n (%)	**235 (79)**	**121 (41)**
Grade 5 TEAEs, n (%)	8 (3)	9 (3)

In the TALA arm, most common TEAE was anemia (Grade 1-2, 20%; Grade 3-4, 51%)

- At baseline, 43% had Grade 1-2 anemia
- Median time to onset of Grade 3-4 anemia: 3.2 months
- 40% received packed RBC transfusion
- Median duration of TALA treatment was **34.2** months for patients with Grade 3-4 anemia and **35.9** months for patients without Grade 3-4 anemia
- 14% had recurrent Grade 3-4 anemia after TALA dose reduction
- 5% permanently discontinued TALA due to anemia

AEs of special interest

- 3 patients with MDS in TALA arm (vs 1 in PBO arm), and 2 with AML (vs 0)
- 7 patients with venous embolic and thrombotic events in TALA arm (vs 5 in PBO arm)

*Includes 1 death due to pancytopenia and 1 due to worsening of idiopathic pulmonary fibrosis

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SUMMARY

TALAPRO-3

- Talazoparib + Enzalutamide (TALA + ENZA) led to rPFS benefit (HR 0.48) vs ENZA control in HRR gene-altered mCSPC
  - rPFS benefit consistent across clinical subgroups, including BRCAm (HR 0.37) and non-BRCAm (HR 0.57)
- Interim OS trended in favor of TALA + ENZA; time to PSA progression and time to subsequent antineoplastic therapy aligned with primary rPFS result
- Most common AEs were hematologic (anemia and decreased neutrophil count) and fatigue

IMPACT

TALA + ENZA is a potential treatment option in HRR gene-altered mCSPC, emphasizing importance of early molecular testing

Not yet FDA approved

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How likely are you to incorporate talazoparib plus enzalutamide into first-line treatment for eligible patients with HRR-altered metastatic castration-sensitive prostate cancer?

1. Very likely
2. Somewhat likely
3. Not likely

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ASCO 2026:
GU/GI Cancer

Key Takeaways

Q&A
@SujithKalmadiMD

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RASolute-302: Daraxonrasib demonstrated statistically significant and clinically meaningful improvements in OS, PFS, and ORR in patients with previously treated metastatic PDAC and was better tolerated than standard chemotherapy (watch for rash, diarrhea, nausea and stomatitis)

May 1, 2026: FDA approved expanded access

EMERALD-3: first Phase 3 trial to show that combining STRIDE with TACE improves outcomes in embolization-eligible unresectable HCC and supports this approach as a potential new standard treatment option pending longer-term OS follow-up; adding lenvatinib did not increase benefit

Not yet FDA approved

PROTEUS: perioperative apalutamide + ADT significantly increases the likelihood of a major pathologic response and reduces the risk of future metastatic disease compared with ADT alone in high-risk localized or locally advanced prostate cancer undergoing surgery;)

Not yet FDA approved

TALAPRO-3: adding talazoparib (a PARP inhibitor) to enzalutamide plus androgen deprivation therapy (ADT) significantly prolonged radiographic progression-free survival (rPFS) in patients with metastatic castration-sensitive prostate cancer (mCSPC) harboring homologous recombination repair (HRR) gene alterations

Not yet FDA approved

Key Studies

Breast

- ASCENT-04
- ASCENT-03
- TROPION-Breast02
- DESTINY-Breast05

Rapid Reviews

- SERENA-6
- persevERA
- KEYNOTE-522

GU/GI

- RASolute 302*
- EMERALD-3
- PROTEUS*
- TALAPRO-3

Other Notable Studies

- frontMIND
- MajesTEC-9
- HARMONi-6*
- LIBRETTO-432*

Rapid Reviews

- SARC041*

*Plenary Session

CLINICAL QUESTION

frontMIND

Does tafasitamab (a monoclonal antibody) plus lenalidomide and R-CHOP benefit patients with newly diagnosed Diffuse Large-B-cell Lymphoma (DLBCL)?

Phase III results

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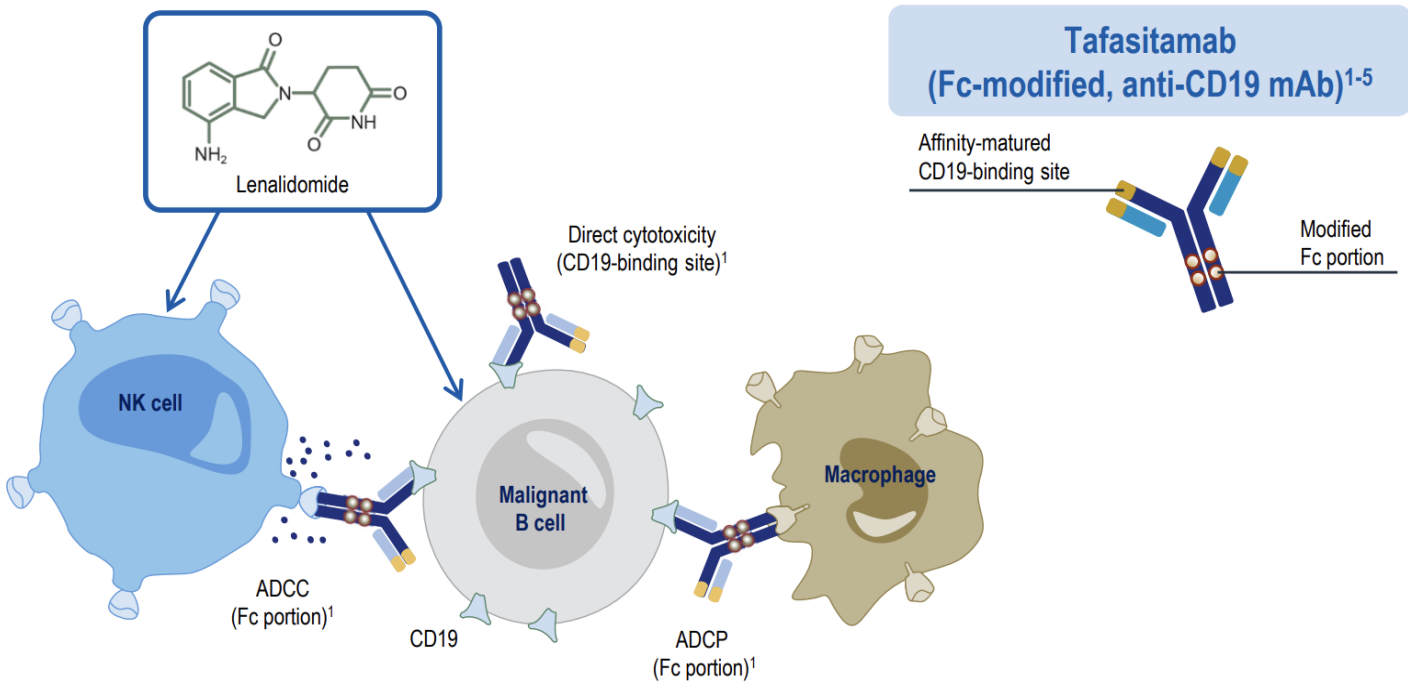
Background: Tafasitamab

- Tafasitamab, a monoclonal antibody, targets CD19 on malignant B cells
- The engineered Fc region increases affinity to immune effector cells
- Lenalidomide expands and activates effector cells and increases the ADCC, ADCP, and direct cell death caused by tafasitamab

Tafasitamab + Lenalidomide Synergy in DLBCL



ASCO 2026. Abstract LBA7000.
Lancet. 2026 Jun 20;407(10547):2528-2541

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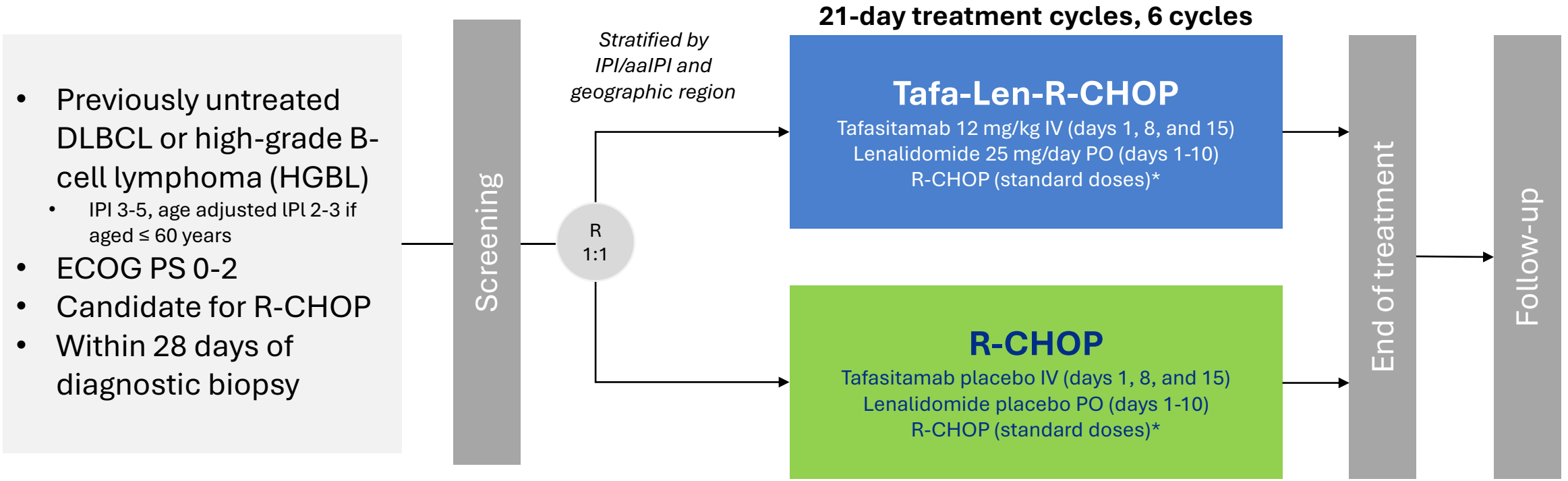
KEY DATA

frontMIND: 1L Tafasitamab + lenalidomide + R-CHOP in DLBCL

Study Design: Phase 3, global, multicenter, placebo-controlled, double-blinded, randomized study



Primary endpoint: Progression-free survival (PFS)
Secondary endpoints: Event-free survival (EFS) and overall survival (OS)
Select other secondary: PET-complete response at end of treatment, objective response rate at end of treatment, PFS by cell-of-origin subtypes, safety
Post-hoc analysis: PFS, EFS, OS for the population with centrally confirmed lymphoma subtypes

ASCO 2026. Abstract LBA7000.
Lancet. 2026 Jun 20;407(10547):2528-2541

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KEY DATA

frontMIND: 1L Tafasitamab + lenalidomide + R-CHOP in DLBCL

Baseline Characteristics

Overall ITT population, n (%)	Tafa-Len-R-CHOP (n=448)	R-CHOP (n=451)
Median age, years (range)	65.0 (20, 80)	65.0 (18, 80)
Male sex	240 (53.6)	233 (51.7)
Ann Arbor stage III or IV at enrollment	432 (96.4)	436 (96.7)
Extranodal involvement a ≥2 sites	173 (38.6)	175 (38.8)
Elevated lactate dehydrogenase level	369 (82.4)	376 (83.4)
Presence of bully disease	254 (56.7)	231 (51.2)
ECOG PS at screening		
• 0-1	311 (69.4)	305 (67.6)
• 2	137 (30.6)	146 (32.4)
Risk group (stratification factor)		
• High-intermediate risk (IPI 3/age adjusted IPI 2)	259 (57.8)	244 (54.1)
• High risk (IPI 4-5/age adjusted IPI 3)	186 (41.5)	202 (44.8)
Median time from diagnostic biopsy to treatment initiation, days (Q1-Q3)	23.5 (17, 28)	24.0 (18, 28)

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Lancet. 2026 Jun 20;407(10547):2528-2541

