Sacituzumab Govitecan Plus Pembrolizumab vs Chemotherapy Plus Pembrolizumab in Patients With Previously Untreated, PD-L1 Positive, Advanced or Metastatic Triple-Negative Breast Cancer: Primary Results From the Randomized, Phase 3 ASCENT-04/KEYNOTE-D19 Study

Clinical solid tumor oncology

SOHC — SWISS ONCOLOGY & HEMATOLOGY CONGRESS

Jens Huober[1], Sara M Tolaney[2], Evandro de Azambuja[3], Kevin Kalinsky[4], Sherene Loi[5], Sung-Bae Kim[6], Clinton Yam[7], Bernardo Rapoport[8,9], Seock-Ah Im[10], Barbara Pistilli[11], Wassim McHayleh[12], David W Cescon[13], Junichiro Watanabe[14], Manuel Alejandro Lara Banuelas[15], Ruffo Freitas-Junior[16], Javier Salvador Bofill[17], Maryam Afshari[18], Dianna Gary[18], Lu Wang[18], Catherine Lai[18], Peter Schmid[19]

[1]Breast Center St. Gallen, HOCH Health Eastern Switzerland St. Gallen, Switzerland; [2]Dana-Farber Cancer Institute, Harvard Medical School, Boston, MA, USA; [3]Institut Jules Bordet Hôpital Universitaire de Bruxelles (H.U.B) and Université Libre de Bruxelles (ULB), Brussels, Belgium; [4]Winship Cancer Institute, Emory University, Atlanta, GA, USA; [5]Peter MacCallum Cancer Centre, Melbourne, Australia; [6]Asan Medical Center, University of Ulsan College of Medicine, Seoul, Republic of Korea; [7]The University of Texas MD Anderson Cancer Center, Houston, TX, USA; [8]The Medical Oncology Centre of Rosebank, Clinical and Translational Research Unit (CTRU), Saxonworld, South Africa; [9]Department of Immunology, Faculty of Health Sciences, University of Pretoria, Pretoria, South Africa; [10]Seoul National University Hospital, Cancer Research Institute, Seoul National University College of Medicine, Seoul National University, Seoul, Republic of Korea; [11]Department of Cancer Medicine, Gustave Roussy, Villejuif, France; [12]AdventHealth Cancer Institute, Orlando, FL, USA; [13]Princess Margaret Cancer Centre, UHN, Toronto, Canada; [14]Juntendo University Graduate School of Medicine, Tokyo, Japan; [15]Oncology Center of Chihuahua, Chihuahua, Mexico; [16]CORA – Advanced Center for Diagnosis of Breast Diseases, Federal University of Goiás, Goiânia, Brazil; [17]Medical Oncology Department, Hospital Universitario Virgen del Rocio, Seville, Spain; [18]Gilead Sciences, Inc., Foster City, CA, USA; [19]Centre for Experimental Cancer Medicine, Barts Cancer Institute, Queen Mary University of London, London, UK

Conclusions[1]

- ASCENT-04/KEYNOTE-D19 is the first randomized, phase 3 study to evaluate the efficacy and safety of an ADC/checkpoint inhibitor combination for first-line treatment of patients with PD-L1+[a] mTNBC
- SG + pembro led to a statistically significant and clinically meaningful improvement in PFS vs chemo + pembro (median 11.2 vs 7.8 months; HR, 0.65; 95% CI, 0.51-0.84; *P* < 0.001)
  — PFS benefit was observed across prespecified subgroups
- OS data are immature, but an early trend in improvement was observed
- ORR was higher (including an increased complete response rate), and responses were more durable with SG + pembro vs chemo + pembro
- The safety profile of SG + pembro was consistent with the established profiles of either agent; no additive toxicity was observed

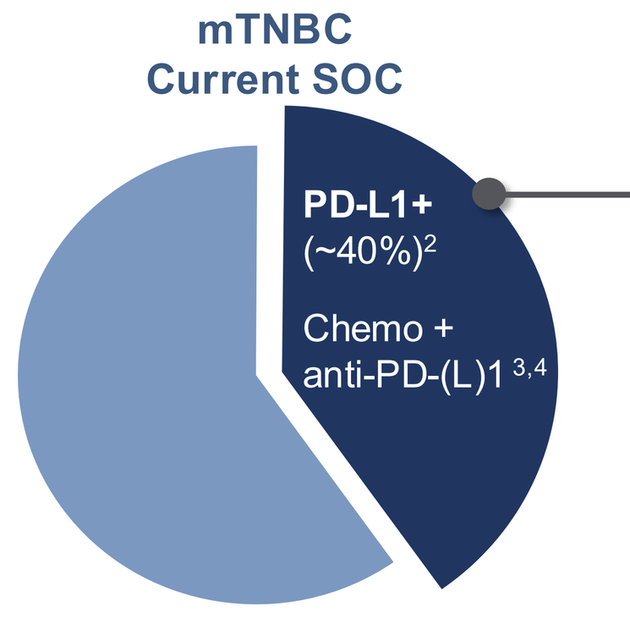
Results from ASCENT-04/KEYNOTE-D19 support the use of SG + pembro as a potential new standard of care for patients with previously untreated, PD-L1+, locally advanced unresectable or metastatic TNBC

Key Takeaways: ASCENT-04/KEYNOTE-D19 Phase 3 Study[1]

- There is an unmet need for better treatments in the first-line setting for patients with PD-L1+ mTNBC
- SG + pembro led to a statistically significant and clinically meaningful improvement in PFS vs chemo + pembro
- These results support SG + pembro as a potential new first-line standard of care

Introduction

Unmet Need in Previously Untreated, PD-L1+, Locally Advanced Unresectable or Metastatic TNBC[1]



Remaining unmet need

- Median PFS observed in prior studies of chemotherapy in combination with immune checkpoint inhibitors was 7.5-9.7 months[2,5]; most patients still experience disease progression[6-8]
- About half of the patients treated for 1L mTNBC do not receive 2L treatment[6]

