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2026 ASCO ANNUAL MEETING

PANKU-Breast02

A Randomized Phase III Study Evaluating Izalontamab Brengitecan (Iza-bren) Versus Physician's Choice of Chemotherapy in Patients with Unresectable Locally Advanced or Metastatic Triple-Negative Breast Cancer (TNBC)

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Presenter: Jiong Wu, MD. PhD.

2 June 2026

*** Jiong Wu and Jian Zhang contributed equally to this work.**

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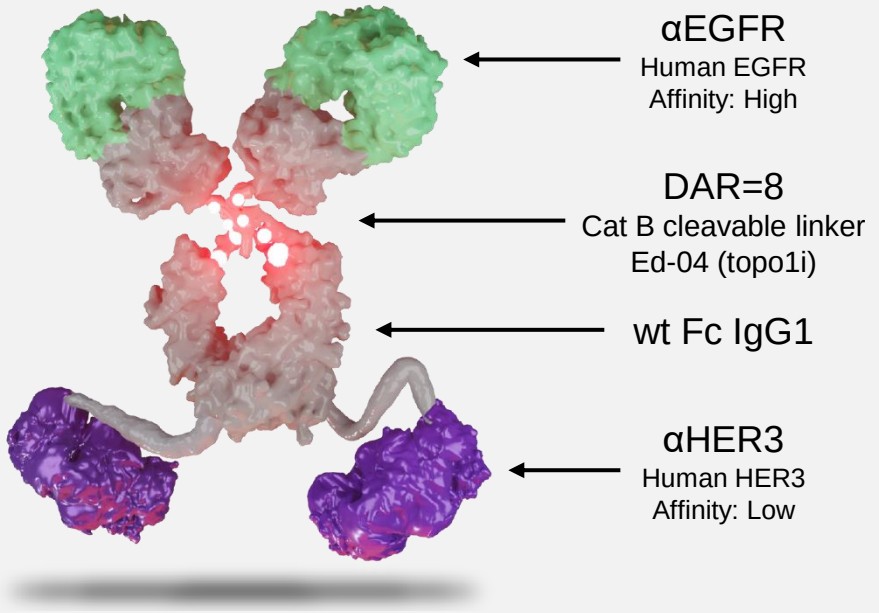
PANKU-Breast02 Key Takeaways

- This study met both dual primary endpoints of PFS by BICR and OS at the pre-specified interim analysis.
  - Median PFS by BICR was 8.5 months for iza-bren versus 3.1 months for chemotherapy. Iza-bren reduced the risk of progression or death by 71% (HR=0.29, p<0.0001).
  - Median OS was 15.9 months for iza-bren versus 12.5 months for chemotherapy. Iza-bren reduced the risk of death by 40% (HR=0.60, p=0.0019).
- Iza-bren demonstrated a statistically significant and clinically meaningful improvement in both PFS and OS compared with chemotherapy, with a manageable safety profile in pre-treated TNBC patients, supporting iza-bren as a new standard of care in this population.

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Background

Iza-bren, EGFR x HER3 bispecific ADC



- Triple-negative breast cancer (TNBC) remains a therapeutic challenge due to its aggressive biology and limited treatment options beyond first-line standard-of-care therapy. Patients who progress after taxane-containing regimens face poor outcomes and have a high unmet need.
- Izalontamab brengitecan (iza-bren) is a potentially first-in-class bispecific antibody–drug conjugate (ADC) targeting EGFRxHER3 with a potent topoisomerase I inhibitor (topo1i) payload.
- Iza-bren showed promising antitumour activity with a manageable safety profile in breast cancer in early-phase clinical study[1].

Here, we present the interim results from PANKU-Breast02, a randomized phase III study conducted in China, evaluating the efficacy and safety of iza-bren versus chemotherapy in patients with pre-treated TNBC (NCT06382142).

wt, wild type; **Cat B**, cathepsin B.

1. Du Y, Zhang J, Wu J, et al., Phase I study of iza-bren (BL-B01D1), an EGFR & HER3 Bispecific Antibody-drug Conjugate (ADC), in Patients with Locally Advanced or Metastatic Breast Cancer (BC). ESMO Breast Cancer Congress 2025; (302MO).

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PANKU-Breast02 Study Design

A multicenter, randomized, open-label, phase III study conducted at 81 study centers across China.

