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Sacituzumab Govitecan vs Chemotherapy as First Therapy After Endocrine Therapy in HR+/HER2− (IHC 0, 1+, 2+/ISH−) Metastatic Breast Cancer: Primary Results From ASCENT-07

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Disclosure Information

Komal Jhaveri

I have the following relevant financial relationships to disclose:

Consultant/advisory board role: Arivinas, AstraZeneca, Bicycle Therapeutics, Blueprint Medicines, Daiichi Sankyo, Eisai, Genentech, Gilead Sciences, Halda Therapeutics, Lilly/Loxo Oncology, Menarini/Stemline, Merck Pharmaceuticals, Novartis, Olema Pharmaceuticals, Pfizer, Rayzebio, Scorpion Therapeutics, Zymeworks

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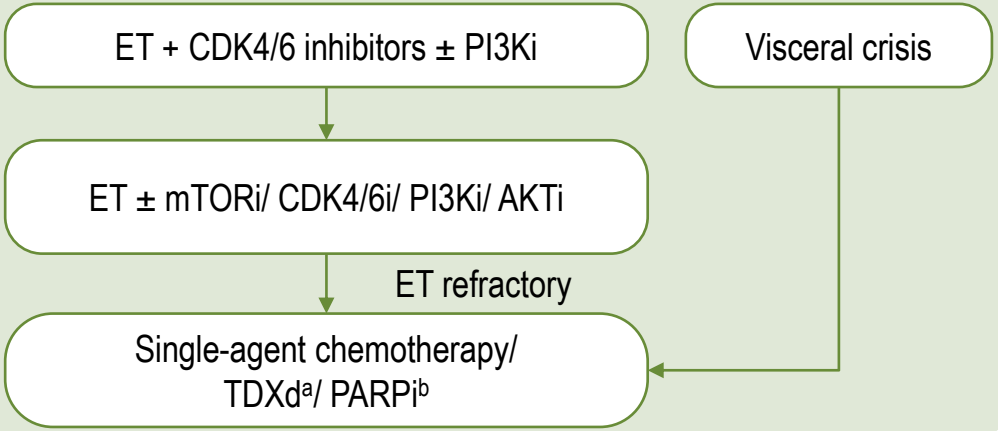
Study Background and Rationale

Current Treatment Landscape: HR+/HER2− mBC[1-5]



Rationale for ASCENT-07

SG is a globally approved Trop-2-directed ADC for ET-refractory HR+/HER2− metastatic BC **following chemotherapy**, based on statistically significant and clinically meaningful improvement in PFS and OS versus chemotherapy in TROPiCS-02[1,6]

We present primary results of the global, randomized, phase 3 ASCENT-07 study:
SG versus TPC in participants with HR+/HER2−, locally advanced unresectable or metastatic BC who have received prior ET and are **candidates for first chemotherapy**

[a]For HER2 low or ultralow tumors, [b]For germline *BRCA*1/2 mutation.
ADC, antibody drug conjugate; **AKTi**, protein kinase B inhibitor; **BC**, breast cancer; **CDK4/6i**, cyclin-dependent kinase 4/6 inhibitor; **ET**, endocrine therapy; **HER2−**, human epidermal growth factor receptor 2 negative; **HR+**, hormone receptor positive; **mBC**, metastatic breast cancer; **mTORi**, mammalian target of rapamycin inhibitor; **OS**, overall survival; **PARPi**, poly-adenosine diphosphate-ribose polymerase inhibitor; **PFS**, progression-free survival; **PI3Ki**, phosphatidylinositol 3-kinase inhibitor; **SG**, sacituzumab govitecan; **TDXd,** trastuzumab deruxtecan; **TPC**, treatment of physician's choice.
1. Jhaveri K, et al. *Cancer Treat Rev*. 2024;123:102670. **2.** Twelves C, et al. *Clin Breast Cancer*. 2022;22:223-34. **3.** Referenced with permission from the NCCN clinical practice guidelines in oncology (NCCN Guidelines®) for breast cancer. V5.2025. National Comprehensive Cancer Network, Inc. ©National Comprehensive Cancer Network, Inc. 2025. All rights reserved. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way. **4.** Trapani D, et al. *Ann Oncol*. 2025;36:1414-18. **5.** Jhaveri K, et al. *N Engl J Med*. 2025;393:151-61. **6.** Rugo HS, et al. *Lancet*. 2023;402:1423-33.

ASCENT-07: Phase 3, Randomized, Open-Label Study

Locally advanced unresectable or metastatic HR+/HER2− BC:

- **No prior chemotherapy** for locally advanced or metastatic HR+/HER2− BC
- Measurable disease per RECIST v1.1
- Must have at least 1 of the following:
  - Progression on ≥ 2 previous lines of ET ± targeted therapy for mBC[a]
  - Progression < 6 mo of starting 1L ET ± CDK4/6i for mBC
  - Recurrence < 24 mo of starting adjuvant ET + CDK4/6i and no longer a candidate for additional ET for mBC

N = 690

R 2:1

Sacituzumab govitecan 10 mg/kg IV Days 1 and 8, every 21 days n = 456

Treatment of physician's choice (capecitabine, paclitaxel, nab-paclitaxel)[b] n = 234

Treatment continued until disease progression[c] or unacceptable toxicity

Stratification factors:

- Duration of prior CDK4/6i[d] for mBC (none vs ≤ 12 mo vs > 12 mo)
- HER2 IHC (HER2 IHC 0 vs HER2 IHC-low [IHC 1+ or IHC 2+/ISH–])
- Geographic region (US/Canada/UK/EU vs ROW)