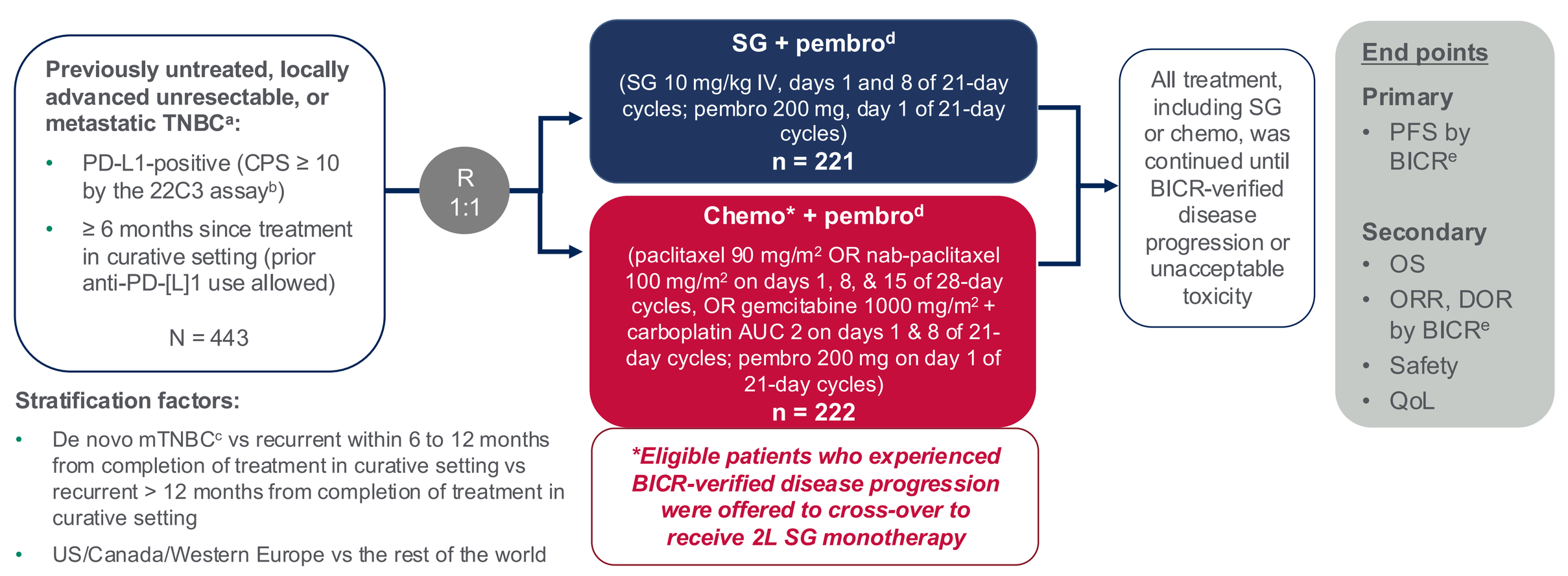
Rationale for this study

- SG is the only Trop-2–directed ADC with demonstrated OS benefit in multiple phase 3 studies; it is approved for 2L+ mTNBC and pre-treated HR+/HER2- mBC in multiple countries[9,10]
- Early studies have observed improved anti-tumor effects when immunotherapy is combined with ADCs[11]

We present the primary results from the global, randomized, phase 3 ASCENT-04/KEYNOTE-D19 study of SG + pembro vs chemo + pembro in previously untreated, PD-L1+, locally advanced unresectable or metastatic TNBC

Methods

ASCENT-04/KEYNOTE-D19 Study Design[1]



Stratification factors:

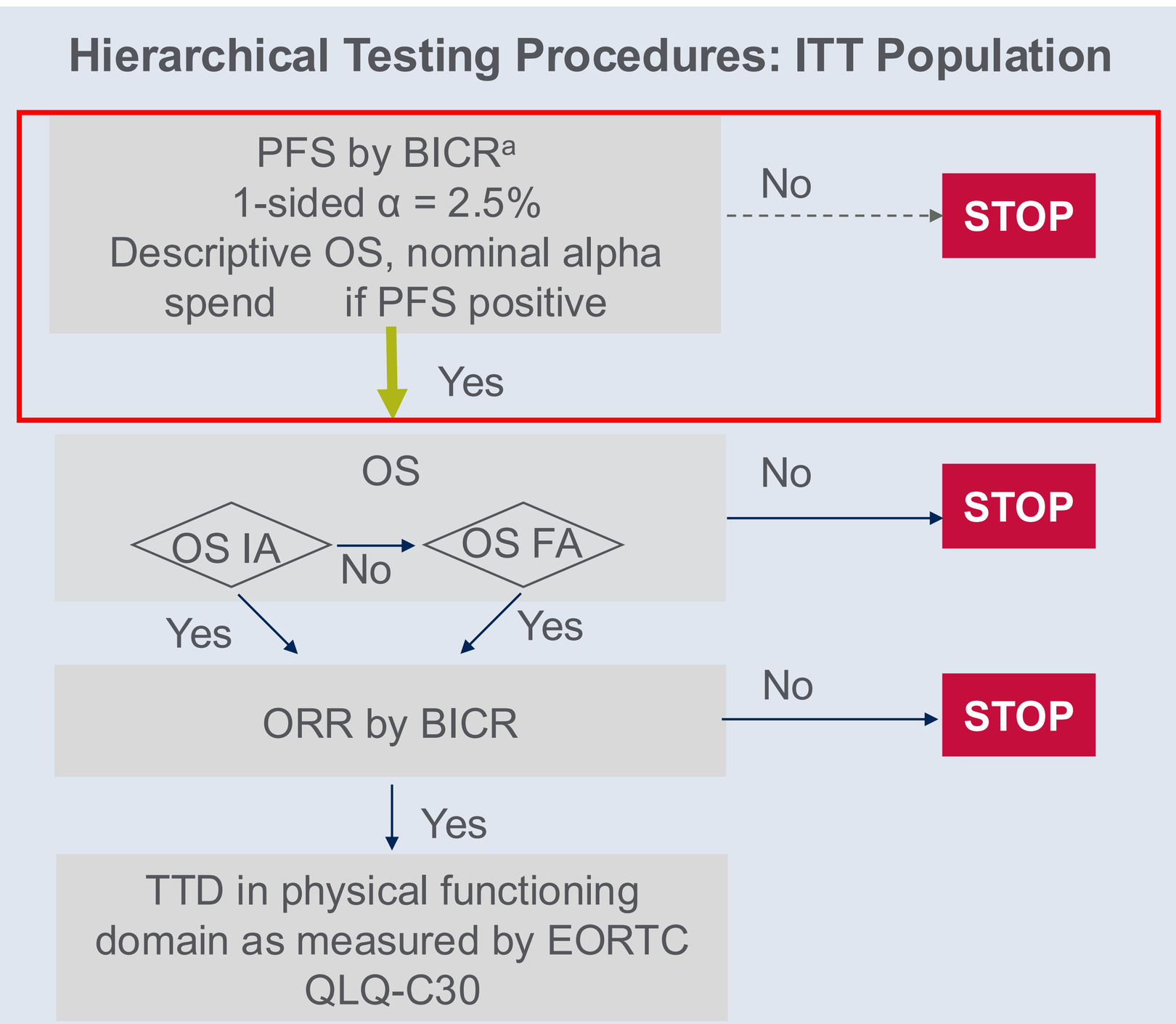
- De novo mTNBC[c] vs recurrent within 6 to 12 months from completion of treatment in curative setting vs recurrent > 12 months from completion of treatment in curative setting
- US/Canada/Western Europe vs the rest of the world
- Prior exposure to anti-PD-(L)1 (yes vs no)