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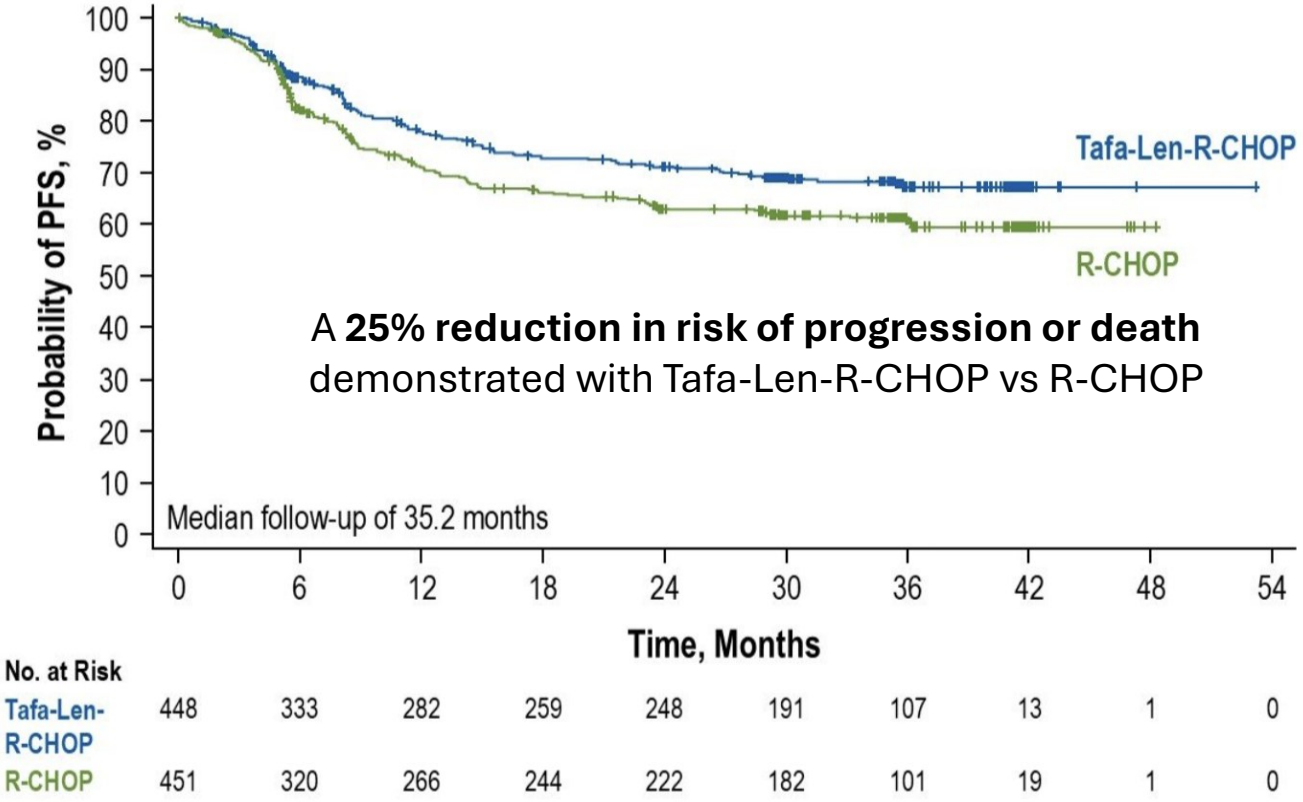
IPP: International Prognostic Index

KEY DATA

frontMIND: 1L Tafasitamab + lenalidomide + R-CHOP in DLBCL

Primary Endpoint: Progression-free survival (PFS) by investigator assessment



A **25% reduction in risk of progression or death** demonstrated with Tafa-Len-R-CHOP vs R-CHOP

n (%)	Tafa-Len-R-CHOP (n=448)		R-CHOP (n=451)
HR (95% CI)	**0.75*** (0.59 - 0.96), p=0.0194		
2-year PFS	**71.1%**	Δ 8.2%	62.9%
3-year PFS	**67.3%**	Δ 6.6%	60.7%

*Calculated using a stratified Cox proportional hazard model

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KEY DATA

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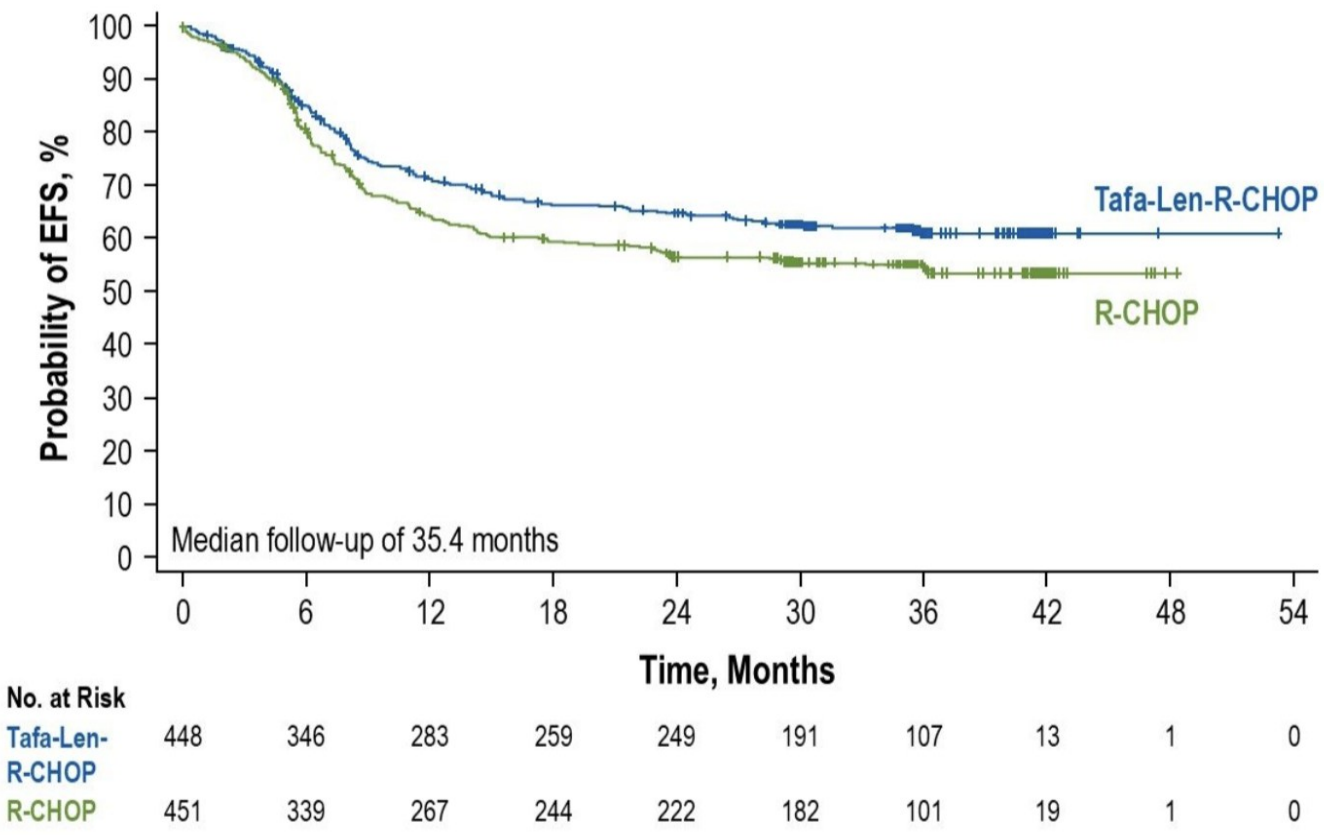
Key Secondary Endpoint: Event-free survival (EFS)



n (%)	Tafa-Len-R-CHOP (n=448)	R-CHOP (n=451)
HR (95% CI)	**0.79*** (0.64 - 0.97), p=0.0260	
2-year EFS	**65.0%**	56.7%
3-year EFS	**61.2%**	54.8%

*Calculated using a stratified Cox proportional hazard model

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KEY DATA

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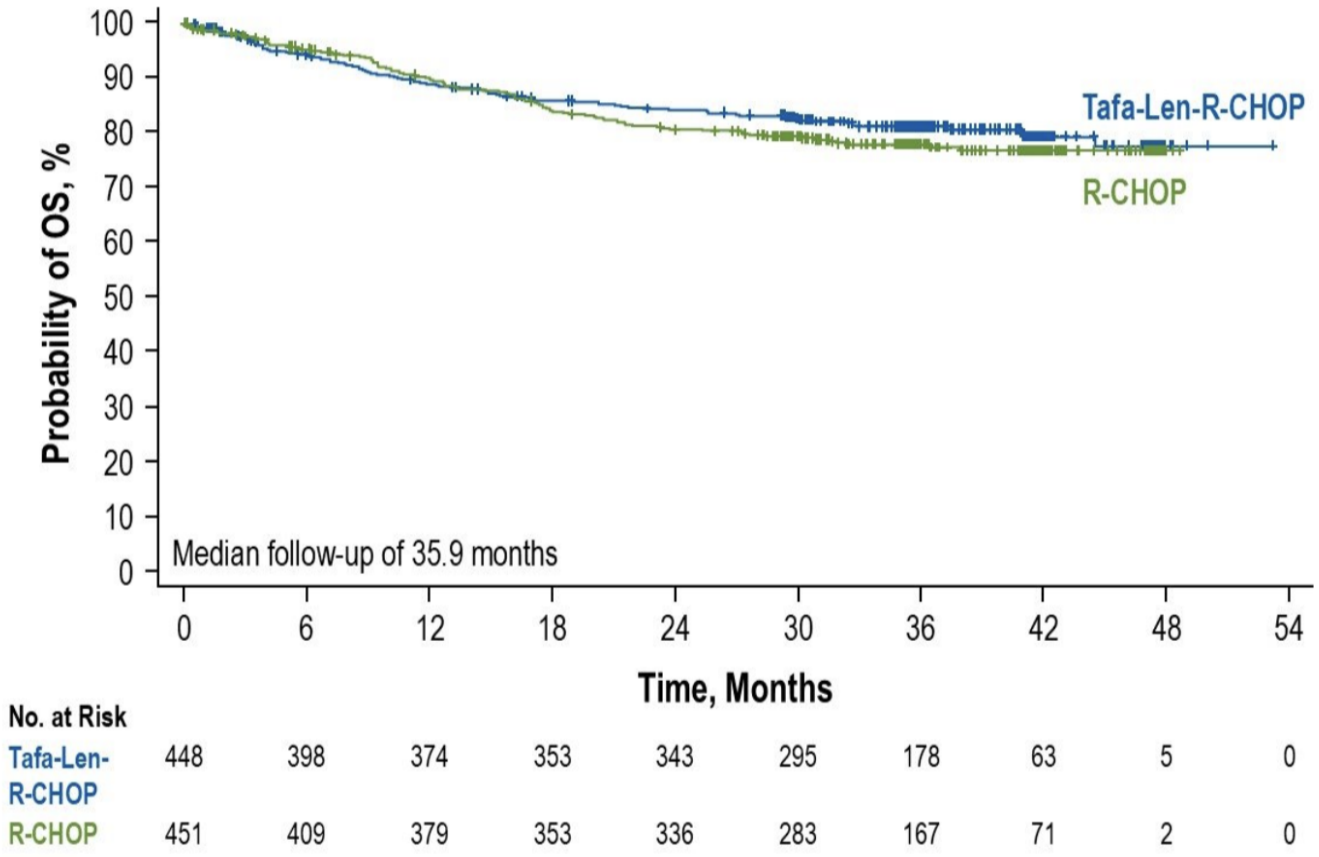
Key Secondary Endpoint: Overall survival



n (%)	Tafa-Len-R-CHOP (n=448)	R-CHOP (n=451)
HR (95% CI)	**0.85*** (0.63 - 1.14), p=0.2703	
2-year OS	**84.1%**	80.5%
3-year OS	**81.1%**	77.8%

*Calculated using a stratified Cox proportional hazard model

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Lancet. 2026 Jun 20;407(10547):2528-2541