Key eligibility criteria:

- Unresectable locally advanced or metastatic TNBC
- Progressed after 1–2 prior lines of systemic therapy for advanced disease—including prior taxanes
- Measurable lesion per RECIST v1.1
- ECOG PS 0-1

Treatment until
Disease progression per RECIST v1.1 or intolerable toxicity

R 1:1
N=406

Iza-bren
2.5 mg/kg D1D8 Q3W

Chemotherapy
- Eribulin, D1D8 Q3W
- Capecitabine, BID, Q3W
- Gemcitabine, D1D8 Q3W
- Vinorelbine, D1D8 Q3W

Stratified by
- Previous lines of chemotherapy (1 line vs 2 lines)
- Prior anti-PD(L)-1 (yes vs no)
- HER2 expression (IHC 0 vs IHC 1+/2+ ISH-)

Dual primary endpoints
PFS (BICR) & OS
H_{PFS} α=0.025 → H_{OS} α=0

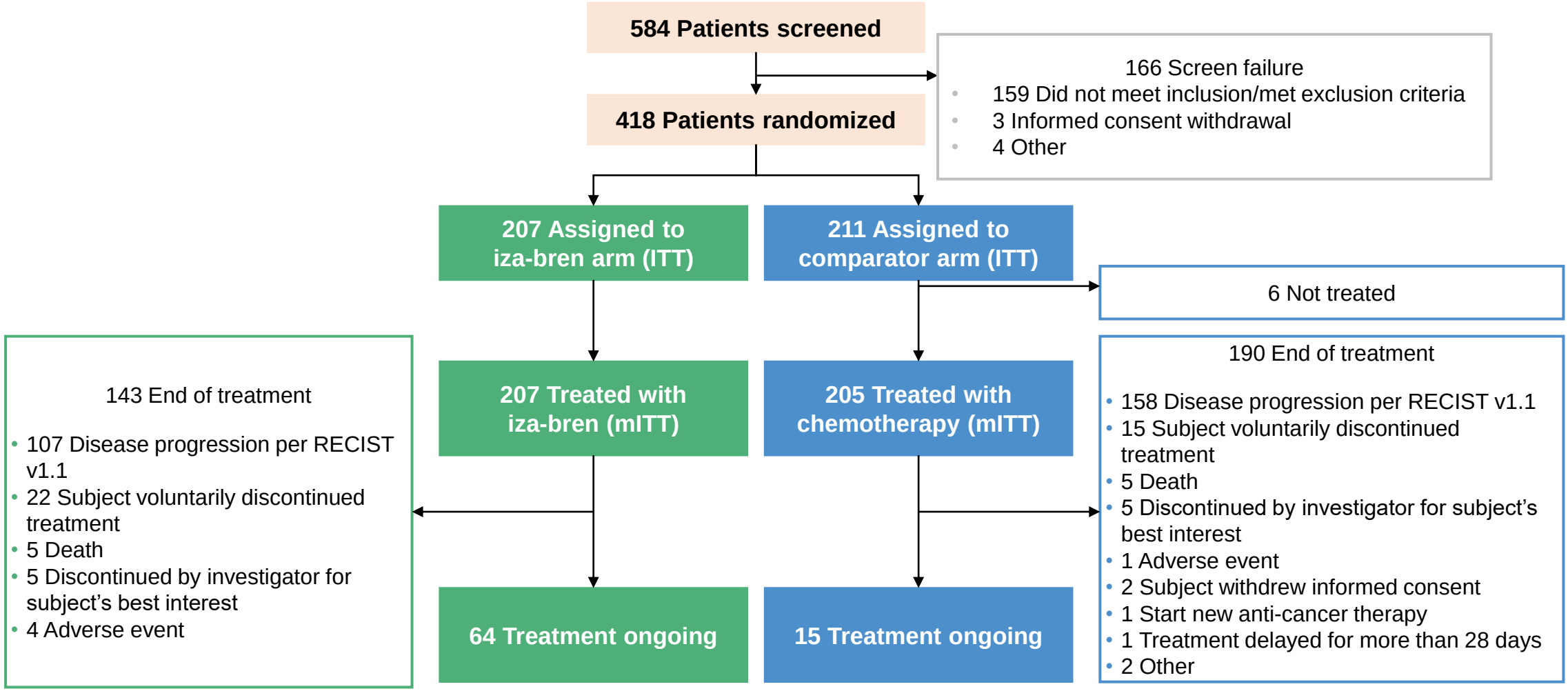
Secondary endpoints
ORR (BICR)
PFS (INV)
DCR, DoR, Safety, PK, Immunogenicity

Note: The planned enrollment was 406 subjects. Iza-bren was dosed with 10% compensation per protocol; eribulin 1.4 mg/m^2 on days 1 and 8 Q3W; capecitabine 1000-1250 mg/m^2, BID from days 1 to 14 Q3W; gemcitabine 1000 mg/m^2 on days 1 and 8 Q3W; vinorelbine 25 mg/m^2 on days 1 and 8 Q3W.

ECOG PS, Eastern Cooperative Oncology Group performance status; **Q3W**, every 3 weeks; **D**, day; **BICR**, blinded independent central review; **INV**, investigator assessed; **PFS**, progression-free survival; **OS**, overall survival; **ORR**, objective response rate (confirmed); **PK**, pharmacokinetics; **DCR**, disease control rate; **DoR**, duration of response.