ClinicalTrials.gov identifier: NCT05382286.
[a]TNBC status determined according to standard American Society of Clinical Oncology-College of American Pathologists criteria. [b]Dako, Agilent Technologies. [c]Up to 35% de novo mTNBC. [d]Pembro was administered for a maximum of 35 cycles. [e]Per RECIST v1.1.
AUC, area under the curve; BICR, blinded independent central review; chemo, chemotherapy; CPS, combined positive score; DOR, duration of response; IV, intravenously; ORR, objective response rate; OS, overall survival; PD-L1, programmed cell death ligand 1; pembro, pembrolizumab; PFS, progression-free survival; QoL, quality of life; R, randomized; RECIST v1.1; Response Evaluation Criteria in Solid Tumors, version 1.1; SG, sacituzumab govitecan; TNBC, triple-negative breast cancer; TTR, time-to-response.
1. Tolaney S, et al. Sacituzumab Govitecan Plus Pembrolizumab vs Chemotherapy Plus Pembrolizumab in Patients With Previously Untreated, PD-L1 Positive, Advanced or Metastatic Triple-Negative Breast Cancer: Primary Results From the Randomized, Phase 3 ASCENT-04/KEYNOTE-D19 Study. Presented at ASCO 2025.

Statistical Analysis

- Enrollment was planned for ~440 eligible patients
- To control for overall type I error, a hierarchical testing procedure was implemented
  — At primary analysis, PFS will be tested at 1-sided alpha of 2.5%
  — OS will be summarized descriptively at the time of primary PFS analysis; if PFS is positive, a nominal alpha will be spent
  — If PFS is significant at primary analysis, at the time of OS analysis, formal sequential testing of OS, ORR, and then TTD of physical functioning will be performed
- Data cutoff date for Primary PFS: March 3, 2025
  — There were 249 observed PFS events by BICR
  — Median follow-up was 14.0 months (range, 0.1-28.6)
  — At the data cutoff date, 95 patients (43%) in the SG + pembro group and 52 patients (23%) in the chemo + pembro group continued to receive study treatment

Statistical Analysis[1]



Results

Demographics and Baseline Characteristics[1]

ITT Population	SG + Pembro (n = 221)	Chemo + Pembro (n = 222)
Female sex, n (%)	221 (100)	222 (100)
Median age, (range) yr	54 (23-88)	55 (27-82)
≥ 65 yr, n (%)	58 (26)	57 (26)
Race or ethnic group,[a] n (%)		
White	139 (63)	118 (53)
Asian	43 (19)	63 (28)
Black	13 (6)	11 (5)
Other/not specified	26 (12)	30 (14)
Geographic region, n (%)		
US/Canada/Western Europe	85 (38)	85 (38)
Rest of the world[b]	136 (62)	137 (62)
ECOG PS at baseline,[c] n (%)		
0	156 (71)	154 (69)
1	65 (29)	67 (30)
Curative treatment-free interval, n (%)		
De novo	75 (34)	75 (34)
Recurrent within 6-12 mo	40 (18)	40 (18)
Recurrent > 12 mo	106 (48)	107 (48)

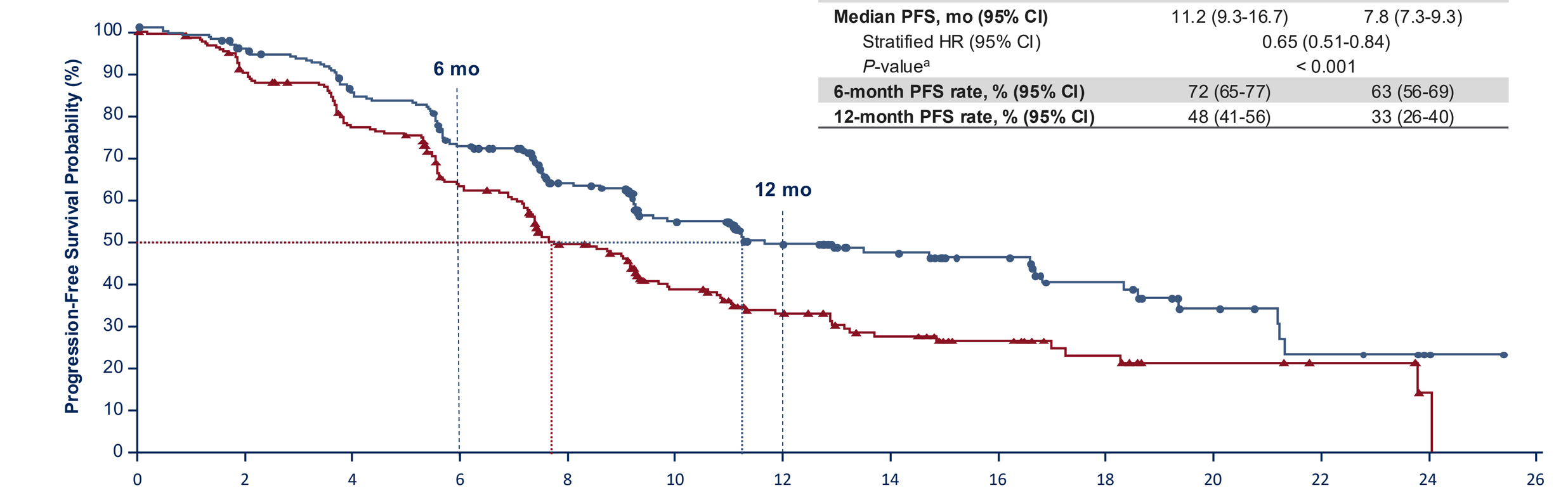
ITT Population	SG + Pembro (n = 221)	Chemo + Pembro (n = 222)
PD-L1 CPS ≥ 10,[d] n (%)	221 (100)	222 (100)
Metastatic sites, n (%)		
Lymph node	159 (72)	154 (69)
Lung	111 (50)	95 (43)
Bone	61 (28)	45 (20)
Liver	55 (25)	57 (26)
Brain	8 (4)	6 (3)
Other[e]	81 (37)	71 (32)
Chemo selected prior to randomization,[f] n (%)		
Taxane	116 (52)	114 (51)
Gemcitabine/carboplatin	105 (48)	108 (49)
Prior anti-PD-(L)1 therapy,[g] n (%)	9 (4)	11 (5)