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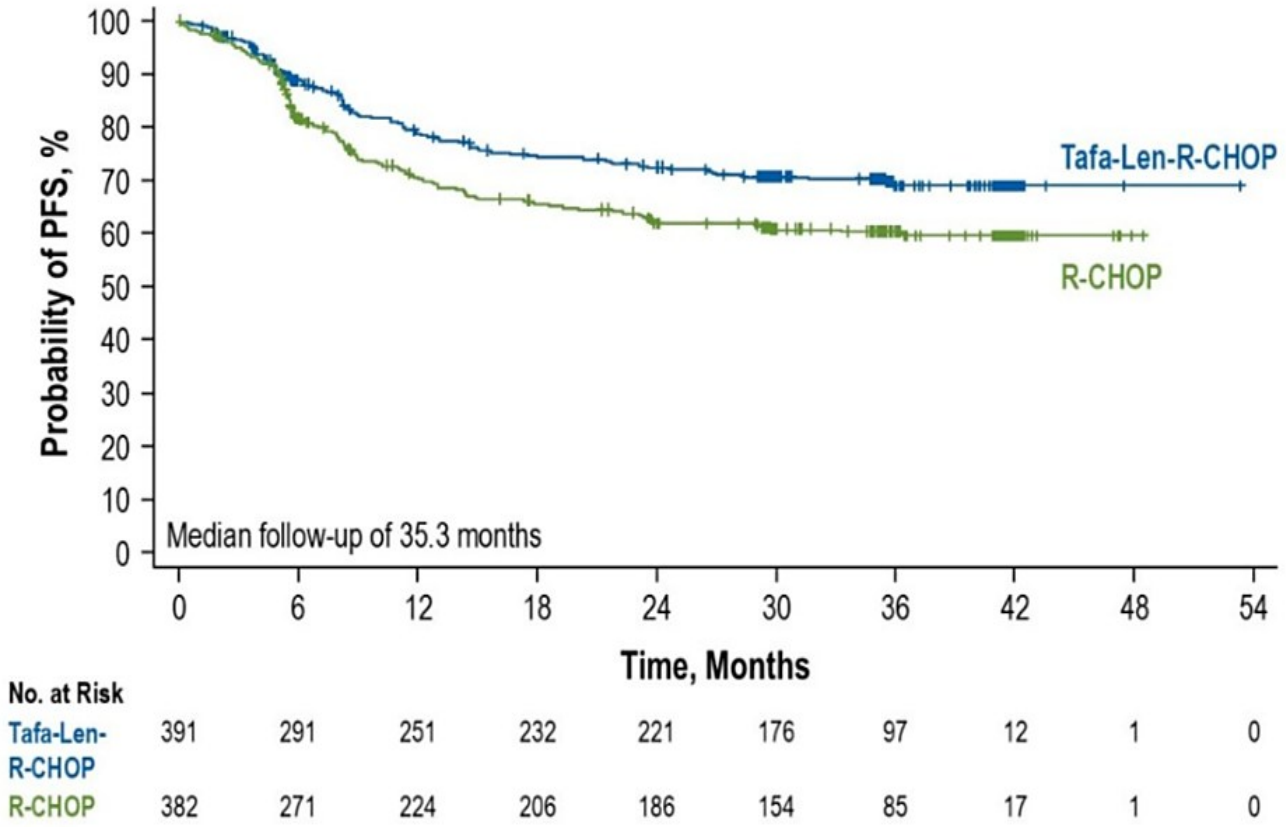
KEY DATA

frontMIND: 1L Tafasitamab + lenalidomide + R-CHOP in DLBCL

Post-hoc Analysis: PFS in Centrally Confirmed Lymphoma Subtypes



n (%)	Tafa-Len-R-CHOP (n=391)	R-CHOP (n=382)
HR (95% CI)	**0.68*** (0.52 – 0.88), p=0.0035	
2-year OS	**72.7%**	62.2%

Differences in 2-year PFS rates:
Δ=**10.5%** in centrally confirmed
Δ=**8.2%** in the ITT

*Calculated using a stratified Cox proportional hazard model

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Lancet. 2026 Jun 20;407(10547):2528-2541

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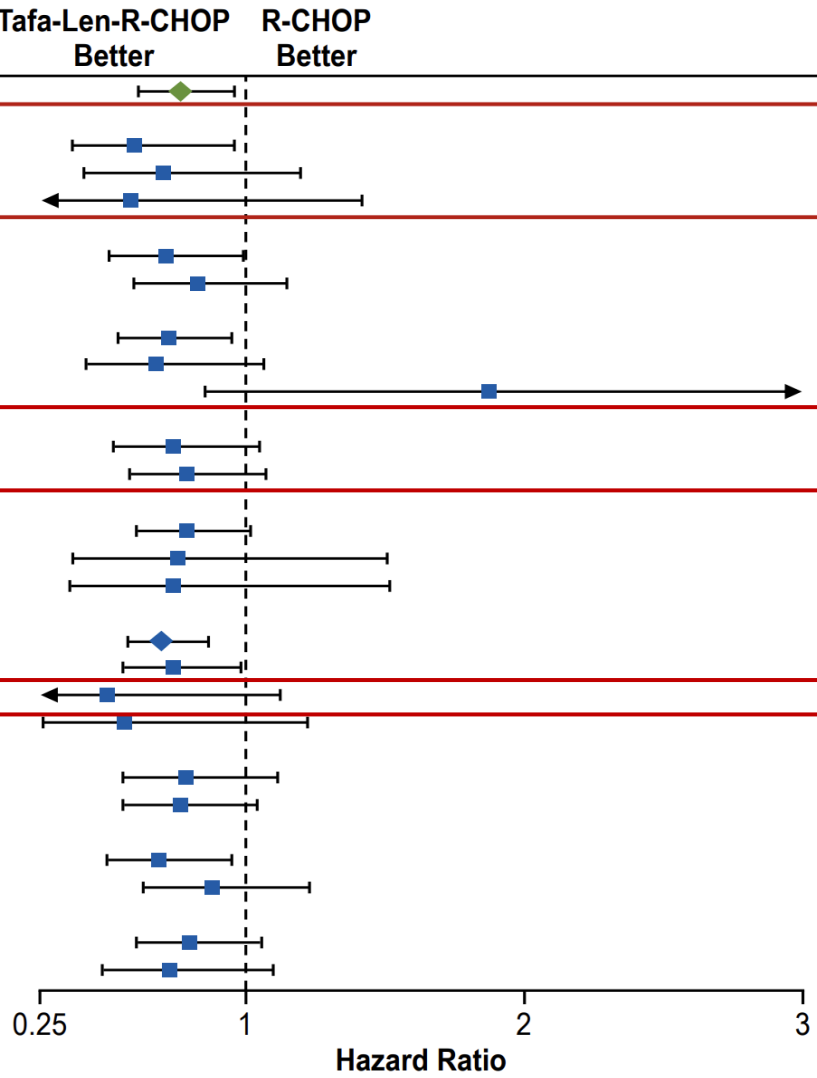
PFS in Prespecified Subgroups

Baseline Risk Factors	Tafa-Len-R-CHOP Patient n/Event n	R-CHOP Patient n/Event n	HR* (95% CI)
Overall	448/121	451/155	0.75 (0.59, 0.96)
Cell of origin by central GEP			
ABC-like	84/27	88/44	0.59 (0.36, 0.95)
GCB-like	131/23	117/29	0.69 (0.40, 1.19)
Unclassified	24/7	40/16	0.58 (0.24, 1.41)
IPI score			
IPI 3/aaIPI 2	259/56	244/75	0.70 (0.50, 0.99)
IPI 4-5/aaIPI 3	186/64	202/79	0.82 (0.59, 1.14)
Geographic region			
EU, US, CAN, AUS, NZ†	324/76	324/104	0.71 (0.53, 0.95)
Asia	90/30	93/41	0.67 (0.42, 1.07)
Rest of the world	34/15	34/10	1.87 (0.84, 4.17)
Bulky disease			
Absent	194/50	220/75	0.73 (0.51, 1.04)
Present	254/71	231/80	0.78 (0.56, 1.07)
Lymphoma subtype (locally determined)			
DLBCL	362/95	361/120	0.77 (0.59, 1.01)
High-grade lymphoma	38/13	41/19	0.74 (0.37, 1.51)
Other	48/13	49/16	0.73 (0.35, 1.51)
Lymphoma subtype (centrally determined)			
Overall	391/99	382/132	0.68 (0.52, 0.88)
DLBCL	307/76	325/107	0.73 (0.54, 0.98)
High-grade lymphoma	41/12	24/11	0.49 (0.22, 1.12)
Other	43/11	33/14	0.55 (0.25, 1.22)
Age			
<65 years	222/53	218/68	0.77 (0.54, 1.10)
≥65 years	226/68	233/87	0.75 (0.55, 1.03)
Sex			
Male	240/59	233/83	0.67 (0.48, 0.94)
Female	208/62	218/72	0.87 (0.62, 1.22)
ECOG PS			
0-1	324/83	326/105	0.79 (0.59, 1.05)
2	123/37	123/49	0.71 (0.47, 1.09)



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Lancet. 2026 Jun 20;407(10547):2528-2541

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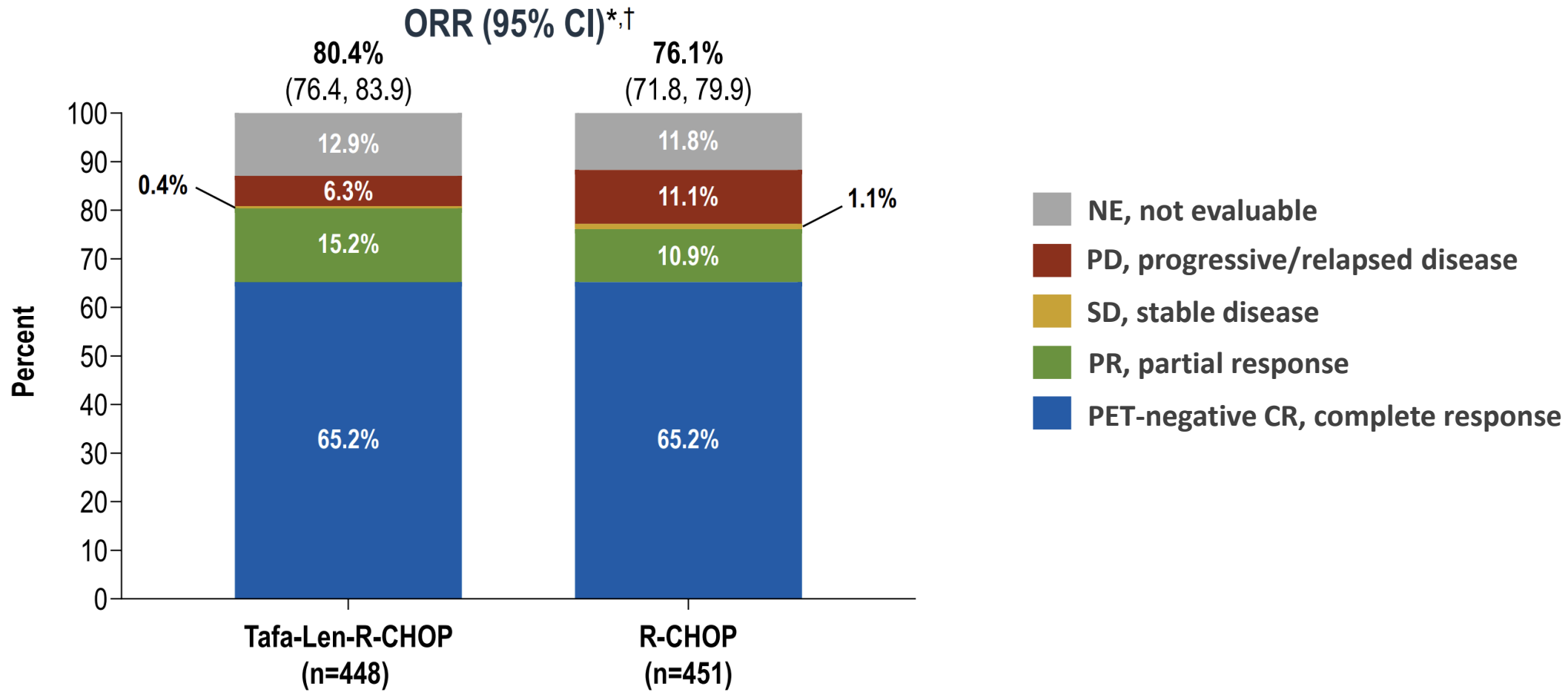
KEY DATA