End points

Primary

- PFS by BICR

Key Secondary

- OS
- ORR by BICR
- QOL

Other Secondary

- PFS by INV
- ORR by INV
- DOR by BICR and INV
- Safety

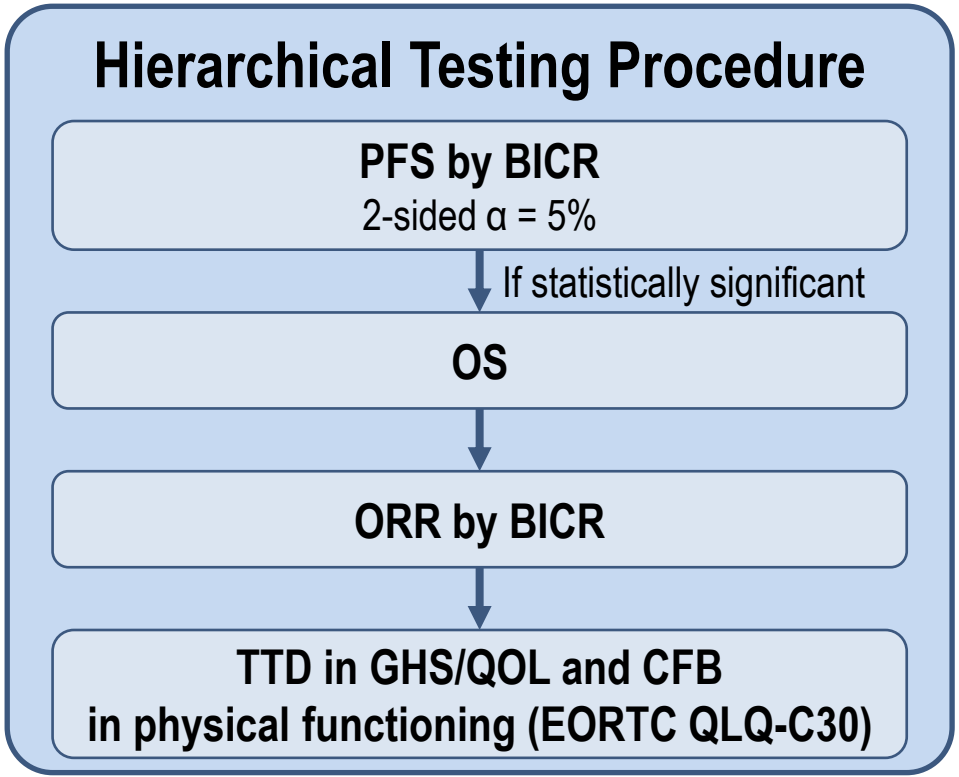
ClinicalTrials.gov identifier: NCT05840211.

[a]Disease recurrence while on the first 24 months of starting adjuvant ET will be considered a line of therapy; these participants will only require 1 line of ET in the metastatic setting. [b]Paclitaxel 80 mg/m^2 or nab-paclitaxel 100 mg/m^2 IV on days 1, 8, and 15 of 28-day cycles, or capecitabine oral 1000 or 1250 mg/m^2 twice daily for first 2 weeks of 21-day cycles. [c]Per RECIST v1.1. [d]Enrollment of CDK4/6i-naïve participants was capped at 10%.

1L, first-line; **BICR**, blinded independent central review; **CDK4/6i**, cyclin-dependent kinase 4/6 inhibitor; **DOR**, duration of response; **ET**, endocrine therapy; **EU**, European Union; **HER2−**, human epidermal growth factor receptor 2 negative; **HR+**, hormone receptor positive; **IHC**, immunohistochemistry; **INV**, investigator assessment; **ISH**, in situ hybridization; **IV**, intravenously; **mBC**, metastatic breast cancer; **mo**, months; **ORR**, objective response rate; **OS**, overall survival; **PFS**, progression-free survival; **QOL**, quality of life; **R**, randomized; **RECIST v1.1**, Response Evaluation Criteria in Solid Tumors, version 1.1; **ROW**, rest of the world.

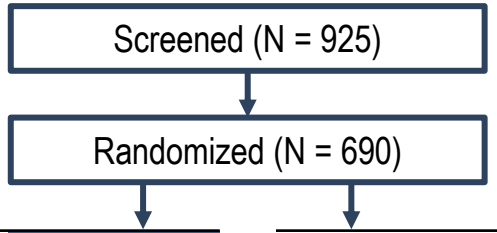
Statistical Analysis

- Planned enrollment: ~654 participants (actual enrolled: 690)
- Data cutoff for primary PFS analysis (planned after ~415 events): September 15, 2025
  - 419 observed PFS events by BICR (61% maturity)
  - 187 observed OS events (27% maturity)
- The study had 99% power to detect a PFS HR of 0.64 at two-sided 5% significance level (MDD HR=0.815)
- Median duration of follow-up: 15.4 months



BICR, blinded independent central review; **CFB**, change from baseline; **EORTC QLQ-C30**, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire C30; **GHS**, Global Health Status; **HR**, hazard ratio; **MDD**, minimum detectable difference; **ORR**, objective response rate; **OS**, overall survival; **PFS**, progression-free survival; **QOL**, quality of life; **TTD**, time to deterioration.

Participant Disposition



n (%)	SG (n = 456)
Treated	449 (98)
Discontinued study treatment	348 (76)
Disease progression	301 (66)
Adverse events	14 (3)
Participant decision	12 (3)
Death	10 (2)
Never dosed with study drug	7 (2)
Investigator decision	4 (1)
Lost to follow-up	1 (< 1)

n (%)	TPC (n = 234)
Treated	232 (99)
Discontinued study treatment	203 (87)
Disease progression	164 (70)
Adverse events	15 (6)
Death	9 (4)
Investigator decision	9 (4)
Participant decision	4 (2)
Never dosed with study drug	2 (1)
Lost to follow-up	0 (0)

- Capecitabine (43%)
- Taxane (57%)
  - Nab-paclitaxel (39%)
  - Paclitaxel (18%)

At data cutoff[a], 139 (20%) participants remained on treatment: 108 (24%) on SG and 31 (13%) on TPC

[a]September 15, 2025.
SG, sacituzumab govitecan; **TPC**, treatment of physician's choice.