Data cutoff date: March 3, 2025.
[a]As reported by the patients; "other" includes American Indian or Alaska Native, other, and not permitted. [b]Rest of the world includes Argentina, Australia, Brazil, Chile, Czech Republic, Hong Kong, Hungary, Israel, Japan, Malaysia, Mexico, Poland, Singapore, South Africa, South Korea, Taiwan, and Turkey. [c]One patient in the chemo + pembro group had an ECOG PS ≥ 2. [d]PD-L1 status assessed using the PD-L1 IHC 22C3 assay (Dako, Agilent Technologies) at the time of enrollment. [e]Other metastatic sites includes pleura, pleural effusion, skin, soft tissue, chest wall, and muscle. [f]Actual chemo received was consistent with what was selected prior to randomization; however, two patients were randomized but did not receive treatment. [g]While 20 patients were included in the stratified subgroup of prior exposure to anti-PD-(L)1 therapy (yes) per the IRT system, only 6 patients received prior treatment with anti-PD-(L)1 agents per the clinical database.
Chemo, chemotherapy; CPS, combined positive score; ECOG PS, Eastern Cooperative Oncology Group performance status; IHC, immunohistochemistry; IRT, interactive response technology; ITT, intent-to-treat; PARPi, poly ADP-ribose polymerase inhibitor; PD-L1, programmed cell death ligand 1; pembro, pembrolizumab; SG, sacituzumab govitecan.
1. Tolaney S, et al. Sacituzumab Govitecan Plus Pembrolizumab vs Chemotherapy Plus Pembrolizumab in Patients With Previously Untreated, PD-L1 Positive, Advanced or Metastatic Triple-Negative Breast Cancer: Primary Results From the Randomized, Phase 3 ASCENT-04/KEYNOTE-D19 Study. Presented at ASCO 2025.

Results, cont'd

Progression-Free Survival by BICR[1]

	SG + Pembro (n = 221)	Chemo + Pembro (n = 222)
Number of PFS events	109	140
Median PFS, mo (95% CI)	11.2 (9.3-16.7)	7.8 (7.3-9.3)
Stratified HR (95% CI)	0.65 (0.51-0.84)	
P-value[a]	< 0.001	
6-month PFS rate, % (95% CI)	72 (65-77)	63 (56-69)
12-month PFS rate, % (95% CI)	48 (41-56)	33 (26-40)



No. of Patients Still at Risk (Events)

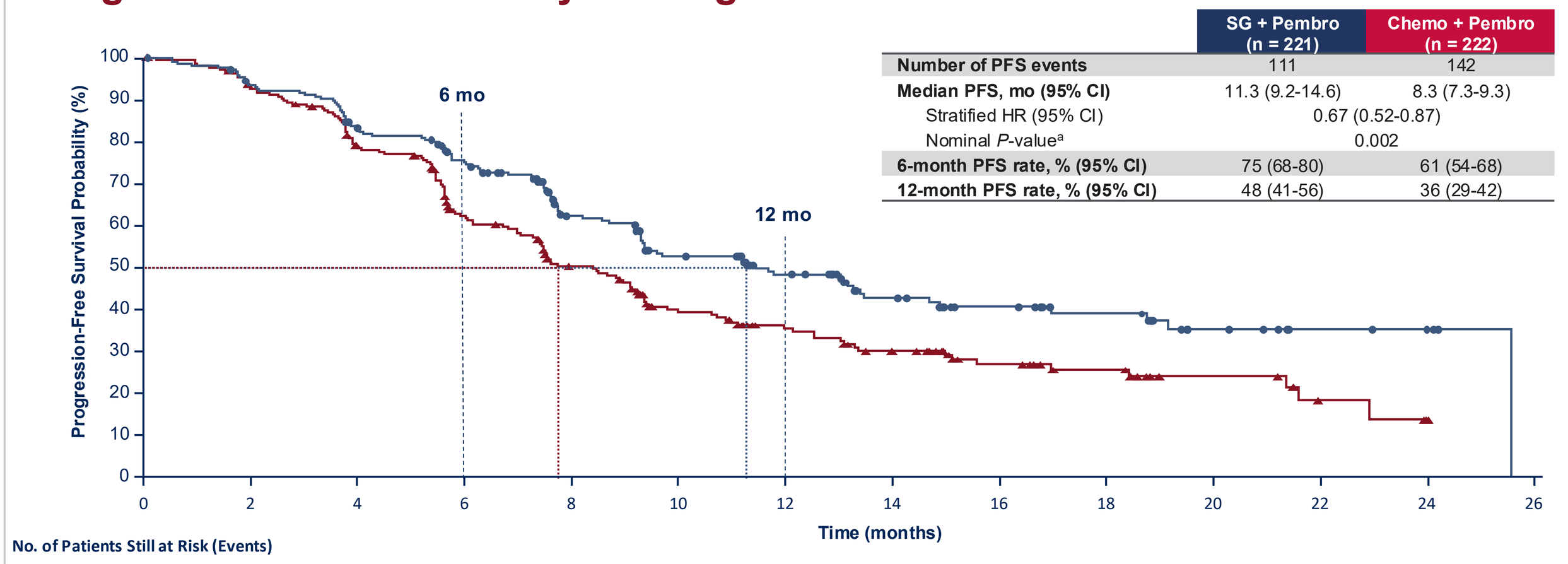
	0	2	4	6	8	10	12	14	16	18	20	22	24	26
SG + Pembro	221 (0)	202 (11)	174 (33)	142 (59)	105 (75)	78 (89)	58 (96)	42 (98)	34 (99)	22 (103)	11 (106)	6 (109)	2 (109)	0 (109)
TPC + Pembro	222 (0)	191 (21)	159 (48)	123 (76)	88 (102)	59 (120)	40 (128)	29 (134)	21 (135)	13 (137)	7 (138)	4 (138)	1 (139)	0 (140)

Data cutoff date: March 3, 2025
[a]Two-sided *P*-value from stratified log-rank test.
BICR, blinded independent central review; chemo, chemotherapy; CI, confidence interval; HR, hazard ratio; PFS, progression-free survival; pembro, pembrolizumab; SG, sacituzumab govitecan.
1. Tolaney S, et al. Sacituzumab Govitecan Plus Pembrolizumab vs Chemotherapy Plus Pembrolizumab in Patients With Previously Untreated, PD-L1 Positive, Advanced or Metastatic Triple-Negative Breast Cancer: Primary Results From the Randomized, Phase 3 ASCENT-04/KEYNOTE-D19 Study. Presented at ASCO 2025.