frontMIND: 1L Tafasitamab + lenalidomide + R-CHOP in DLBCL

ORR and CR Rate by Investigator Assessment



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KEY DATA

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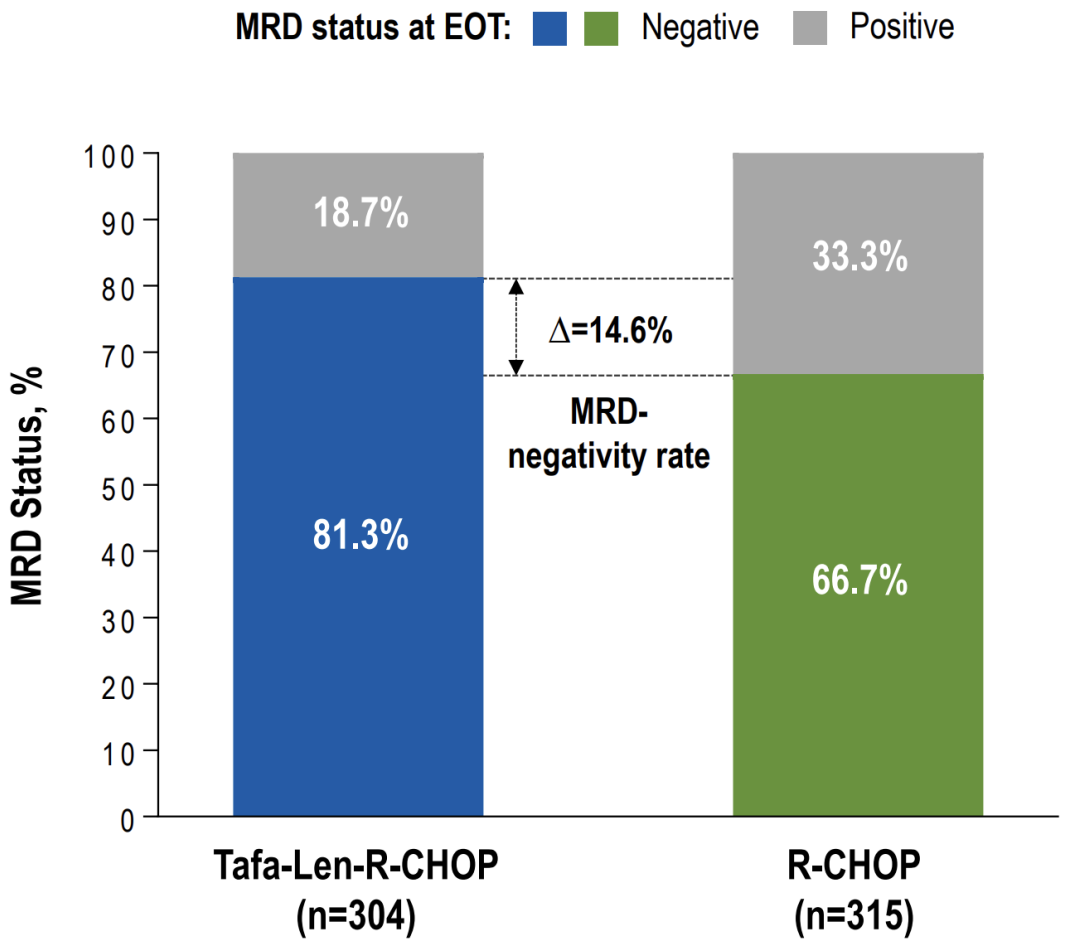
Higher MRD-negativity rate with Tafa-Len-R-CHOP at end of treatment



MRD	Tafa-Len-R-CHOP (n=336)	R-CHOP (n=349)
MRD evaluated (baseline positive, EOT positive/negative, n	304	315
Negative status at EOT, n (%) **95% CI**	**247 (81.3)** (76.4, 85.5)	**210 (66.7)** (61.2, 71.9)

- MRD tested by a capture-based ctDNA assay

EHA 2026. Abstract #S101.
Lancet. 2026 Jun 20;407(10547):2528-2541

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KEY DATA

frontMIND: 1L Tafasitamab + lenalidomide + R-CHOP in DLBCL

Safety Summary

n (%)	Tafa-Len-R-CHOP (n=443)	R-CHOP (n=447)
Patients with ≥1 TEAE		
• Any TEAE	437 (98.6)	434 (97.1)
• Any treatment-related TEAE	423 (95.5)	407 (91.1)
• Grade ≥3 TEAE	**384 (86.7)**	**340 (76.1)**
• Serious TEAE	222 (50.1)	174 (38.9)
• Fatal TEAE	26 (5.9)	17 (3.8)
TEAEs leading to discontinuation of all components of treatment	23 (5.2)	24 (5.4)

Median Relative Dose Intensities, % (across 6 cycles)	Tafa-Len-R-CHOP (n=443)	R-CHOP (n=447)
R-CHOP component: rituximab, cyclophosphamide, doxorubicin, prednisone/prednisolone	100	100
R-CHOP component: vincristine	92.9	92.1

- Fatal TEAEs were predominantly balanced between both groups; expectations included higher rates of COVID-19 (7[1.6%] vs 2 [0.4%]) and sepsis (7[1.6%] vs 3 [0.7%]) with Tafa-Len-R-CHOP
- Overall, 82 (18.5%) patients died in the Tafa-Len-R-CHOP and 97 (21.7%) in the R-CHOP groups
- Most common grade ≥3 adverse events were related to cytopenias – Rate of serious febrile neutropenia: 13.3% with Tafa-Len-R-CHOP and 9.8% with R-CHOP

ASCO 2026. Abstract LBA7000.
Lancet. 2026 Jun 20;407(10547):2528-2541

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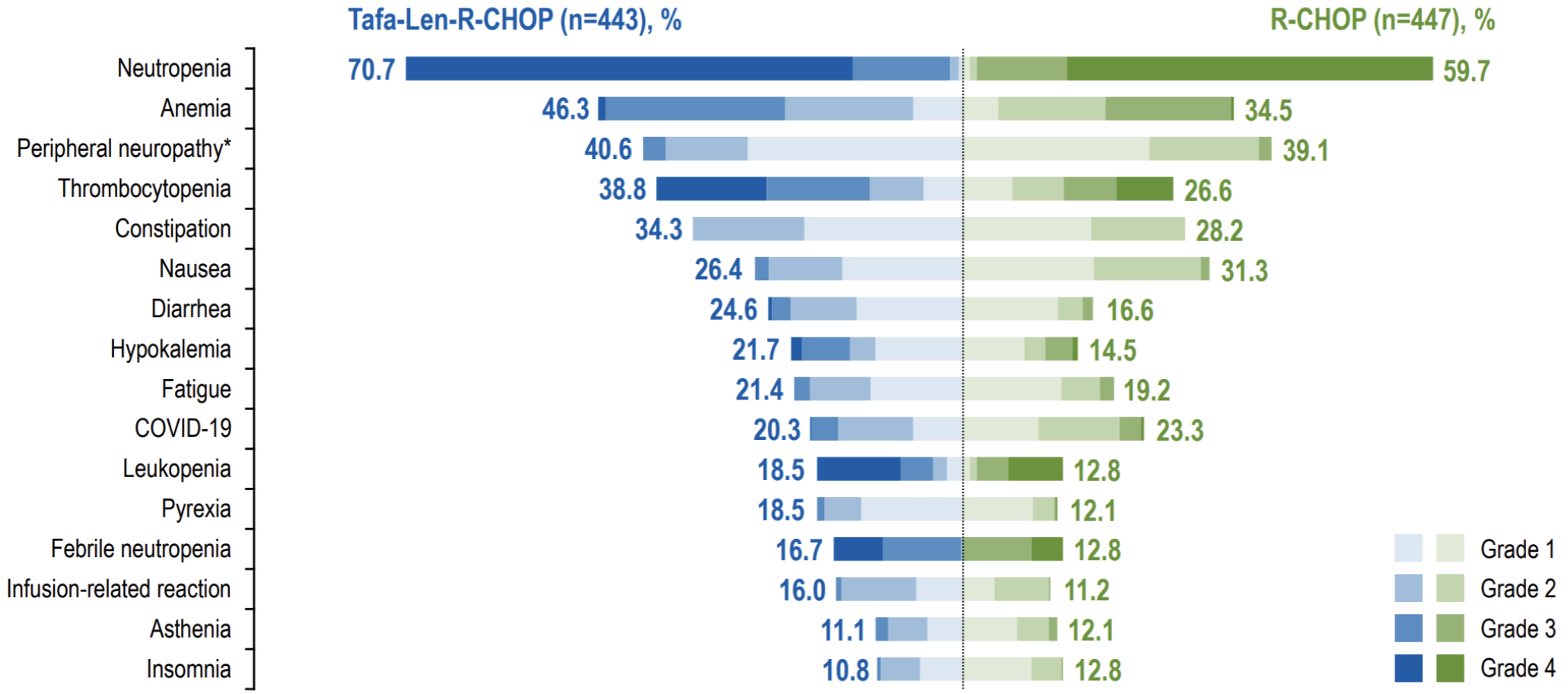
KEY DATA

frontMIND: 1L Tafasitamab + lenalidomide + R-CHOP in DLBCL

Safety: Most frequent TEAEs (≥12% in any group)



Rate of serious febrile neutropenia: 13.3% with Tafa-Len-R-CHOP and 9.8% with R-CHOP

ASCO 2026. Abstract LBA7000.
Lancet. 2026 Jun 20;407(10547):2528-2541

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SUMMARY

frontMIND

- Tafa-Len-R-CHOP significantly prolonged PFS compared with R-CHOP in patients with previously untreated high–risk DLBCL and HGBL
  - HR 0.75; 2-year PFS rate, Δ=8.2%
- Trend toward PFS advantage with Tafa-Len-R-CHOP in key prespecified subgroup analyses
- Incremental safety events observed with Tafa-Len-R-CHOP were well-managed and did not impact delivery of the R-CHOP backbone

IMPACT

Tafa-Len-R-CHOP is a potential new standard first-line treatment option for patients with high-risk DLBCL or HGBL, regardless of cell of origin molecular subtype

Not yet FDA approved

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What is your current preferred 1L treatment approach for patients with newly diagnosed DLBCL?

1. R-CHOP
2. Pola-R-CHP
3. EPOCH or DA-EPOCH
4. Other

If tafasitamab + lenalidomide + R-CHOP were approved, which regimen would be your preferred 1L treatment for eligible DLBCL patients?

1. R-CHOP
2. Pola-R-CHP
3. EPOCH or DA-EPOCH
4. Tafa-Len-R-CHOP
5. Other

Key Studies

Breast

- ASCENT-04
- ASCENT-03
- TROPION-Breast02
- DESTINY-Breast05

Rapid Reviews

- SERENA-6
- persevERA
- KEYNOTE-522

GU/GI

- RASolute 302*
- EMERALD-3
- PROTEUS*
- TALAPRO-3

Other Notable Studies

- frontMIND
- MajesTEC-9
- HARMONi-6*
- LIBRETTO-432*

Rapid Reviews

- SARC041*

*Plenary Session

CLINICAL QUESTION

MajesTEC-9

Does teclistamab monotherapy improve survival in patients with relapsed refractory multiple myeloma and prior exposure to anti-CD38 mAB and lenalidomide?

Phase III results

*On **March 5, 2026**, the FDA approved **teclistamab** (Tecvayli, Janssen Biotech, Inc.) **in combination with daratumumab hyaluronidase-fihj** for adult patients with **relapsed or refractory multiple myeloma** who have received at least one prior line of therapy including a proteasome inhibitor and an immunomodulatory agent evaluated in **MajesTEC-3***

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KEY DATA

MajesTEC-9: teclistamab vs PVd/Kd in 2L+ RRMM

Study Design: Randomized phase 3 trials

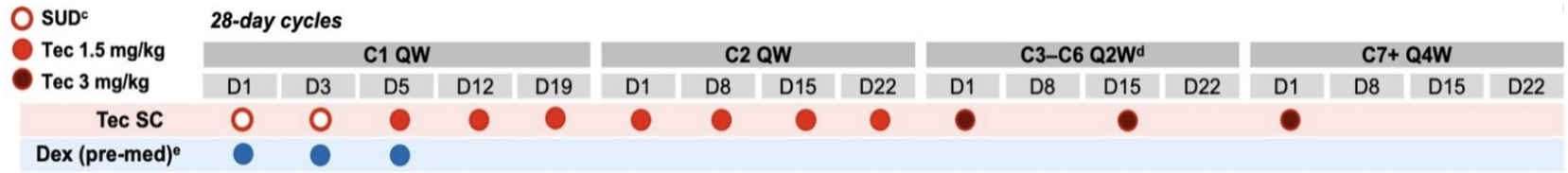
- RRMM
- 1-3 prior lines of therapy including an anti-CD38 mAb
- ECOG PS 0-2
- No prior BCMA-directed therapy

N=593

R 1:1

Tec
(n=296)

PVd/Kd†
by investigator's choice
(n=297)



- **Step-up dosing (SUD) with premedication dexamethasone**
- **Weekly → Q2W → Q4W transitions**

Primary endpoint: Progression-free survival per IRC*
Key secondary endpoints: ≥Complete response*, overall response (OS), MySim-Q total symptom score

Other secondary end points: Overall response rate, safety, PK and immunogenicity
Exploratory endpoints: MRD-negative ≥CR (10^{-5})

†Administered per the approved schedule. Kd was administered either twice weekly (20/56 mg/m^2) or once weekly 20/70 mg/m^2) depending on the local clinical practice.
*Disease progression and response were assessed by an IRC per IMWG 2016 criteria.