Demographics and Baseline Characteristics

ITT Population	SG (n = 456)	TPC (n = 234)
Female sex, n (%)	452 (99)	232 (99)
Median age, (range) year	57 (29-88)	58 (27-80)
≥ 65 years, n (%)	106 (23)	74 (32)
Geographic region[a], n (%)		
US/Canada/UK/EU	181 (40)	93 (40)
Rest of the world	275 (60)	141 (60)
Race[b], n (%)		
White	227 (50)	106 (45)
Asian	176 (39)	95 (41)
Black	10 (2)	3 (1)
Other/Not specified	43 (9)	30 (13)
ECOG PS at baseline[c], n (%)		
0	269 (59)	145 (62)
1	187 (41)	89 (38)

ITT Population	SG (n = 456)	TPC (n = 234)
ER/PR status[d], n (%)		
ER+ and PR+	286 (63)	165 (71)
ER+ and PR−	164 (36)	66 (28)
ER− and PR+	2 (<1)	2 (1)
HER2 expression[d,e], n (%)		
IHC 0	192 (42)	100 (43)
HER2 low (IHC 1+; IHC2+/ISH-)	264 (58)	134 (57)
Primary endocrine resistance[f], n (%)	143 (31)	62 (26)
Time from metastatic diagnosis to randomization, median (range) months	23.9 (0.5-192.0)	26.2 (0.3-152.1)
De novo metastatic disease at diagnosis, n (%)	111 (24)	48 (21)
Visceral disease, n (%)	407 (89)	205 (88)
Liver metastasis n (%)	320 (70)	156 (67)
Brain metastasis, n (%)	18 (4)	14 (6)
Bone-only disease, n (%)	18 (4)	11 (5)

[a]EU includes Austria, Belgium, Czech Republic, France, Germany, Greece, Hungary, Italy, Poland, Portugal, and Spain; rest of the world includes Argentina, Australia, Brazil, Chile, China, Hong Kong, Israel, Japan, Malaysia, Mexico, Republic of Korea, Singapore, South Africa, and Taiwan.
[b]As reported by the participants; Other/Not specified includes American Indian or Alaska Native, other races, and not provided/collection not permitted. [c]Scores range from 0 to 5, with higher scores indicating greater disability. [d]Per local testing. [e]Per IRT. [f]Primary endocrine resistance was defined as relapse that had occurred during the first 2 years of adjuvant endocrine therapy or progressive disease that had occurred during the first 6 months of first-line endocrine therapy for metastatic breast cancer.
ECOG PS, Eastern Cooperative Oncology Group performance status; **ER**, estrogen receptor; **EU**, European Union; **HER2**, human epidermal growth factor receptor 2; **IHC**, immunohistochemistry; **IRT**, interactive response technology; **ISH**, in situ hybridization; **ITT**, intent-to-treat; **PR**, progesterone receptor; **SG**, sacituzumab govitecan; **TPC**, treatment of physician's choice.

Prior Therapies

ITT Population	SG (n = 456)	TPC (n = 234)
Metastatic setting		
Median number of lines (range)	2 (0-8)	2 (0-4)
Lines of ET, n (%)		
None	8 (2)	1 (<1)
1 line	122 (27)	63 (27)
2 lines	263 (58)	139 (59)
≥ 3 lines	63 (14)	31 (13)
Previous endocrine-based therapies[a], n (%)		
ET with CDK4/6i	416 (91)	216 (92)
ET with CDK4/6i ≤ 6 months[b]	74 (16)	35 (15)
ET monotherapy	182 (40)	95 (41)
ET with other targeted therapy[c]	160 (35)	74 (32)

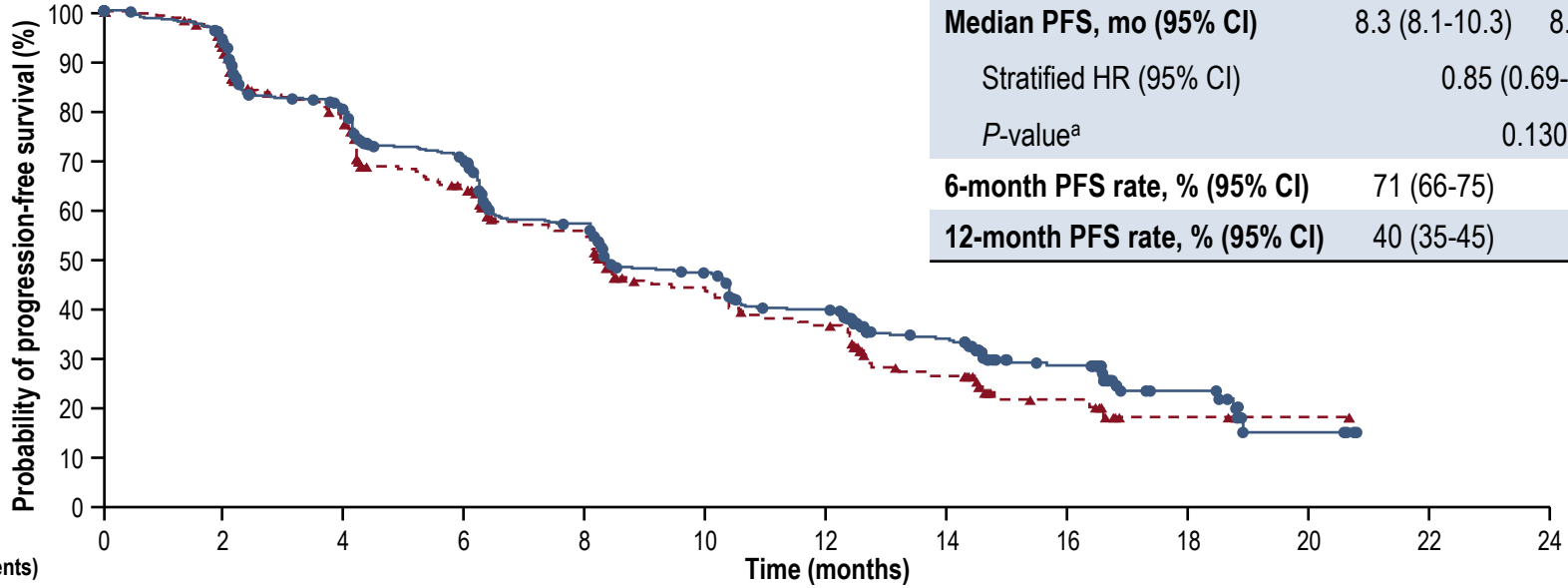
ITT Population	SG (n = 456)	TPC (n = 234)
Adjuvant/neoadjuvant setting[a,d], n (%)		
ET[e]	295 (65)	158 (68)
ET with CDK4/6i	17 (4)	8 (3)
Chemotherapy	260 (57)	140 (60)
Taxane	211 (46)	115 (49)
Anthracycline	217 (48)	118 (50)
Prior CDK4/6i use in metastatic setting, n (%)		
None	32 (7)	19 (8)
≤ 12 months	197 (43)	98 (42)
> 12 months	227 (50)	117 (50)

[a]Therapies reported are not mutually exclusive. [b]In first line. [c]Other targeted therapies in the SG and TPC groups included everolimus (25% and 22%), alpelisib (5% and 3%), and olaparib (2% and 3%). [d]Some participants had unknown adjuvant therapy history. [e]ET includes ET monotherapy and combination therapy.