- SG + pembro demonstrated statistically significant and clinically meaningful improvement in PFS vs chemo + pembro by BICR analysis, with a 35% reduction in risk of disease progression or death

Progression-Free Survival by Investigator Assessment[1]

	SG + Pembro (n = 221)	Chemo + Pembro (n = 222)
Number of PFS events	111	142
Median PFS, mo (95% CI)	11.3 (9.2-14.6)	8.3 (7.3-9.3)
Stratified HR (95% CI)	0.67 (0.52-0.87)	
Nominal *P*-value[a]	0.002	
6-month PFS rate, % (95% CI)	75 (68-80)	61 (54-68)
12-month PFS rate, % (95% CI)	48 (41-56)	36 (29-42)

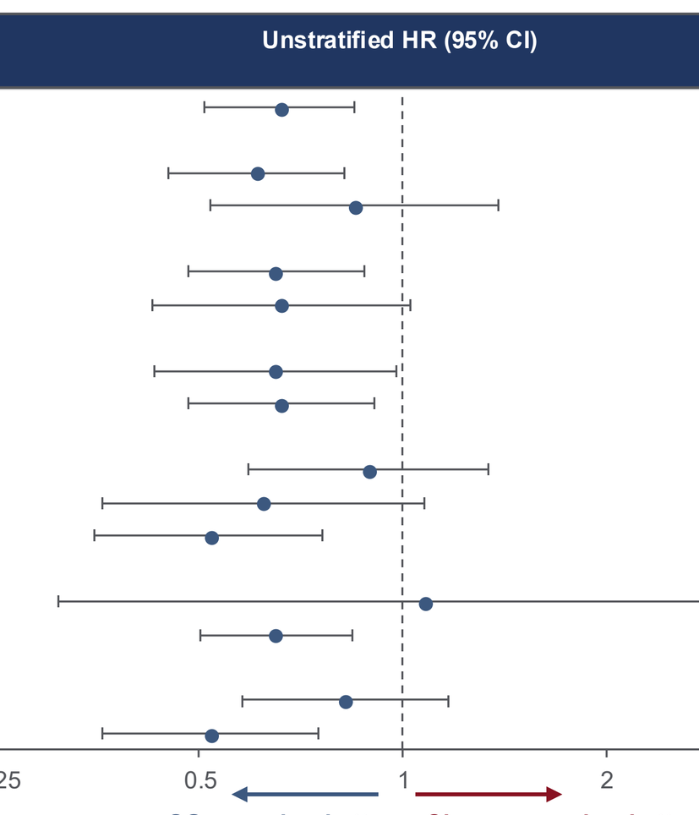


Data cutoff date: March 3, 2025
[a]Two-sided *P*-value from stratified log-rank test.

- PFS by investigator assessment was consistent with the BICR analysis, demonstrating PFS benefit with SG + pembro vs chemo + pembro

Subgroup Analysis of Progression-Free Survival by BICR[1]

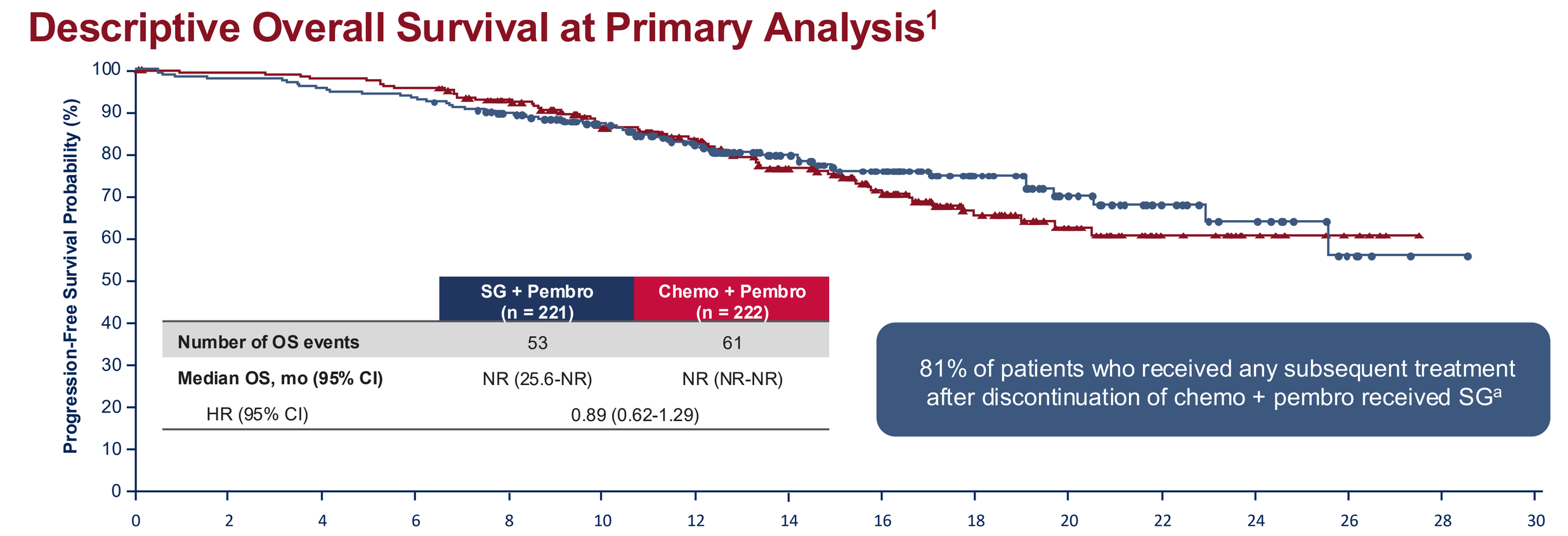
	SG + Pembro n	SG + Pembro Median PFS, Mo (95% CI)	Chemo + Pembro n	Chemo + Pembro Median PFS, Mo (95% CI)	Unstratified HR (95% CI)
ITT population	221	**11.2** (9.3-16.7)	222	**7.8** (7.3-9.3)	0.66 (0.51-0.85)
Age group					
< 65 yr	163	**11.3** (9.3-16.8)	165	**7.5** (7.0-9.2)	0.61 (0.45-0.82)
≥ 65 yr	58	**11.1** (7.5-NR)	57	**9.3** (7.3-13.2)	0.85 (0.52-1.39)
ECOG PS					
0	156	**12.9** (9.3-16.8)	154	**8.7** (7.3-9.9)	0.65 (0.48-0.88)
≥ 1	65	**9.2** (7.5-18.3)	67	**7.5** (5.6-9.3)	0.66 (0.43-1.03)
Geographic region					
US/Canada/Western Europe	85	**11.7** (7.5-19.4)	85	**7.4** (5.7-9.9)	0.65 (0.43-0.98)
Rest of the world	136	**11.2** (9.3-16.7)	137	**8.4** (7.4-9.3)	0.66 (0.48-0.91)
Curative treatment-free interval					
De novo	75	**8.1** (7.3-18.6)	75	**7.7** (6.1-11.9)	0.89 (0.59-1.34)
Recurrent 6-12 mo	40	**9.9** (5.7-16.8)	40	**7.2** (4.4-9.1)	0.62 (0.36-1.08)
Recurrent > 12 mo	106	**16.6** (11.0-NR)	107	**8.7** (7.3-10.8)	0.52 (0.35-0.76)
Prior (neo)adjuvant anti-PD-(L)1 therapy					
Yes	9	**7.5** (0.9-NR)	11	**6.6** (2.1-NR)	1.08 (0.31-3.75)
No	212	**11.7** (9.3-16.8)	211	**7.8** (7.4-9.3)	0.65 (0.50-0.84)
Chemo selected prior to randomization					
Taxane	116	**11.1** (8.6-16.7)	114	**9.2** (7.2-12.9)	0.82 (0.58-1.17)
Gemcitabine/Carboplatin	105	**11.3** (9.2-21.2)	108	**7.4** (6.9-9.0)	0.52 (0.36-0.75)