ASCO 2026. Abstract 7507.
N Engl J Med. 2026 May 29. doi: 10.1056/NEJMoa2603870.

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KEY DATA

MajesTEC-9: teclistamab vs PVd/Kd in 2L+ RRMM

Baseline Characteristics

n (%)	Tec (n=296)	PVd/Kd (n=297)
Age, median (range), years	70 (34-85)	70 (36-86)
• ≥75 years	**84 (28.4)**	**89 (30.0)**
Male	150 (50.7)	153 (51.5)
Female	146 (49.3)	144 (48.5)
Race		
• White	190 (64.2)	198 (66.7)
• Asian	62 (20.9)	56 (18.9)
• Black or African American	10 (3.4)	10 (3.4)
• Other	34 (11.4)	33 (11.1)
ECOG PS		
• 0	156 (52.7)	135 (45.5)
• 1	121 (40.9)	137 (46.1)
• 2	19 (6.4)	24 (8.1)
• 3	0	1 (0.3)

n (%)	Tec (n=296)	PVd/Kd (n=297)
ISS stage		
• I	168 (56.8)	170 (57.2)
• II	86 (29.1)	82 (27.6)
• **III**	**42 (14.2)**	**45 (15.2)**
BMPCs ≥60%, n/N (%)	31/292 (10.6)	40/295 (13.6)
Soft-tissue plasmacytomas	**54 (18.2)**	**65 (21.9)**
• Extramedullary	19 (6.4)	22 (7.4)
• Paraskeletal	43 (14.5)	52 (17.5)
High-risk cytogenetics, n/N (%)	**105/294 (35.7)**	**104/296 (35.1)**

ASCO 2026. Abstract 7507.
N Engl J Med. 2026 May 29. doi: 10.1056/NEJMoa2603870.

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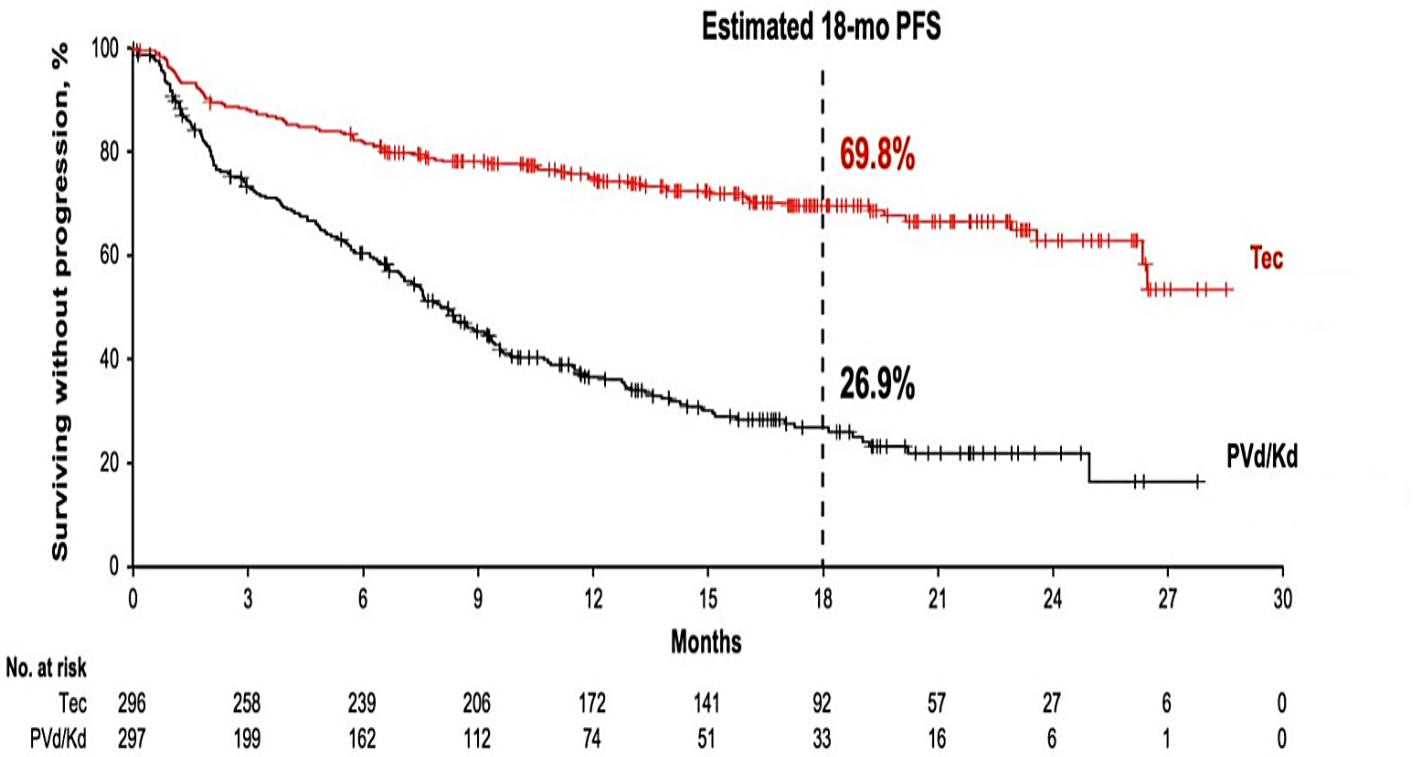
KEY DATA

MajesTEC-9: teclistamab vs PVd/Kd in 2L+ RRMM

Primary Endpoint: Progression-free survival



n (%)	Tec (n=296)	PVd/Kd (n=297)
Median PFS, mo	**NR**	8.2
HR (95% CI)	**0.29** (0.23-0.38) P<0.0001	

Median follow-up: 17.3 mo

PFS benefit across all subgroups including high-risk cytogenetics and anti-CD38 or lenalidomide refractory disease

ASCO 2026. Abstract 7507.
N Engl J Med. 2026 May 29. doi: 10.1056/NEJMoa2603870.

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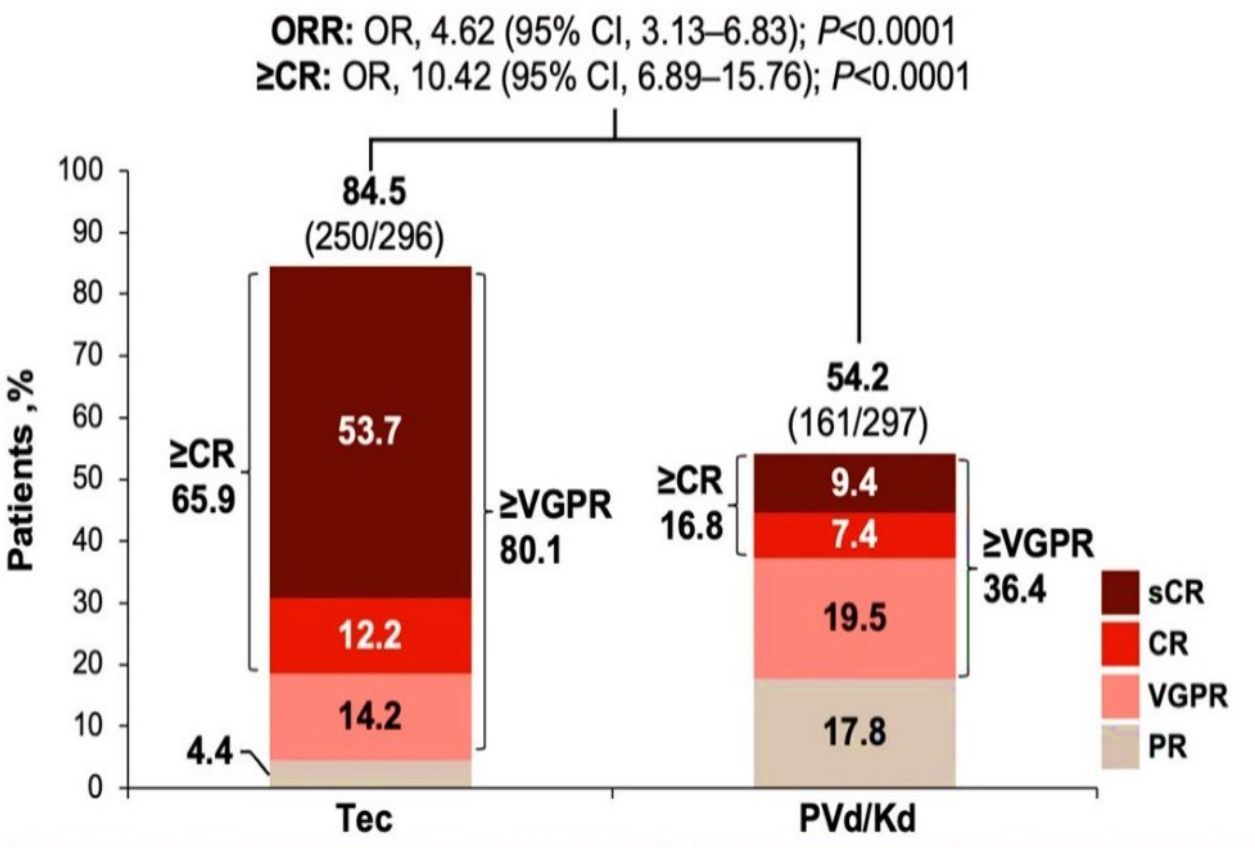
KEY DATA

MajesTEC-9: teclistamab vs PVd/Kd in 2L+ RRMM

Secondary Endpoint: Treatment response and duration response



n (%)	Tec (n=250)	PVd/Kd (n=161)
Media (range) time to first response, months	**1.2** (0.9-7.9)	1.1 (0.7-11.1)
Median (range) time to first ≥CR, months	**5.8** (1.0-23.0)	5.6 (0.9-16.3)
Media (95% CI) DOR, months	**NE** (25.2-NE)	13.4 (10.4-17.3)
Estimated 18-month DOR, % (95% CI)	**80.6** (74.1-85.5)	40.1 (30.8-49.1)

NE: Not estimable

ASCO 2026. Abstract 7507.
N Engl J Med. 2026 May 29. doi: 10.1056/NEJMoa2603870.