CDK4/6i, cyclin-dependent kinase 4/6 inhibitor; **ET**, endocrine therapy; **ITT**, intent-to-treat; **SG**, sacituzumab govitecan; **TPC**, treatment of physician's choice.

Primary End Point: Progression-Free Survival by BICR

	SG (n = 456)	TPC (n = 234)
Median PFS, mo (95% CI)	8.3 (8.1-10.3)	8.3 (6.9-10.0)
Stratified HR (95% CI)	0.85 (0.69-1.05)	
P-value[a]	0.130	
6-month PFS rate, % (95% CI)	71 (66-75)	64 (57-71)
12-month PFS rate, % (95% CI)	40 (35-45)	37 (29-44)



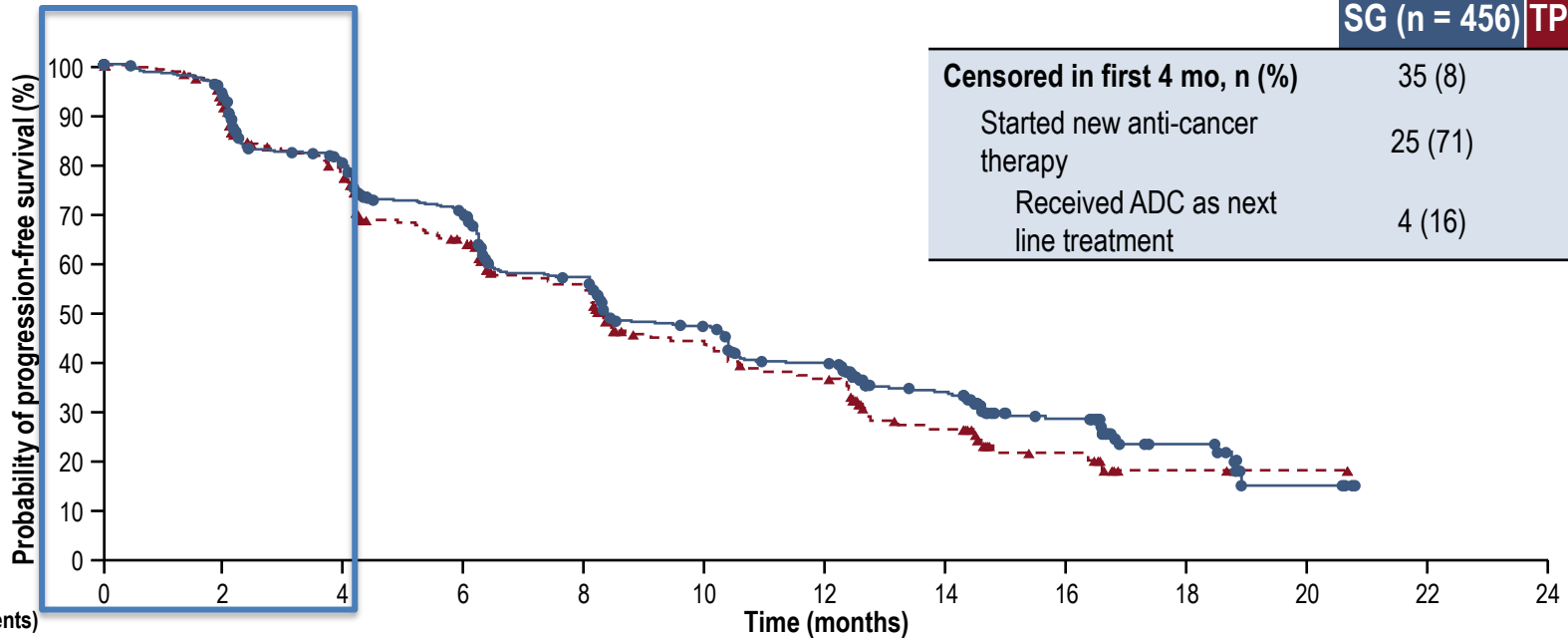
No. at risk (events)												
SG	456 (0)	415 (25)	335 (86)	285 (126)	219 (179)	168 (216)	136 (242)	92 (260)	49 (272)	17 (278)	4 (282)	0 (282)
TPC	234 (0)	204 (16)	159 (49)	119 (74)	90 (90)	63 (108)	52 (118)	30 (131)	14 (135)	5 (137)	2 (137)	0 (137)

With a hazard ratio of 0.85, PFS by BICR did not meet statistical significance

[a]Two-sided *P*-value from stratified log-rank test.

BICR, blinded independent central review; **HR**, hazard ratio; **mo**, months; **PFS**, progression-free survival; **SG**, sacituzumab govitecan; **TPC**, treatment of physician's choice.