Data cutoff date: March 3, 2025
BICR, blinded independent central review; chemo, chemotherapy; ECOG PS, Eastern Cooperative Oncology Group performance status; HR, hazard ratio; mo, months; NR, not reached; PARPi, poly ADP-ribose polymerase inhibitor; PD-(L)1, programmed death (ligand) 1; pembro, pembrolizumab; PFS, progression-free survival; SG, sacituzumab govitecan.
1. Tolaney S, et al. Sacituzumab Govitecan Plus Pembrolizumab vs Chemotherapy Plus Pembrolizumab in Patients With Previously Untreated, PD-L1 Positive, Advanced or Metastatic Triple-Negative Breast Cancer: Primary Results From the Randomized, Phase 3 ASCENT-04/KEYNOTE-D19 Study. Presented at ASCO 2025.

- PFS benefit was observed for SG + pembro vs chemo + pembro across pre-specified subgroups

Descriptive Overall Survival at Primary Analysis[1]



	SG + Pembro (n = 221)	Chemo + Pembro (n = 222)
Number of OS events	53	61
Median OS, mo (95% CI)	NR (25.6-NR)	NR (NR-NR)
HR (95% CI)	0.89 (0.62-1.29)	

No. of Patients Still at Risk (Events)

	0	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30
SG + Pembro	221 (0)	216 (5)	211 (10)	206 (15)	190 (23)	162 (28)	138 (37)	111 (41)	88 (46)	55 (47)	36 (50)	21 (51)	14 (52)	5 (53)		
TPC + Pembro	222 (0)	218 (2)	215 (5)	210 (10)	193 (16)	166 (29)	142 (34)	111 (45)	87 (53)	56 (58)	38 (60)	19 (61)	11 (61)	6 (61)		

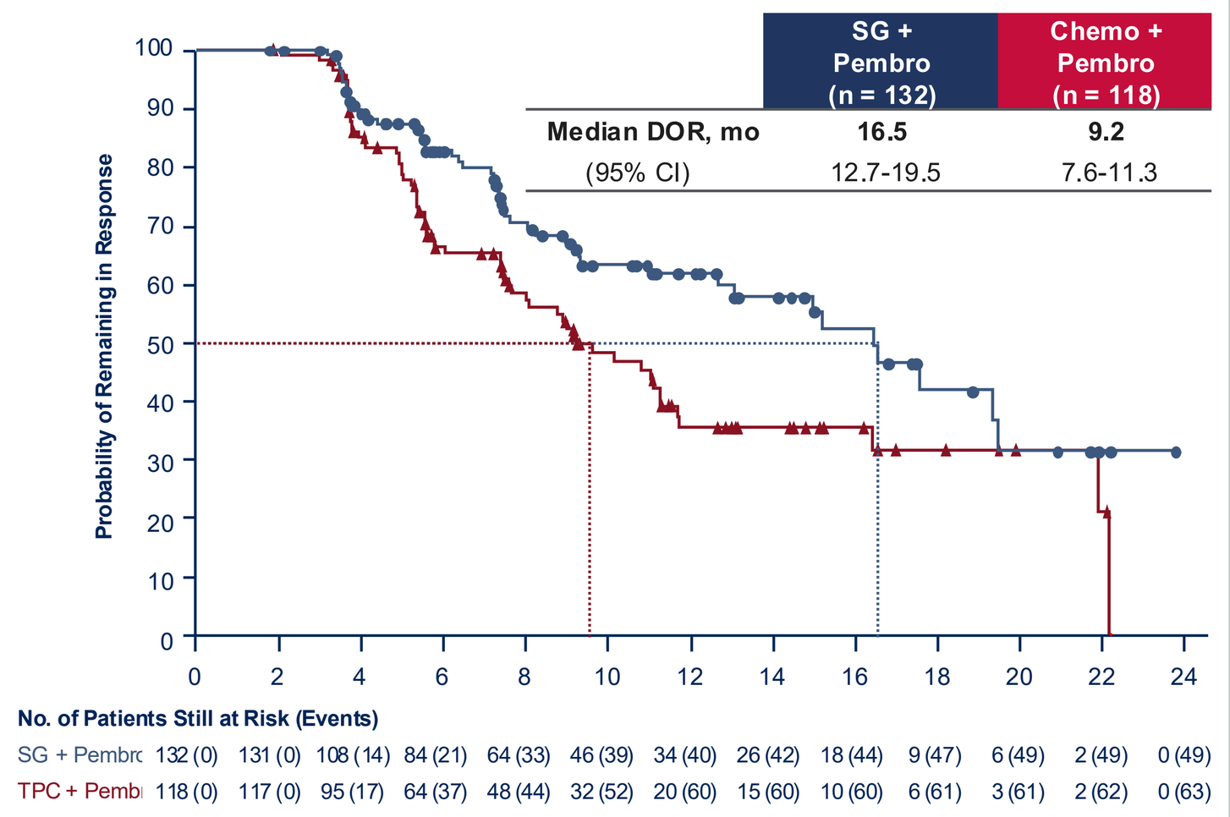
Data cutoff date: March 3, 2025
[a]Two-sided *P*-value from stratified log-rank test.