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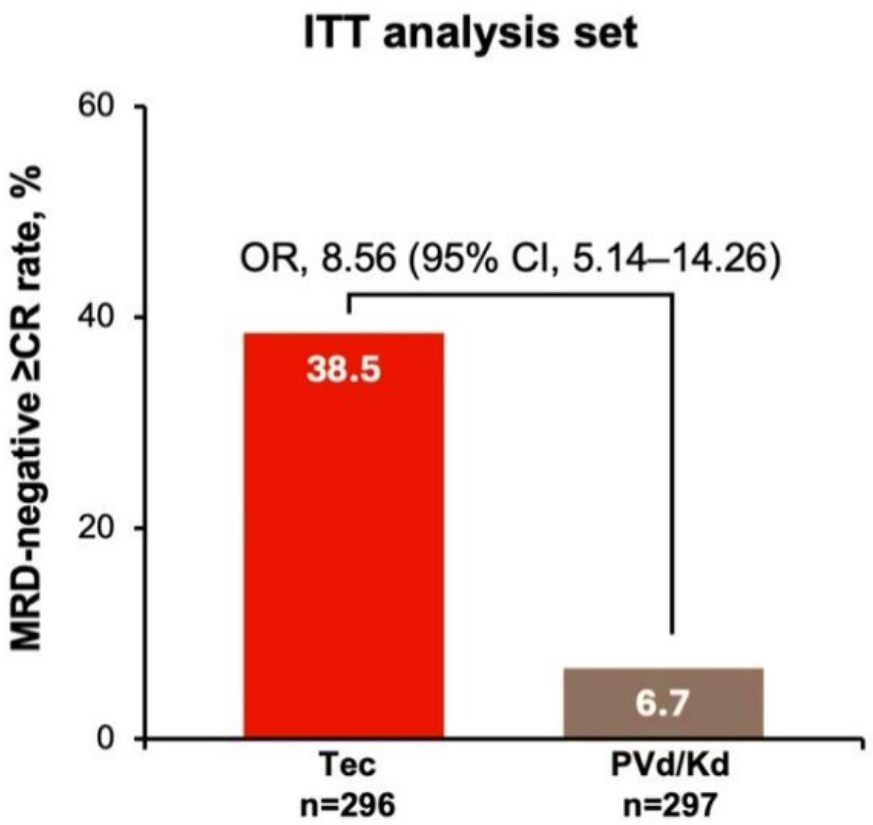
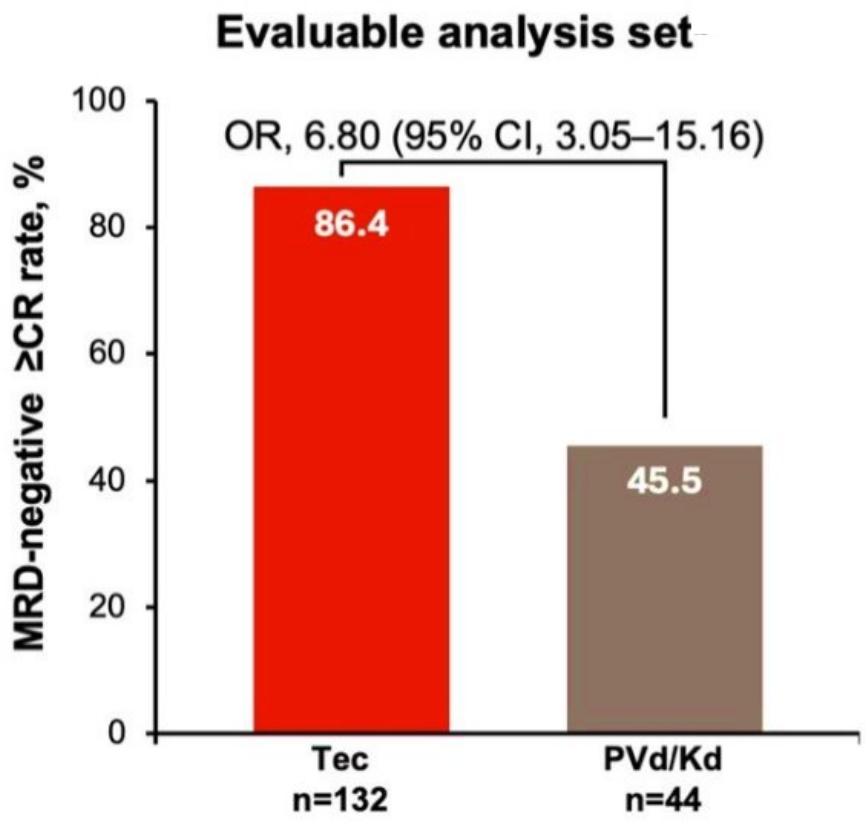
KEY DATA

MajesTEC-9: teclistamab vs PVd/Kd in 2L+ RRMM

Secondary Endpoint: MRD-Negative (10^{-5}) ≥CR Rate





ASCO 2026. Abstract 7507.
N Engl J Med. 2026 May 29. doi: 10.1056/NEJMoa2603870.

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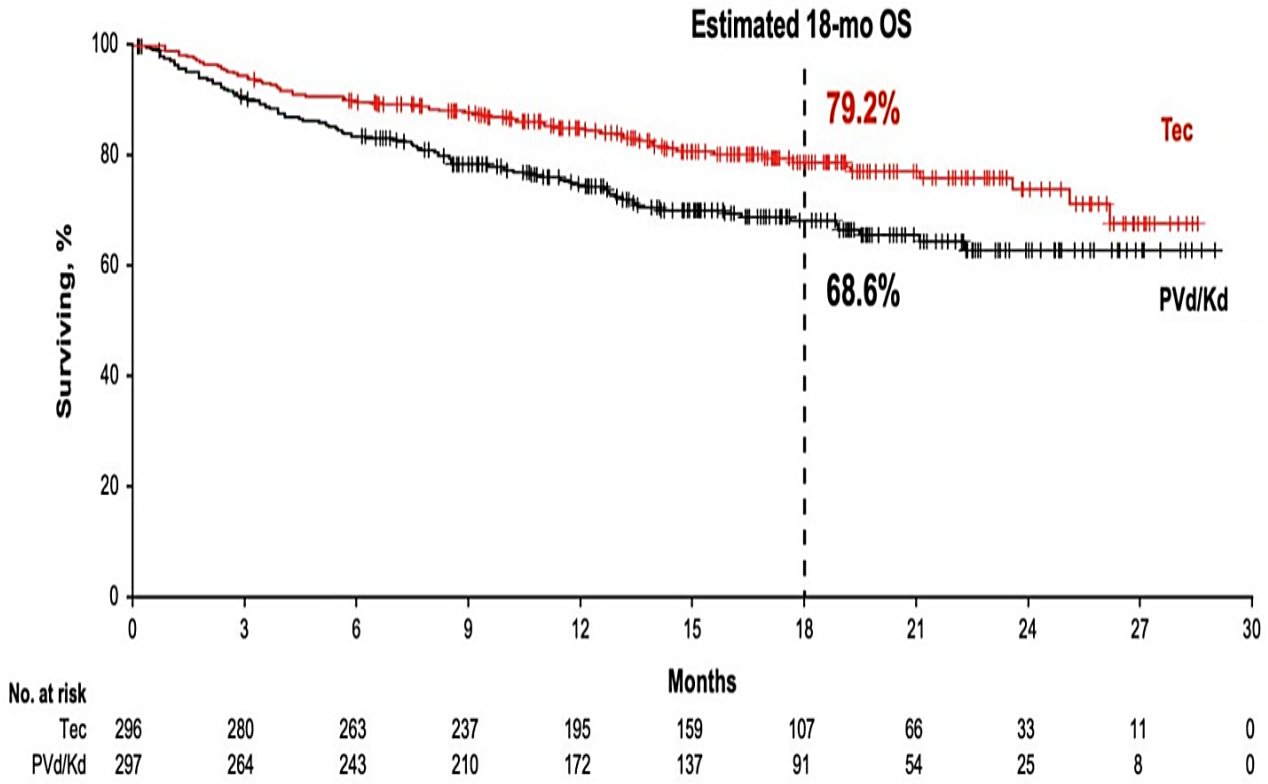
KEY DATA

MajesTEC-9: teclistamab vs PVd/Kd in 2L+ RRMM

Secondary Endpoint: Overall survival



n (%)	Tec (n=296)	PVd/Kd (n=297)
Median OS, mo	NR	NR
HR (95% CI)	**0.60** (0.43-0.83) P=0.0020	

Median follow-up: 17.3 months

2/3rds of patients received subsequent bispecific antibody or CAR T-cell therapy

ASCO 2026. Abstract 7507.
N Engl J Med. 2026 May 29. doi: 10.1056/NEJMoa2603870.

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KEY DATA

MajesTEC-9: teclistamab vs PVd/Kd in 2L+ RRMM

Safety Summary

TEAE, n (%)	Tec (n=291)		PVd/Kd (n=283)	
	Any grade	Grade 3/4	Any grade	Grade 3/4
Any TEAE	290 (99.7)	**247 (84.9)**	277 (97.9)	**216 (76.3)**
Hematologic				
• Neutropenia	182 (62.5)	158 (54.3)	81 (28.6)	63 (22.3)
• Anemia	110 (37.8)	52 (17.9)	119 (42.0)	46 (16.3)
• Thrombocytopenia	80 (27.5)	31 (10.7)	110 (38.9)	60 (21.2)
• Lymphopenia	71 (24.4)	59 (20.3)	49 (17.3)	32 (11.3)
Nonhematologic				
• CRS	192 (66.0)	2 (0.7)	0	0
• Diarrhea	124 (42.6)	15 (5.2)	72 (25.4)	4 (1.4)
• Cough	80 (27.5)	2 (0.7)	39 (13.8)	0
• Injection-site erythema	71 (24.4)	0	8 (2.8)	0
• Hypertension	20 (6.9)	13 (4.5)	51 (18.0)	32 (11.3)

ASCO 2026. Abstract 7507.
N Engl J Med. 2026 May 29. doi: 10.1056/NEJMoa2603870.

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SUMMARY

MajesTEC-9

- Teclistamab monotherapy showed significant PFS (HR 0.29) and OS (HR 0.60) benefit in highly exposed and relapsed / refractory multiple myeloma
- PFS favored Tec in all subgroups, including anti-CD38 and lenalidomide-refractory disease
- Tec demonstrated superior ORR and ≥CR and increased MRD-negative ≥CR
- CRS and ICANS were mostly grade 1 and managed with established protocols
- Infections were common; need for use of IgRT and antimicrobial prophylaxis

IMPACT

Teclistamab monotherapy may become a new standard of care for earlier-stage relapsed or refractory multiple myeloma

Monotherapy not yet FDA approved

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Does your practice currently administer bispecific (T-cell engager) therapy, including step-up dosing and/or maintenance treatment?

1. Yes
2. No
3. No, but we plan to within the next 6 months

For a patient who relapses after frontline CD38-containing triplet or quadruplet therapy, what would be your preferred next treatment approach today?

1. Teclistamab-based regimen
2. Carfilzomib-based regimen (e.g., KPd/Kd)
3. Selinexor-based regimen
4. Cellular therapy (CAR-T) or transplant-based strategy
5. Unsure, given the rapidly evolving multiple myeloma treatment landscape

Key Studies

Breast

- ASCENT-04
- ASCENT-03
- TROPION-Breast02
- DESTINY-Breast05

Rapid Reviews

- SERENA-6
- persevERA
- KEYNOTE-522

GU/GI

- RASolute 302*
- EMERALD-3
- PROTEUS*
- TALAPRO-3

Other Notable Studies

- frontMIND
- MajesTEC-9
- HARMONi-6*
- LIBRETTO-432*

Rapid Reviews

- SARC041*

*Plenary Session

CLINICAL QUESTION

HARMONi-6*

*Plenary Session

Does adding ivonescimab to chemotherapy benefit patients in first-line treatment for advanced squamous non-small cell lung cancer?

Overall survival results

The FDA has accepted for filing Summit's Biologics License Application (BLA) seeking approval for ivonescimab in combination with chemotherapy in patients with EGFR-mutated locally advanced or metastatic non-squamous NSCLC post-TKI therapy

PDUFA date: November 14, 2026

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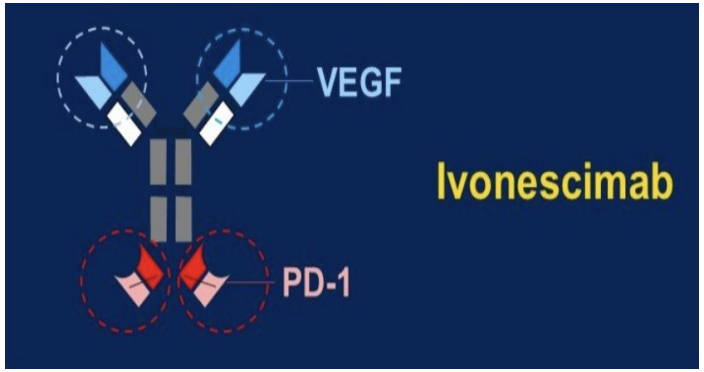
VEGF's Role in Immunotherapy in NSCLC

- VEGF/PD-1 bispecific antibodies
  - Dual-targeting localizes the antibody in the TME
    - Increased affinity for PD-1
    - Potentially enhances antitumor immunity
    - In theory could reduce systemic VEGF- related toxicity

- Ivonescimab – first-in-class IgG1 targeting both VEGF/PD-1
  - Approved for use in China
    - Combined with chemo for EGFR-mt (+) non-squamous NSCLC post TKI failure
    - First-line monotherapy for PD-L1 + advanced NSCLC



ASCO 2026. Abstract LBA4.