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Patient Disposition



Data cut off: January 13, 2026

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Baseline Characteristics

Characteristics	Iza-bren (N=207)	Chemotherapy (N=205)
Median (range) age, years	53.0 (28.0, 73.0)	54.0 (27.0, 71.0)
Age group (years), n (%)		
< 65	184 (88.9)	187 (91.2)
≥ 65	23 (11.1)	18 (8.8)
ECOG PS, n (%)		
0	56 (27.1)	63 (30.7)
1	151 (72.9)	142 (69.3)
Previous chemotherapy lines, n (%)		
1 line	146 (70.5)	143 (69.8)
2 lines	61 (29.5)	62 (30.2)
Prior anti-PD(L)-1, n (%)		
Yes	49 (23.7)	51 (24.9)
No	158 (76.3)	154 (75.1)
Previous radiotherapy, n (%)	107 (51.7)	113 (55.1)

Characteristics	Iza-bren (N=207)	Chemotherapy (N=205)
Overall stage at baseline, n (%)		
Stage III	3 (1.4)	2 (1.0)
Stage IV	204 (98.6)	203 (99.0)
Metastatic site at baseline, n (%)		
Lymph node	145 (70.0)	134 (65.4)
Lung	96 (46.4)	104 (50.7)
Bone	75 (36.2)	78 (38.0)
Liver	65 (31.4)	72 (35.1)
Previous (neo)adjuvant chemotherapy, n (%)		
Yes	164 (79.2)	161 (78.5)
No	43 (20.8)	44 (21.5)
HER2 expression, n (%)		
IHC 0	110 (53.1)	111 (54.1)
IHC1+ or IHC2+/ISH-	97 (46.9)	94 (45.9)

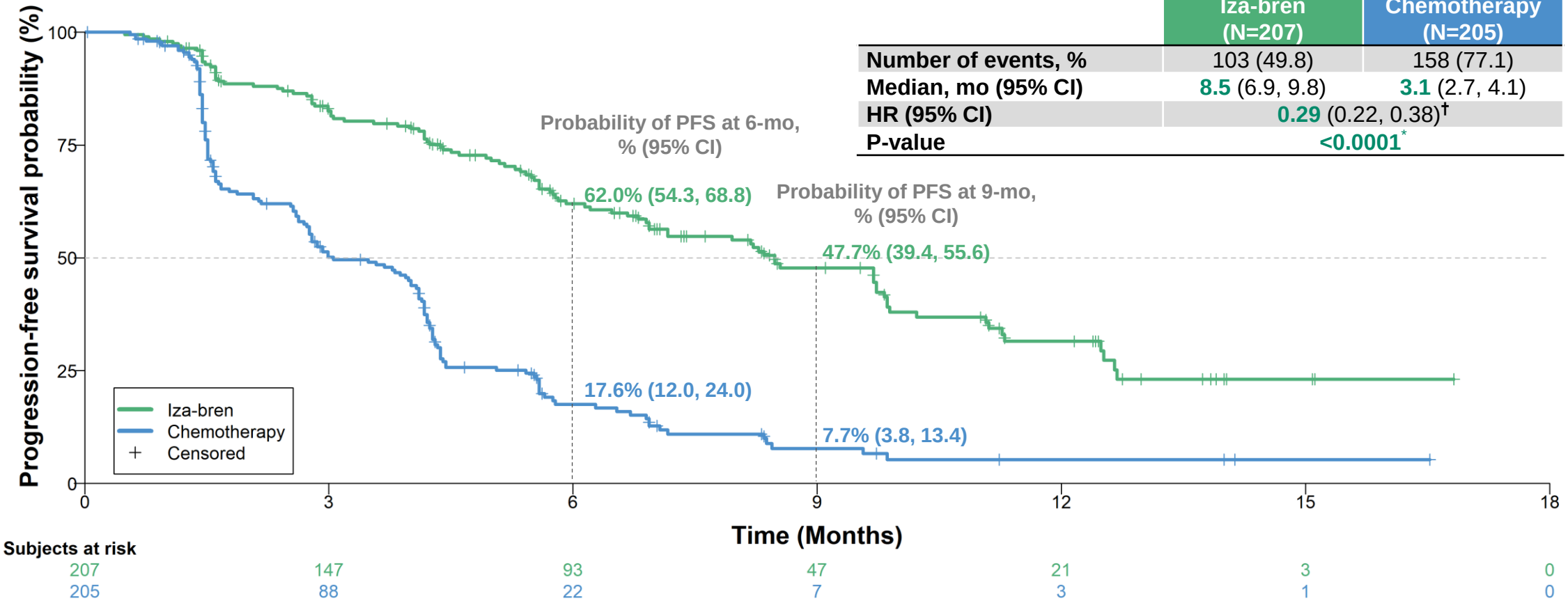
Baseline characteristics were balanced between the two groups.