- OS data were immature (maturity rate, 26%), however, a positive trend in improvement was observed for SG + pembro vs chemo + pembro

Tumor Response and Duration of Response by BICR[1]

Variable	SG + Pembro (n = 221)	Chemo + Pembro (n = 222)
Objective response rate[a] (95% CI), %	60 (52.9-66.3)	53 (46.4-59.9)
Stratified odds ratio (95% CI)	1.3 (0.9-1.9)	
Best overall response, n (%)		
Complete response	28 (13)	18 (8)
Partial response	104 (47)	100 (45)
Stable disease	70 (32)	70 (32)
Stable disease ≥ 6 months	23 (10)	29 (13)
Progressive disease	9 (4)	26 (12)
Not evaluable	10 (5)	8 (4)
Time to response,[b] median (range), months	1.9 (1.0-9.3)	1.9 (1.1-11.4)

	SG + Pembro (n = 132)	Chemo + Pembro (n = 118)
Median DOR, mo	**16.5**	**9.2**
(95% CI)	12.7-19.5	7.6-11.3



No. of Patients Still at Risk (Events)

	0	2	4	6	8	10	12	14	16	18	20	22	24
SG + Pembro	132 (0)	131 (0)	108 (14)	84 (21)	64 (33)	46 (39)	34 (40)	26 (42)	18 (44)	9 (47)	6 (49)	2 (49)	0 (49)
TPC + Pembro	118 (0)	117 (0)	95 (17)	64 (37)	48 (44)	32 (52)	20 (60)	15 (60)	10 (60)	6 (61)	3 (61)	2 (62)	0 (63)

Data cutoff date: March 3, 2025.
[a]Objective response rate is defined as the proportion of patients who achieved a best overall response of complete response/partial response; [b]Time to response (months) = (date of first documented complete or partial response - date of randomization + 1)/30.4375.
BICR, blinded independent central review; DOR, duration of response; mo, months; pembro, pembrolizumab; SG, sacituzumab govitecan.
1. Tolaney S, et al. Sacituzumab Govitecan Plus Pembrolizumab vs Chemotherapy Plus Pembrolizumab in Patients With Previously Untreated, PD-L1 Positive, Advanced or Metastatic Triple-Negative Breast Cancer: Primary Results From the Randomized, Phase 3 ASCENT-04/KEYNOTE-D19 Study. Presented at ASCO 2025.

- A substantially longer duration of response and a higher overall response rate (including an increased complete response rate) was observed for SG + pembro vs chemo + pembro

Exposure and Safety Summary[1]

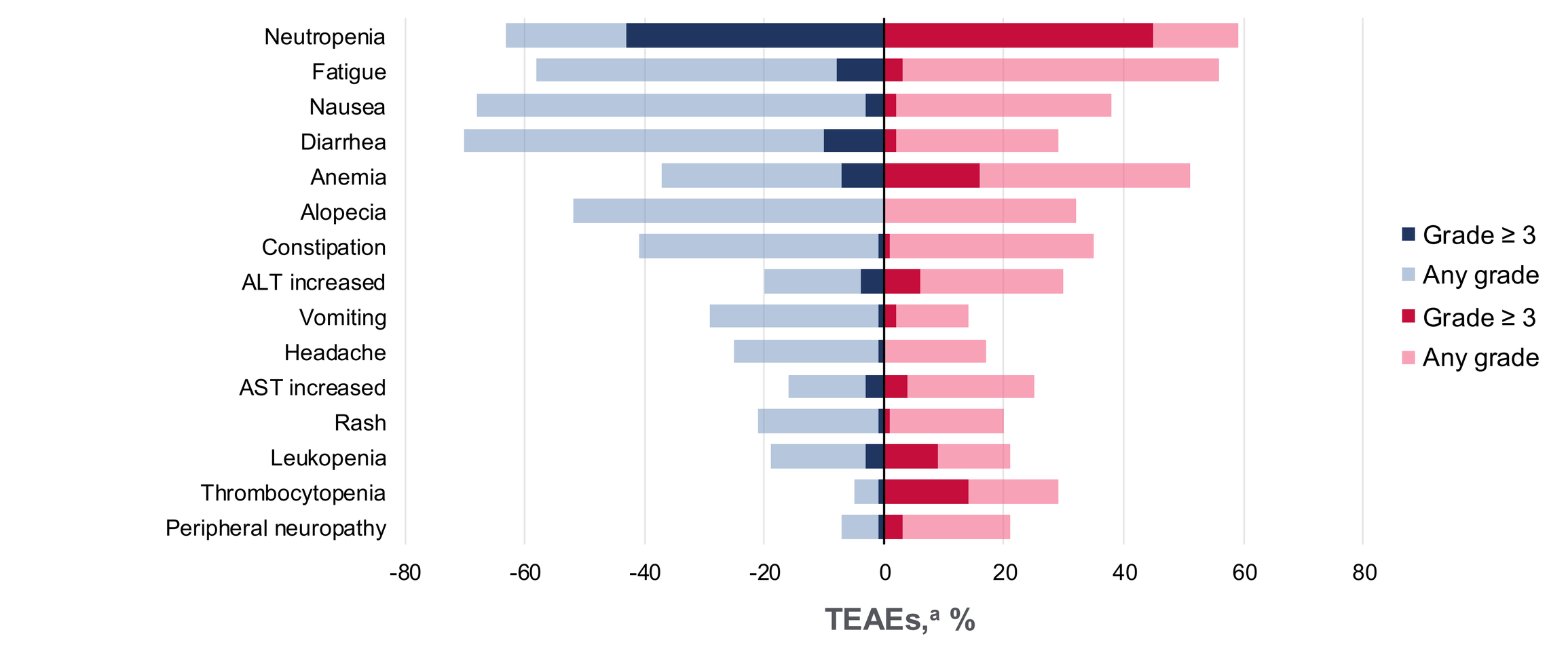
ITT population	SG + Pembro (n = 221)		Chemo + Pembro (n = 222)	
Treatment component	**SG**	**Pembro**	**Chemo**	**Pembro**
All treated patients, n	221	221	220	220
Median duration of treatment, mo (range)	8.9 (0.0-27.1)	8.5 (0.0-26.8)	6.2 (0.0-26.3)	6.4 (0.0-25.6)