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KEY DATA

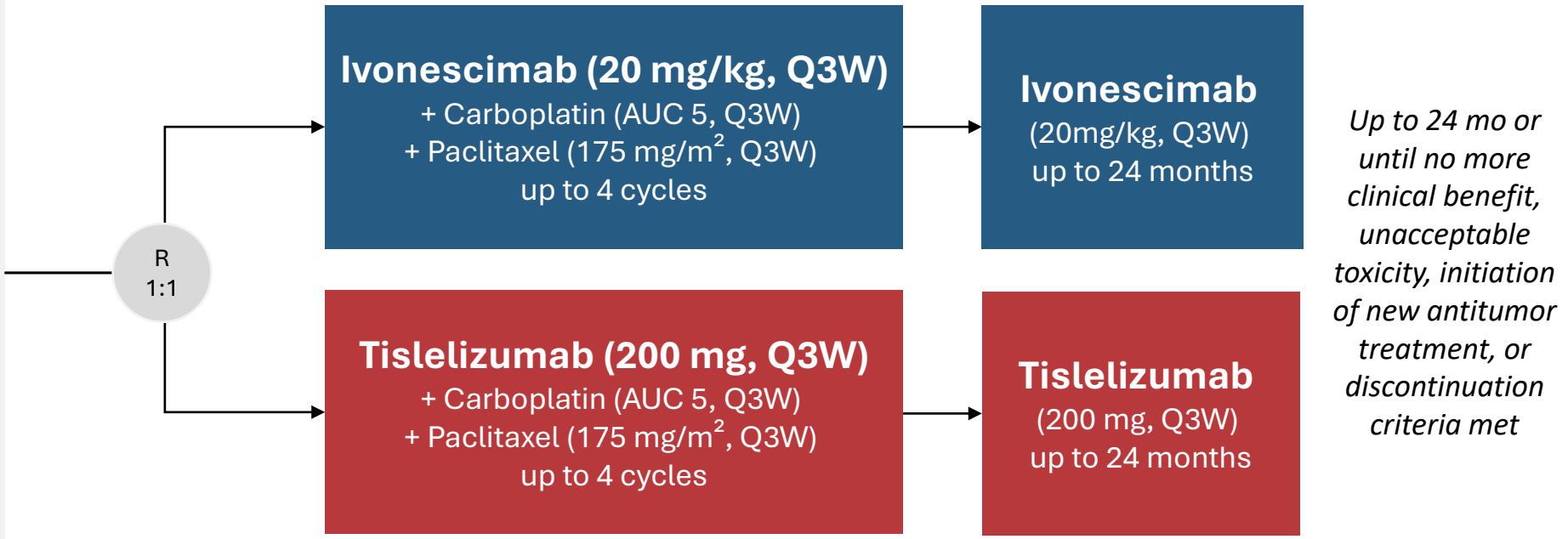
HARMONi-6: 1L ivonescimab + chemo vs tislelizumab + chemo in squamous NSCLC

Study Design: A multicenter, randomized, double-blinded, parallel-controlled phase 3 study

- Pathologically confirmed sq-NSCLC
- Stage IIIB-IV
- No prior systemic therapy
- No EGFR mutations or ALK rearrangements
- ECOG PS 0 or 1

(n = 532)

Stratified by stage (IIIB/IIIC vs IV) and PD-L1 TPS (≥1% vs <1%)



Primary endpoint: Progression-free survival (PFS) by IRRC per RECIST v1.1
Key secondary endpoint: Overall survival (OS)
Secondary endpoints: PFS by investigator, overall response rate, disease control rate, duration of response, time to response and safety

ASCO 2026. Abstract LBA4.
Lancet. 2026 Jun 27;407(10548):2620-2629.

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KEY DATA

HARMONi-6: 1L ivonescimab + chemo vs tislelizumab + chemo in squamous NSCLC

Baseline Characteristics

Characteristic, n (%)	Ivonescimab + chemo (n = 266)	Tislelizumab + chemo (n = 266)
Age		
• <65 yr	135 (50.8)	139 (52.3)
• ≥65 yr	131 (49.2)	127 (47.7)
Sex		
• Male	256 (96.2)	238 (89.5)
• Female	10 (3.8)	28 (10.5)
ECOG PS*		
• 0	42 (15.8)	42 (15.8)
• 1	224 (84.2)	222 (83.5)
Smoking history		
• Never	21 (7.9)	37 (13.9)
• Current/former	245 (92.1)	229 (86.1)
Disease stage		
• IIIB/IIIC	21 (7.9)	20 (7.5)
• IV	245 (92.1)	246 (92.5)

Characteristic, n (%)	Ivonescimab + chemo (n = 266)	Tislelizumab + chemo (n = 266)
Tumor characteristics		
• Central type	178 (66.9)	158 (59.4)
• Major blood vessel encasement	49 (18.4)	44 (16.5)
• With cavity	24 (9.0)	23 (8.6)
• With hemoptysis	86 (32.3)	79 (29.7)
PD-L1 TPS		
• <1%	105 (39.5)	105 (39.5)
• ≥1%	161 (60.5)	161 (60.5)
• 1-49%	112 (42.1)	99 (37.2)
• ≥50%	49 (18.4)	62 (23.3)
Metastases sites		
• ≥3 metastatic sites	42 (15.8)	39 (14.7)
• Liver metastases	28 (10.5)	45 (16.9)
• Brain metastases	9 (3.4)	17 (6.4)

ASCO 2026. Abstract LBA4.
Lancet. 2026 Jun 27;407(10548):2620-2629.

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KEY DATA

HARMONi-6: 1L ivonescimab + chemo vs tislelizumab + chemo in squamous NSCLC

Primary Endpoint: Progression-free survival per IRRC per RECIST v1.1 – *previously reported*

	Ivonescimab + chemo (N=266)	Tislelizumab + chemo (N=266)
Median PFS, mo (95% CI)	**11.14** (9.86, NE)	6.90 (5.82, 8.57)
Stratified HR (95% CI)	**0.60** (0.46, 0.78)	
P-value	**<0.0001**	

Median follow-up: 10.3 months

The PFS benefit with ivonescimab plus chemotherapy was consistent regardless of PD-L1 status

ESMO 2025. Abstr. LBA4
The Lancet Volume 406, Issue 10515p2078-2088November 01, 2025

Secondary Endpoint: Overall survival (interim analysis)

	Ivonescimab + chemo (N=266)	Tislelizumab + chemo (N=266)
Median OS, mo (95% CI)	**27.89** (27.89, NE)	23.69 (20.11, NE)
Stratified HR (95% CI)	**0.66** (0.50, 0.87)	
P-value	**0.0017**	

Median follow-up: 21.36 months

ASCO 2026. Abstract LBA4.
Lancet. 2026 Jun 27;407(10548):2620-2629.

IRRC: independent radiology review committee; NE: not evaluable

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HARMONi-6: 1L ivonescimab + chemo vs tislelizumab + chemo in squamous NSCLC

Safety Summary

n (%)	Ivonescimab + chemo (N=266)	Tislelizumab + chemo (N=265)
TRAE	264 (99.2)	263 (99.2)
Grade ≥3 TRAE	**184 (69.2)**	**156 (58.9)**
Serious TRAE	110 (41.4)	91 (34.3)
Leading to ivonescimab or tislelizumab discontinuation	14 (5.3)	12 (4.5)
Leading to death	10 (3.8)	11 (4.2)
Grade ≥ 3 irAE	**34 (14)**	**36 (14)**

Select TRAEs, %	Ivonescimab + CT		Tislelizumab + CT	
	All Grades	Grade ≥3	All Grades	Grade ≥3
Anemia	57.1	7.1	60.8	4.9
Decreased neutrophils	47.0	32.3	44.5	26.0
Decreased WBCs	38.0	10.9	37.0	9.4

ASCO 2026. Abstract LBA4.
Lancet. 2026 Jun 27;407(10548):2620-2629.

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SUMMARY

HARMONi-6

- Ivonescimab with chemotherapy significantly improved OS in advanced squamous NSCLC as first-line treatment compared with tislelizumab plus chemotherapy
  - mOS: 27.89 vs 23.69

    HR = 0.66 (95%CI: 0.50, 0.87), p=0.0017
- Ivonescimab with chemotherapy showed comparable safety profile to tislelizumab plus chemotherapy
  - Grade ≥3 TRAEs: 69.2% vs 58.9%
  - Similar rates of AEs leading to discontinuation or death between the two arms

IMPACT

Ivonescimab with chemotherapy may become a new standard of care option for patients with advanced squamous NSCLC

Not yet FDA approved

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First-line treatment of squamous NSCLC

HARMONi-6		KEYNOTE-407	
Not yet FDA approved		*FDA approved*	
• **Pathologically confirmed sq-NSCLC** • **Stage IIIB-IV** • **No prior systemic therapy** • **No EGFR mutations or ALK rearrangements** • **ECOG PS 0 or 1**		• **Untreated stage IV sq-NSCLC** • **ECOG PS 0 or 1** • **Provisions of a sample for PD-L1 assessment** • **No symptomatic brain metastases** • **No pneumonitis requiring systemic steroids**	
Ivonescimab + chemo (N=266)	Tislelizumab + chemo (N=266)	**Pembrolizumab + carboplatin paclitaxel or nab-paclitaxel** (n=278)	Placebo + carboplatin paclitaxel or nab-paclitaxel (n=281)
Medium follow-up: **10.8 months**		Medium follow-up: **7.8 months**	
mPFS: 11.14 months	6.9 months	**6.4 months**	4.8 months
mOS: 27.9 months	23.7 months	**15.9 months**	11.3 months

ASCO 2026 Abstr. LBA4.

N Engl J Med 2018;379:2040-2051

Key Studies

Breast

- ASCENT-04
- ASCENT-03
- TROPION-Breast02
- DESTINY-Breast05

Rapid Reviews

- SERENA-6
- persevERA
- KEYNOTE-522

GU/GI

- RASolute 302*
- EMERALD-3
- PROTEUS*
- TALAPRO-3

Other Notable Studies

- frontMIND
- MajesTEC-9
- HARMONi-6*
- LIBRETTO-432*

Rapid Reviews

- SARC041*

*Plenary Session

CLINICAL QUESTION

LIBRETTO-432*

*Plenary Session

Does adjuvant selpercatinib improve event-free survival in patients with resected stage IB–IIIA RET fusion-positive NSCLC after definitive therapy?

Primary phase III results

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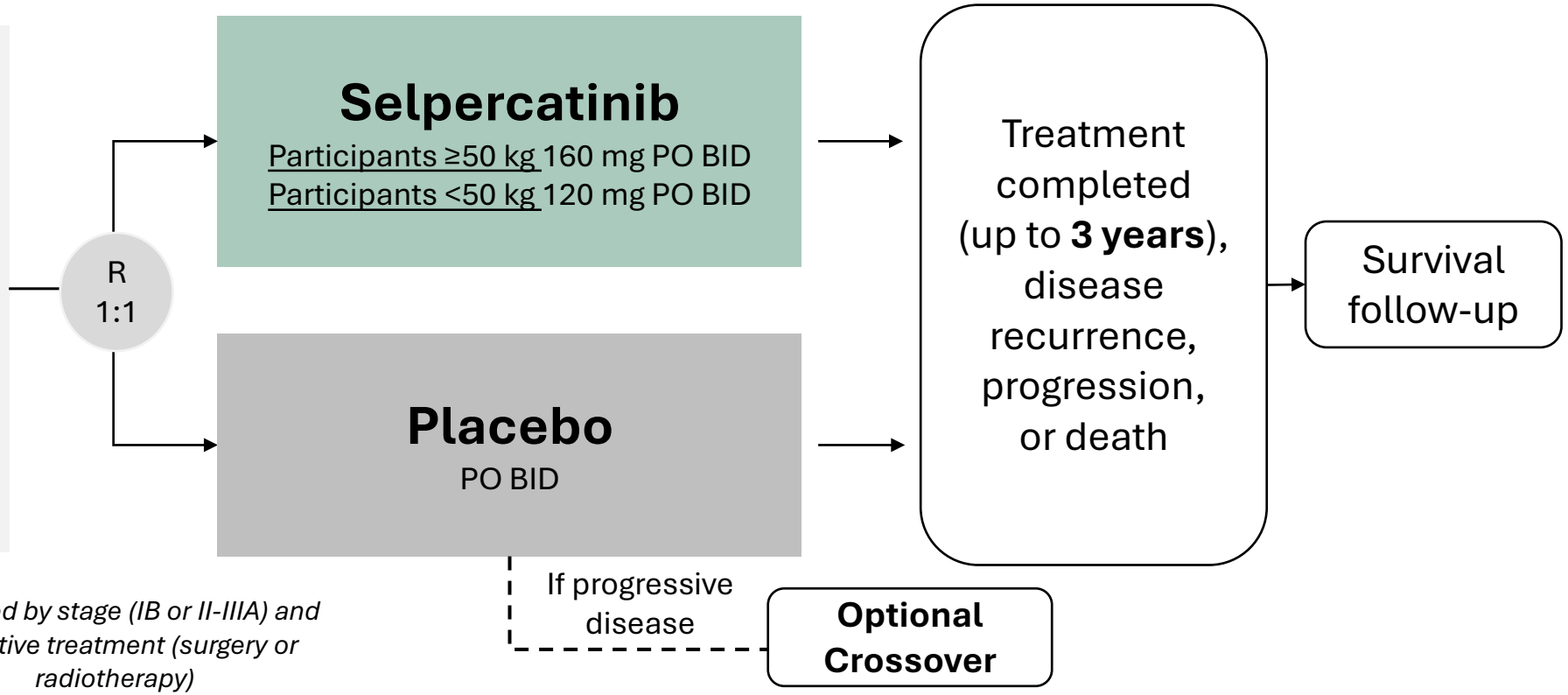
LIBRETTO-432: Adjuvant selpercatinib in stage IB-IIIA RET fusion-positive NSCLC

Study Design: A global, multicenter, phase 3, double-blind, randomized, placebo-controlled study

- *RET* fusion-positive NSCLC stage IB, II, or IIIA
- Received definitive therapy (surgery or radiotherapy, +/- systemic adjuvant chemotherapy)
- No evidence of disease recurrence or progression following definitive therapy

(n = 151)



Primary endpoint: Investigator-assessed event-free survival (EFS) in primary analysis population (stage II-IIIA)
Secondary endpoints: EFS by BICR in primary analysis population, EFS by investigator and BICR assessment in overall population (stage IB-IIIA), safety, and overall survival

ASCO 2026. Abstract LBA3.
N Engl J Med. 2026 May 31. doi: 10.1056/NEJMoa2602628.