Primary End Point: Progression-Free Survival by BICR



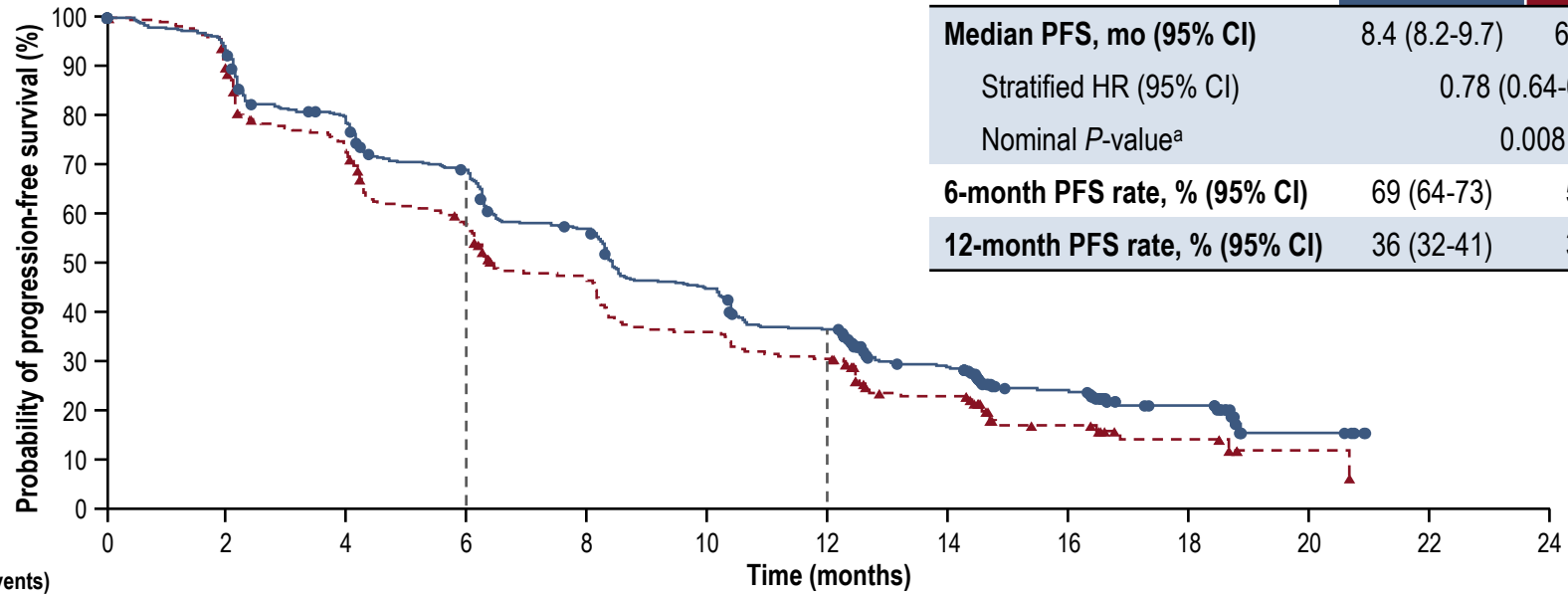
	SG (n = 456)	TPC (n = 234)
Censored in first 4 mo, n (%)	35 (8)	26 (11)
Started new anti-cancer therapy	25 (71)	23 (88)
Received ADC as next line treatment	4 (16)	10 (43)

With a hazard ratio of 0.85, PFS by BICR did not meet statistical significance

[a]Two-sided *P*-value from stratified log-rank test.

BICR, blinded independent central review; **mo**, months; **PFS**, progression-free survival; **SG**, sacituzumab govitecan; **TPC**, treatment of physician's choice.

Secondary End Point: Progression-Free Survival by Investigator Assessment



	SG (n = 456)	TPC (n = 234)
Median PFS, mo (95% CI)	8.4 (8.2-9.7)	6.4 (6.0-8.1)
Stratified HR (95% CI)	0.78 (0.64-0.93)	
Nominal *P*-value[a]	0.008	
6-month PFS rate, % (95% CI)	69 (64-73)	58 (51-64)
12-month PFS rate, % (95% CI)	36 (32-41)	30 (24-36)

No. at risk (events)												
SG	456 (0)	417 (30)	345 (96)	298 (138)	242 (190)	188 (242)	150 (277)	98 (306)	58 (321)	24 (326)	5 (330)	0 (330)
TPC	234 (0)	203 (23)	160 (62)	124 (94)	92 (118)	71 (139)	60 (150)	34 (163)	15 (170)	8 (172)	2 (173)	0 (174)

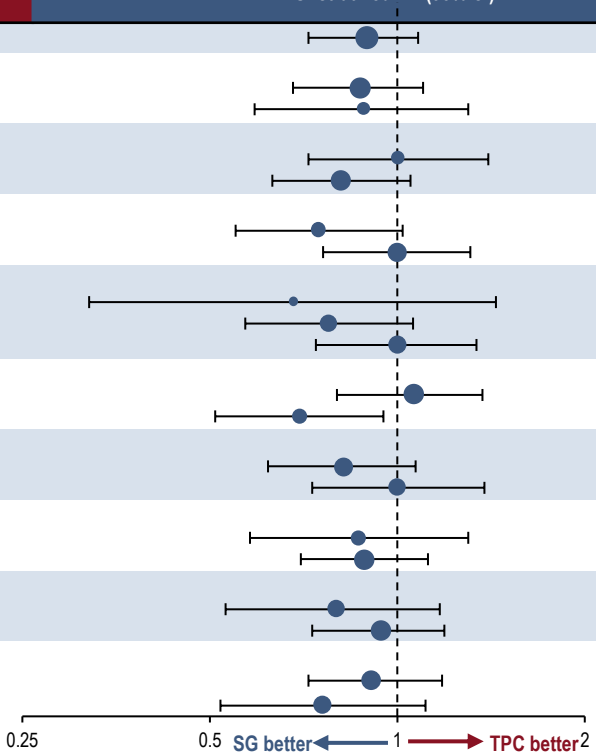
There was a numerical improvement in investigator-assessed PFS with SG versus TPC

[a]Two-sided *P*-value from stratified log-rank test

HR, hazard ratio; **mo**, months; **PFS**, progression-free survival; **SG**, sacituzumab govitecan; **TPC**, treatment of physician's choice.