n (%)	SG + Pembro (n = 221)	Chemo + Pembro (n = 220)
Any TEAE	220 (> 99)	219 (> 99)
Grade ≥ 3	158 (71)	154 (70)
Treatment-emergent SAE	84 (38)	68 (31)
Treatment-related	61 (28)	42 (19)
TEAEs leading to treatment discontinuation[a]	26 (12)	68 (31)
TEAEs leading to dose interruption	171 (77)	162 (74)
TEAEs leading to dose reduction[b]	78 (35)	96 (44)
TEAEs leading to death[c]	7 (3)	6 (3)
Treatment-related	3 (1)	1 (< 1)

TEAEs were defined as any adverse events that began or worsened on or after the first dose date of study drug up to 30 days (or up to 90 days for SAEs) after the last dose date of study drug or the initiation of subsequent anticancer therapy (including crossover treatment), whichever occurred first. Data cutoff date: March 3, 2025.
[a]The most common any-grade TEAEs that led to treatment discontinuation were pneumonitis (1%) for the SG + pembro group and neuropathy peripheral (5%), pneumonitis (3%), and thrombocytopenia (3%) for the chemo + pembro group. [b]There was no dose reduction for pembrolizumab per the protocol. [c]TEAEs leading to death were pneumonia, sepsis, neutropenic sepsis, pulmonary embolism, and suicide (1 each), as well as 2 deaths of unknown cause in the SG + pembro group, and cardiac arrest, large intestine perforation, pneumonia, sepsis, post-procedural complication, and death of unknown cause (1 each) in the chemo + pembro group.
Chemo, chemotherapy; pembro, pembrolizumab; SAE, serious adverse event; SG, sacituzumab govitecan; TEAE, treatment-emergent adverse event.
1. Tolaney S, et al. Sacituzumab Govitecan Plus Pembrolizumab vs Chemotherapy Plus Pembrolizumab in Patients With Previously Untreated, PD-L1 Positive, Advanced or Metastatic Triple-Negative Breast Cancer: Primary Results From the Randomized, Phase 3 ASCENT-04/KEYNOTE-D19 Study. Presented at ASCO 2025.

- Despite longer duration of treatment with SG + pembro, rates of grade ≥ 3 AEs were similar for both groups. TEAEs leading to dose reduction or treatment discontinuation were lower with SG + pembro

Most Common Adverse Events (≥20% in any group)[1]



- The AEs observed are consistent with the known profiles of both SG and Pembro

Adverse Events of Special Interest[1]

	AESI,[a] n (%)	SG + Pembro (n = 221) Any Grade	SG + Pembro (n = 221) Grade ≥ 3	Chemo + Pembro (n = 220) Any Grade	Chemo + Pembro (n = 220) Grade ≥ 3
SG AESIs	Neutropenia[b]	143 (65)	104 (47)	132 (60)	100 (45)
	Hypersensitivity[b]	43 (19)	4 (2)	51 (23)	5 (2)
	Serious infections secondary to neutropenia[b]	6 (3)	5 (2)	3 (1)	3 (1)
	Diarrhea (Grade 3 or higher)	NA	22 (10)	NA	5 (2)
Pembro AESIs	Overall	30 (14)	9 (4)	56 (26)	16 (7)
	Infusion reactions (not immune-mediated)[a]	11 (5)	3 (1)	19 (9)	5 (2)
	Pneumonitis[b]	5 (2)	3 (1)	10 (5)	2 (1)
	Colitis[b]	4 (2)	1 (< 1)	1 (< 1)	1 (< 1)
	Hypothyroidism[b]	4 (2)	0	19 (9)	0
	Hypophysitis[b]	2 (1)	0	2 (1)	0
	Hyperthyroidism[b]	2 (1)	0	5 (2)	0
	Severe skin reactions[b], including Stevens-Johnson syndrome and toxic epidermal necrolysis	2 (1)	2 (1)	2 (1)	2 (1)
	Hepatitis[b]	1 (< 1)	0	2 (1)	2 (1)
	Adrenal insufficiency[b]	1 (< 1)	0	2 (1)	1 (< 1)
	Pancreatitis[b]	0	0	2 (1)	2 (1)

AESIs were adverse events determined based on a prespecified list of Medical Dictionary for Regulatory Activities (MedDRA) terms, which was updated with each new version of MedDRA. Immune-mediated adverse events were determined based on a prespecified list of Medical Dictionary for Regulatory Activities (MedDRA) terms, which was updated with each new version of MedDRA and specified as immune-mediated by the investigator. Data cutoff date: March 3, 2025. [a]AESIs observed in ≥1% of patients in either group are presented; [b]Grouped term.
AESI, adverse event of special interest; chemo, chemotherapy; pembro, pembrolizumab; SG, sacituzumab govitecan.
1. Tolaney S, et al. Sacituzumab Govitecan Plus Pembrolizumab vs Chemotherapy Plus Pembrolizumab in Patients With Previously Untreated, PD-L1 Positive, Advanced or Metastatic Triple-Negative Breast Cancer: Primary Results From the Randomized, Phase 3 ASCENT-04/KEYNOTE-D19 Study. Presented at ASCO 2025.

- AESIs were consistent with the known safety profiles of each agent; no new safety concerns were observed and no increased rates of AESIs were observed when combining SG with pembro

Presented at SOHC 2025 from 19 – 21 November 2025