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KEY DATA

LIBRETTO-432: Adjuvant selpercatinib in stage IB-IIIA RET fusion-positive NSCLC

Baseline Characteristics

n (%)	Selpercatinib (n=54)	Placebo (n=55)
Age, years, median (range)	59.5 (41.0-84.0)	61.0 (26.0-78.0)
Female	34 (63.0)	30 (54.5)
Male	20 (37.0)	25 (45.5)
Race		
• Asian	33 (61.1)	32 (58.2)
• White	21 (38.9)	21 (38.2)
Geographic Region		
• East Asia	31 (57.4)	31 (56.4)
• Europe/North America	18 (33.3)	21 (38.2)
• Other	5 (9.3)	3 (5.5)
Smoking Status		
• Never	37 (68.5)	38 (69.1)
• Former / Current	17 (31.5)	17 (30.9)

n (%)	Selpercatinib (n=54)	Placebo (n=55)
ECOG PS		
• 0	30 (55.6)	36 (65.5)
• 1	24 (44.4)	18 (32.7)
RET fusion		
• KIF5B:: RET	33 (61.1)	34 (61.8)
• CCDC6:: RET	14 (25.9)	11 (20.0)
• Other	7 (13.0)	10 (18.2)
PD-L1		
• Negative	11 (20.4)	16 (29.1)
• Positive	25 (46.3)	28 (50.9)
• Unknown	17 (31.5)	11 (20.0)
Prior anti-cancer therapy		
• Surgery	54 (100.0)	54 (98.2)
• Radiotherapy	2 (3.7)	6 (10.9)
• Systemic therapy	50 (92.6)	50 (90.9)

ASCO 2026. Abstract LBA3.
N Engl J Med. 2026 May 31. doi: 10.1056/NEJMoa2602628.

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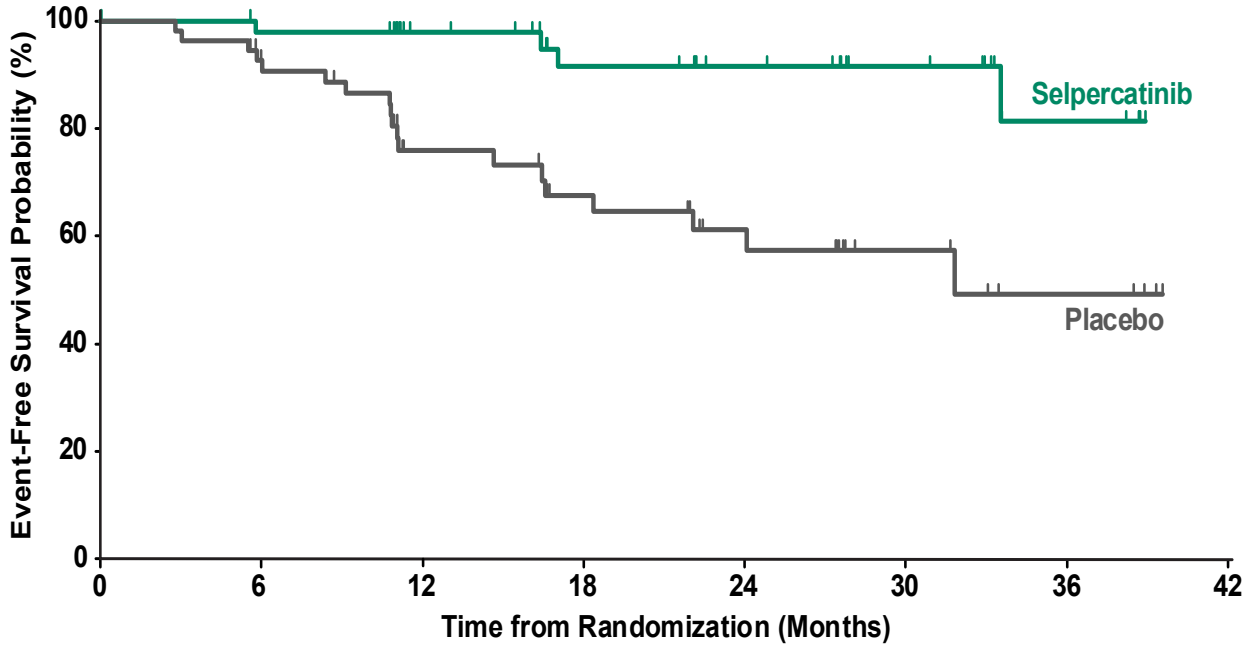
KEY DATA

LIBRETTO-432: Adjuvant selpercatinib in stage IB-IIIA RET fusion-positive NSCLC

Primary Endpoint: Event-free survival (EFS) by investigator assessment in primary analysis population



Number at risk								
Selpercatinib	54	45	37	27	22	15	7	0
Placebo	55	47	28	22	16	8	4	0

n (%)	**Selpercatinib** (n=54)	**Placebo** (n=55)
Events	4	19
24-month EFS rate (95%CI)	**91.5** (75.4 - 97.2)	**61.1** (44.2 - 74.3)
HR (95% CI)	**0.172 (0.058 - 0.509)**	
P-value	0.0003	

ASCO 2026. Abstract LBA3.
N Engl J Med. 2026 May 31. doi: 10.1056/NEJMoa2602628.

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LIBRETTO-432: Adjuvant selpercatinib in stage IB-IIIA RET fusion-positive NSCLC

Safety Summary

Events, n (%)	Selpercatinib (n=75)	Placebo (n=76)
Any TEAE	75 (100)	74 (97.4)
Grade ≥3 TEAEs	**50 (66.7)**	**18 (23.7)**
Serious TEAEs ≥1	17 (22.7)	10 (13.2)
Discontinued study treatment due to TEAEs*	13 (17.3)	1 (1.3)
Discontinued due to SAE	2 (2.7)	1 (1.3)
Dose modifications	66 (88.0)	35 (46.1)
Dose interruptions due to TEAEs	58 (77.3)	20 (26.3)
Dose reductions due to TEAEs	41 (54.7)	6 (7.9)
TEAEs leading to death, on study treatment	0	0

*Most common reasons for selpercatinib discontinuation were ALT increase n=4; AST increase n=2; interstitial lung disease n=2

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SUMMARY

LIBRETTO-432

- Selpercatinib improved EFS vs placebo in early-stage RET fusion–positive NSCLC
- 24-mo EFS rate of 91.5% vs 61.1% (HR: 0.172) in stage II-IIIA primary analysis population; benefit was consistent across predefined subgroups and by BICR
- Selpercatinib demonstrated a manageable safety profile
    - Common all grade AEs included ALT increase (62.7%), AST increase (60.0%), diarrhea (38.7%), and dry mouth (40.0%)
- Comprehensive biomarker testing needed to determine actionable oncogenic drivers at time of diagnosis

IMPACT

Adjuvant selpercatinib should be considered as a new standard of care in patients with early-stage RET fusion-positive NSCLC

Not yet FDA approved for the adjuvant treatment of resected stage IB–IIIA RET fusion-positive NSCLC; approved for locally advanced or metastatic RET fusion-positive NSCLC

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At what point do you order comprehensive molecular testing for patients with resectable NSCLC?

1. At the time of initial diagnostic biopsy
2. Immediately after surgical resection
3. After completion of adjuvant chemotherapy (if given)
4. Only if recurrence develops

RAPID REVIEW

SARC041*

*Plenary Session

Key Question

SARC041*

*Plenary Session

Does abemaciclib improve clinical outcomes in patients with advanced dedifferentiated liposarcoma vs placebo?

Study Design

SARC041

Stratified by prior systemic treatment (0 vs ≥1)

- Advanced / metastatic differentiated liposarcoma

N=108, R 1:1

Abemaciclib
200 mg PO bid

Placebo
200 mg PO bid

Crossover allowed

CT q6w x 36w then q12w

Primary Endpoints: Progression-free survival (PFS)

Secondary Endpoints: Objective response rate, PFS after crossover for patients initially randomized to placebo, overall survival, toxicity (CTCAW v 5)

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SARC041

Primary Endpoint:
Progression-free survival (PFS)

	Abemaciclb (n=54)	Placebo (n=54)
Median PFS	**9.7 mo**	1.5 mo
HR (90% CI)	**0.38** (0.25-0.59, p <0.001)	
6-mo PFS	**60%**	22%
12-mo PFS	**39%**	13%

Secondary Endpoints:

	Abemaciclb (n=54)	Placebo (n=54)
ORR	**9%**	0%
Median PFS after crossover*	**3.4 months**	-
24-mo OS	**72%**	51%

*46 patients (85%) received abemaciclib after progression on placebo

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Key Takeaways SARC041

- Abemaciclib demonstrated a statistically significant improvement in PFS vs placebo
  - mPFS: 9.67 vs 1.52 mo
  - HR 0.38 (0.25–0.59); p < 0.001
- Overall response rate was 9.3% for abemaciclib vs 0% for placebo (p = 0.057)
- Overall survival after 24 months was 72% with abemaciclib vs 51% with placebo
- No new safety signals were observed

Impact SARC041

Abemaciclib, an oral CDK4/6 inhibitor, may become a new standard of care for patients with advanced dedifferentiated liposarcoma

Not yet FDA approved

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ASCO 2026:
Other Notable Studies

Key Takeaways

Q&A
@EricSchaeferMD

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FrontMIND: Tafa-Len-R-CHOP significantly prolonged PFS compared with R-CHOP (HR 0.75; 2-year PFS rate, Δ=8.2%) and may become a new standard first-line treatment option for patients with previously untreated high–risk DLBCL and HGBL – *not yet FDA approved*

MajesTEC-9: Teclistamab monotherapy showed significant PFS (HR 0.29) and OS (HR 0.60) benefit in highly exposed and relapsed / refractory multiple myeloma and may be a new standard of care as early as the second line setting – *not yet FDA approved; approved for 4 prior lines of therapy*

HARMONI-6*: Ivonescimab with chemotherapy significantly improved OS (27.89 vs 23.69 months) in advanced squamous NSCLC as first-line treatment compared with tisleizumab plus chemotherapy – *not yet FDA approved*

LIBRETTO*: Selpercatinib showed a clinically meaningful and statistically significant EFS (24-mo EFS rate of 91.5% vs 61.1%) improvement vs placebo in early-stage RET fusion–positive NSCLC – *not yet FDA approved for the adjuvant treatment of resected stage IB–IIIA RET fusion-positive NSCLC; approved for locally advanced or metastatic RET fusion-positive NSCLC*

SARC041*: Abemaciclib demonstrated a statistically significant improvement in PFS at 9.67 months vs placebo at 1.52 months (HR: 0.39) and may become a new standard of care for patients with advanced dedifferentiated liposarcoma – *not yet FDA approved*