Subgroup Analysis of Progression-Free Survival by BICR

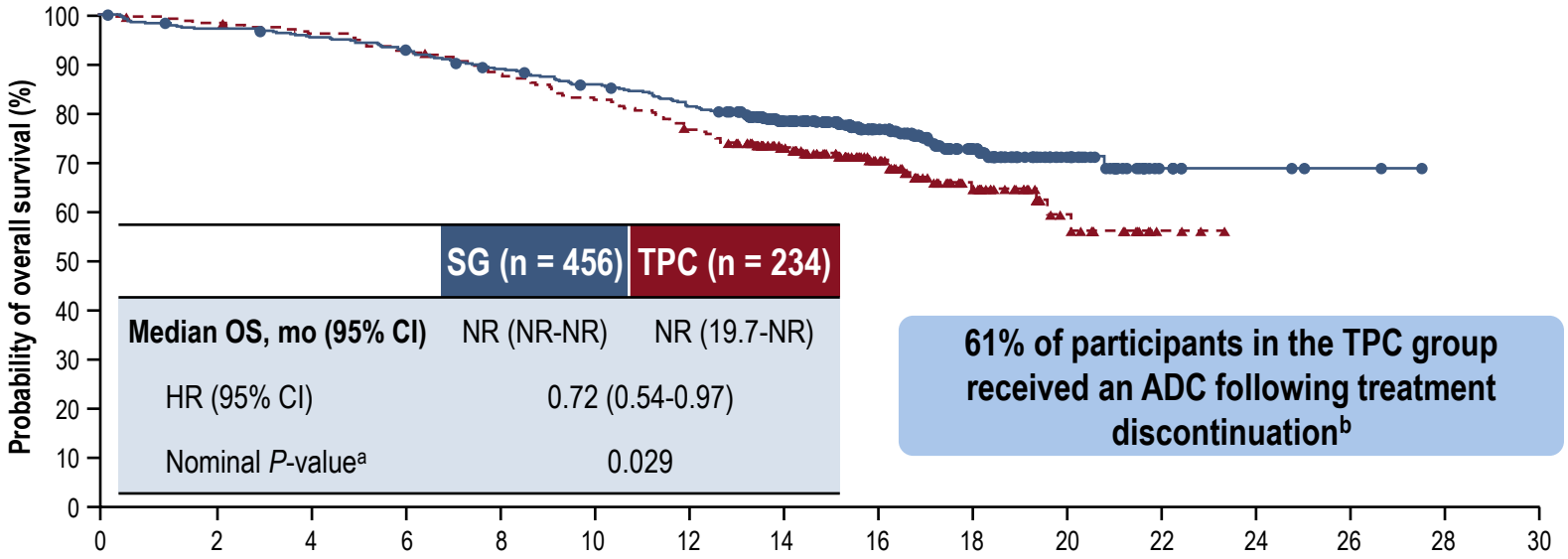
Prespecified subgroup	SG n	SG mPFS, mo	TPC n	TPC mPFS, mo	Unstratified HR (95% CI)
ITT population	456	**8.3**	234	**8.3**	0.88 (0.72-1.08)
Age group					
< 65 years	350	**8.3**	160	**8.2**	0.87 (0.68-1.10)
≥ 65 years	106	**9.7**	74	**9.4**	0.88 (0.59-1.30)
Geographic region					
US/Canada/UK/EU	181	**8.3**	93	**8.3**	1.00 (0.72-1.40)
Rest of the world	275	**8.5**	141	**8.2**	0.81 (0.63-1.05)
HER2 IHC status[a]					
HER2 IHC0	192	**9.2**	100	**8.1**	0.75 (0.55-1.02)
HER2 IHC low	264	**8.2**	134	**8.4**	1.00 (0.76-1.31)
Prior CDK4/6 inhibitor use in metastatic setting					
None	32	**12.2**	19	**8.2**	0.68 (0.32-1.44)
≤ 12 months	197	**8.3**	98	**6.2**	0.78 (0.57-1.06)
> 12 months	227	**8.3**	117	**9.1**	1.00 (0.74-1.34)
Received chemotherapy in neoadjuvant/adjuvant setting					
Yes	260	**8.3**	140	**9.1**	1.05 (0.80-1.37)
No	196	**10.3**	94	**8.0**	0.70 (0.51-0.95)
Choice of chemotherapy[b]					
Taxane (paclitaxel or nab-paclitaxel)	236	**8.3**	134	**8.1**	0.81 (0.62-1.07)
Capecitabine	220	**8.5**	100	**9.4**	1.00 (0.73-1.38)
Number of prior lines of ET in metastatic setting					
≤1	130	**8.8**	64	**10.2**	0.87 (0.58-1.30)
>1	326	**8.3**	170	**8.1**	0.88 (0.70-1.12)
Endocrine resistance					
Primary	143	**10.2**	62	**8.4**	0.79 (0.53-1.17)
Secondary	313	**8.3**	172	**8.2**	0.93 (0.73-1.19)
Liver metastases					
Yes	320	**8.2**	156	**8.0**	0.92 (0.72-1.18)
No	136	**14.1**	78	**10.2**	0.76 (0.52-1.11)



PFS among subgroups was generally consistent with the overall population

[a]Per local testing and per IRT. [b]Choice of chemotherapy was specified by the investigator before randomization. **BICR**, blinded independent central review; **CDK4/6**, cyclin-dependent kinase 4/6; **ET**, endocrine therapy; **EU**, European Union; **HER2**, human epidermal growth factor receptor 2; **HR**, hazard ratio; **IHC**, immunohistochemistry; **IRT**, interactive response technology; **ITT**, intent-to-treat; **mo**, months; **mPFS**, median progression-free survival; **SG**, sacituzumab govitecan; **TPC**, treatment of physician's choice.

Overall Survival at Primary Analysis (27% maturity)



	SG (n = 456)	TPC (n = 234)
Median OS, mo (95% CI)	NR (NR-NR)	NR (19.7-NR)
HR (95% CI)	0.72 (0.54-0.97)	
Nominal *P*-value[a]	0.029	

61% of participants in the TPC group received an ADC following treatment discontinuation[b]

No. at risk (events)															
SG	456 (0)	442 (12)	436 (17)	423 (30)	402 (48)	385 (64)	368 (79)	315 (95)	206 (101)	112 (109)	43 (111)	10 (112)	4 (112)	2 (112)	0 (112)
TPC	234 (0)	229 (4)	225 (7)	217 (15)	205 (26)	192 (39)	181 (50)	145 (61)	95 (65)	51 (71)	19 (74)	4 (75)	0 (75)		

While the OS data were not mature, an early trend was observed favoring SG over TPC

Median follow-up was 15.4 months. [a]The nominal P-value was reported as a descriptive measure of the observed treatment effect and does not support statistical significance. [b]97/160 participants in the TPC group received at least one ADC as subsequent therapy after treatment discontinuation.

ADC, antibody drug conjugate; **HR**, hazard ratio; **mo**, months; **NR**, not reached; **OS**, overall survival; **SG**, sacituzumab govitecan; **TPC**, treatment of physician's choice.

Subsequent Anticancer Therapy

n (%)	SG (n = 348)	TPC (n = 203)
Participants without subsequent anticancer therapy[a]	66 (19)	43 (21)
Participants with any subsequent anticancer therapy[b]	282 (81)	160 (79)
ADC	91 (32)	97 (61)
T-DXd	83 (29)	66 (41)
SG	1 (0.4)	29 (18)
Dato-DXd	0	3 (2)
Other ADC	8 (3)	7 (4)
Chemotherapy	238 (84)	106 (66)
Targeted therapy[c]	65 (23)	24 (15)
Endocrine therapy	42 (15)	24 (15)
Immunotherapy	10 (4)	3 (2)
All other	5 (2)	3 (2)

Among participants who discontinued treatment, almost twice as many in the TPC group compared to the SG group received at least one subsequent ADC

[a]Due to death or due to no subsequent treatment data available. [b]Participants could have received more than 1 treatment type across subsequent lines of treatment. [c]Targeted therapies received included PARPi, bevacizumab, mTORi, AKTi, PI3Ki, CDK4/6i, other.
ADC, antibody drug conjugate; **AKTi**, protein kinase B inhibitor; **CDK4/6i**, cyclin-dependent kinase 4/6 inhibitor; **Dato-DXd**, datopotamab deruxtecan; **mo**, months; **mTORi**, mammalian target of rapamycin inhibitor; **PARPi**, poly-adenosine diphosphate-ribose polymerase inhibitor; **PI3Ki**, phosphatidylinositol 3-kinase inhibitor; **SG**, sacituzumab govitecan; **TDXd**, trastuzumab deruxtecan; **TPC**, treatment of physician's choice.

Tumor Responses and Duration of Response by BICR

Variable	SG (n = 456)	TPC (n = 234)
Objective response rate[a], % (95% CI)	37 (32-42)	33 (27-39)
Stratified odds ratio (95% CI)	1.20 (0.86-1.69)	
Best overall response, n (%)		
Complete response	4 (1)	0 (0)
Partial response	164 (36)	77 (33)
Stable disease	202 (44)	112 (48)
Stable disease ≥ 6 months	126 (28)	48 (21)
Progressive disease	64 (14)	33 (14)
Not evaluable[b]	22 (5)	12 (5)

Variable	SG (n = 456)	TPC (n = 234)
Clinical benefit rate[c], % (95% CI)	65 (60-69)	53 (47-60)
Responders, n	**SG (n = 168)**	**TPC (n = 77)**
Median (range) time to response[d], mo	2.3 (1.2-14.6)	2.3 (1.4-12.5)
Median duration of response, mo (95% CI)	12.1 (8.5-13.8)	9.3 (6.5-14.3)

ORR was similar, with a longer duration of response for SG versus TPC

[a]Objective response rate is defined as the proportion of participants who achieved a best overall response of complete response/partial response. [b]Participants without any evaluable post-baseline tumor assessment are included in Not Evaluable. [c]Clinical benefit rate is defined as the proportion of participants who achieved best overall response of CR/PR or durable SD with duration ≥ 6 months. The 95% CI is based on Clopper-Pearson method. [d]Time to response (months) = (date of first documented complete or partial response - date of randomization + 1)/30.4375.

BICR, blinded independent central review; **CR**, complete response; **ORR**, objective response rate; **mo**, months; **PR**, partial response; **SD**, stable disease; **SG**, sacituzumab govitecan; **TPC**, treatment of physician's choice.

Exposure and Safety Summary

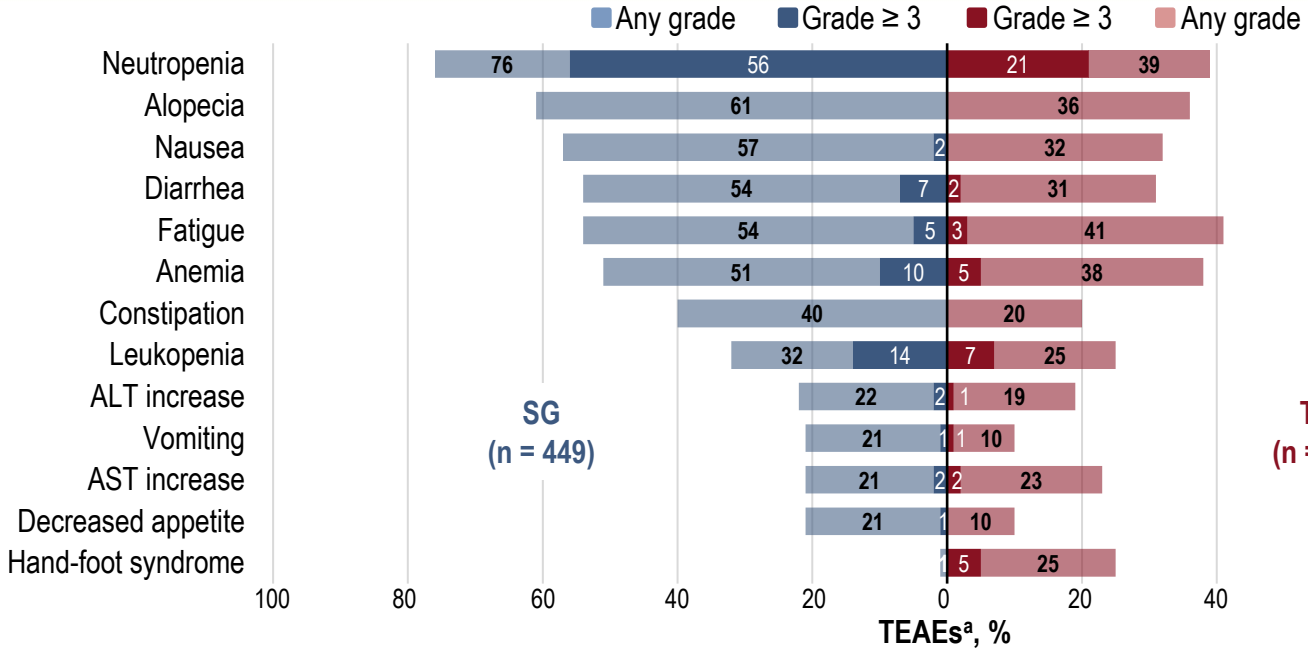
Safety Population	SG (n = 449)	TPC (n = 232)
Median (range) duration of treatment, months	8.3 (0.0-22.1)	6.1 (0.3-21.1)
Median (range) relative dose intensity[a], %	86.2 (33.1-135.5)	93.0 (43.2-108.4)

AEs, n (%)	SG (n = 449)	TPC (n = 232)
Any TEAE	448 (> 99)	226 (97)
Treatment related	447 (> 99)	216 (93)
Grade ≥ 3 TEAEs	323 (72)	112 (48)
Treatment related	305 (68)	86 (37)
Excluding neutropenia[b]	161 (36)	64 (28)
Treatment-emergent SAE	105 (23)	35 (15)
Treatment related	71 (16)	11 (5)
TEAEs leading to treatment discontinuation[c]	13 (3)	16 (7)
TEAEs leading to dose interruption	337 (75)	107 (46)
TEAEs leading to dose reduction	174 (39)	88 (38)
TEAEs leading to death[d]	7 (2)	5 (2)
Treatment related	6 (1)	2 (1)

AEs for SG were consistent with the known SG safety profile.
TEAEs leading to treatment discontinuation were lower with SG versus TPC

TEAEs began on or after the first dose date of study drug up to 30 days after the last dose date of the study drug, if applicable, or the initiation of subsequent anticancer therapy, whichever occurred first.
[a]Relative dose intensity calculated as (total amount of study drug administered/total amount of actual study drug planned by protocol)*100. [b]Combined preferred terms of Neutropenia includes neutrophil count decreased; [c]The most common any-grade TEAEs that led to treatment discontinuation were pneumonia (< 1%) in the SG group and peripheral neuropathy (2%) and infusion-related reaction (< 1%) in the TPC group. [d]TEAEs leading to death were respiratory failure (n = 2) and febrile neutropenia, intestinal ischemia, Klebsiella bacteremia, pneumonia, and septic shock (1 each) in the SG group, and septic shock, sepsis, diabetic ketoacidosis, and acute kidney injury (1 each), as well as 1 death of unknown cause in the TPC group.
AE, adverse event; **SG**, sacituzumab govitecan; **SAE**, serious adverse event; **TEAE**, treatment-emergent adverse event; **TPC**, treatment of physician's choice.

Most Common (Occurring in ≥ 20%) Treatment-Emergent Adverse Events



G-CSF prophylaxis, n (%)	SG (n = 449)	TPC (n = 232)
Primary	89 (20)	11 (5)
Secondary	192 (43)	24 (10)

The most common grade ≥ 3 adverse events in both groups were neutropenia, leukopenia, and anemia

TEAEs began on or after the first dose date of study drug up to 30 days after the last dose date of the study drug or the day before initiation of subsequent anticancer therapy, whichever occurred first. Adverse events were coded using Medical Dictionary for Regulatory Activities. Any-grade hypersensitivity was 14% with SG and 9% with TPC; grade ≥ 3 was < 1% in both groups. Any-grade febrile neutropenia was 8% with SG and 1% with TPC.

[a]Combined preferred terms of Neutropenia includes neutrophil count decreased, Fatigue includes asthenia, Anemia includes hemoglobin decreased and red blood cell count decreased, and Leukopenia includes white blood cell count decreased.

ALT, alanine aminotransferase; **AST**, aspartate aminotransferase; **SG**, sacituzumab govitecan; **TEAE**, treatment-emergent adverse event; **TPC**, treatment of physician's choice.

Conclusions

- PFS by BICR was not statistically significant
  - PFS by investigator showed a numerical improvement for SG

PFS by BICR

HR = 0.85, *P* = 0.130

- Early trend in improvement of OS favoring SG over TPC (27% maturity)
  - Study will continue to further assess OS

Overall survival

Trend in favor of SG vs TPC (HR = 0.72)

- ORR was similar between treatment groups
  - DOR was longer with SG versus TPC

DOR by BICR

Longer with SG vs TPC (12.1 vs 9.3 months)

- Safety profile of SG was manageable and consistent with prior breast cancer studies, with no new safety signals

Treatment discontinuation

Lower rate with SG vs TPC (3% vs 7%)

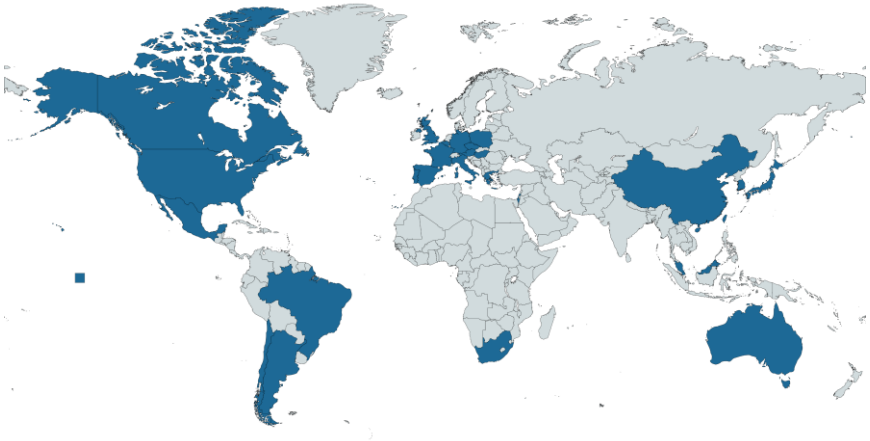
The ASCENT-07 study in participants with HR+/HER2- mBC eligible for first chemotherapy did not meet statistical significance for the primary end point of PFS by BICR

SG remains a standard of care for HR+/HER2- mBC after prior endocrine therapy and chemotherapy, based on the TROPiCS-02 study[1]

1. Rugo HS, et al. *Lancet.* 2023;402:1423-33.

BICR, blinded independent central review; **DOR**, duration of response; **ET**, endocrine therapy; **HER2−**, human epidermal growth factor receptor 2 negative; **HR+**, hormone receptor positive; **HR**, hazard ratio; **mBC**, metastatic breast cancer; **ORR**, objective response rate; **OS**, overall survival; **PFS**, progression-free survival; **SG**, sacituzumab govitecan; **TPC**, treatment of physician's choice.

Acknowledgments



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