Analysis set: mITT population, defined as all randomized patients who received at least one dose of study drug.

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PFS (BICR): Dual Primary Endpoint

	Iza-bren (N=207)	Chemotherapy (N=205)
Number of events, %	103 (49.8)	158 (77.1)
Median, mo (95% CI)	**8.5** (6.9, 9.8)	**3.1** (2.7, 4.1)
HR (95% CI)	**0.29** (0.22, 0.38)†	
P-value	**<0.0001***	

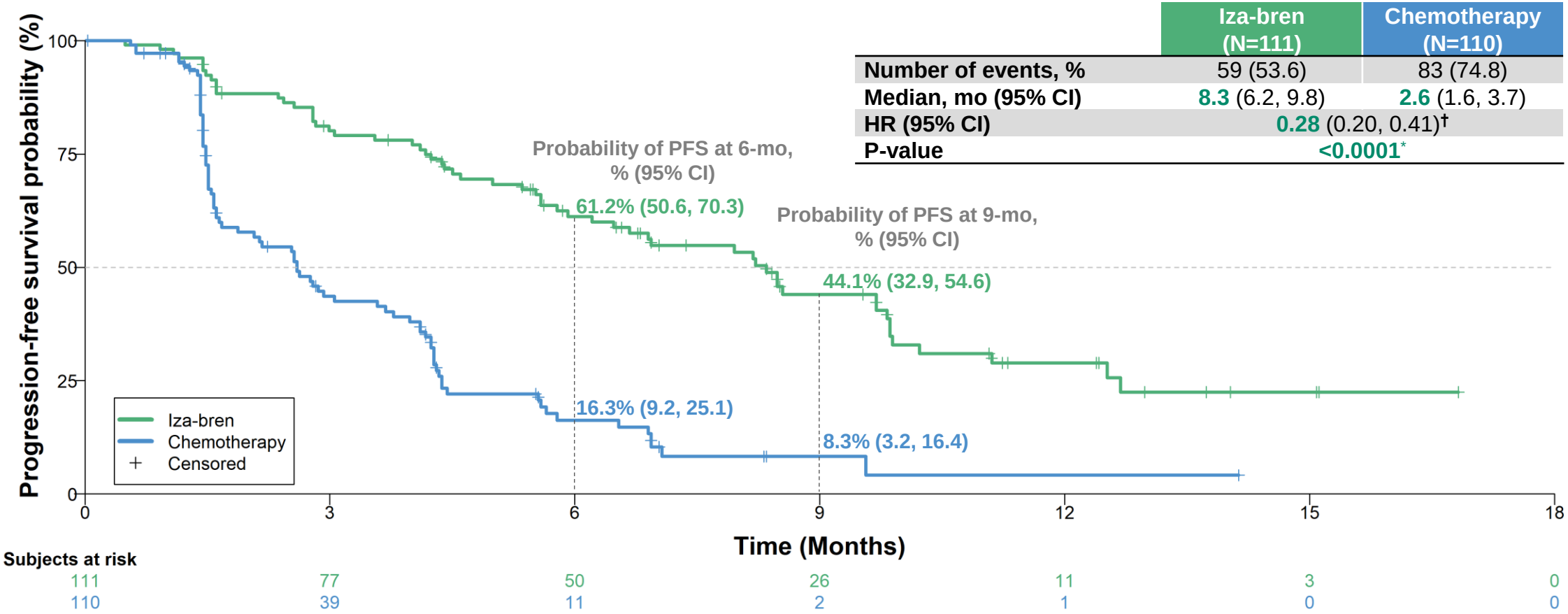


Iza-bren showed statistically significant and clinically meaningful improvement in PFS vs chemotherapy (median Δ 5.4 mo).

PFS (BICR) was evaluated in the mITT population. The median duration of follow-up for PFS was 8.5 months.
Similar results were observed for PFS (BICR) in the ITT population, with 103 events in the iza-bren arm and 158 events in the chemotherapy arm. The hazard ratio (95% CI) was 0.29 (0.22,0.38).
†Based on a stratified Cox regression model. *One-sided, based on a stratified log-rank test.

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PFS (BICR) in HER2 IHC 0 Population



	Iza-bren (N=111)	Chemotherapy (N=110)
Number of events, %	59 (53.6)	83 (74.8)
Median, mo (95% CI)	**8.3** (6.2, 9.8)	**2.6** (1.6, 3.7)
HR (95% CI)	**0.28** (0.20, 0.41)†	
P-value	**<0.0001***	

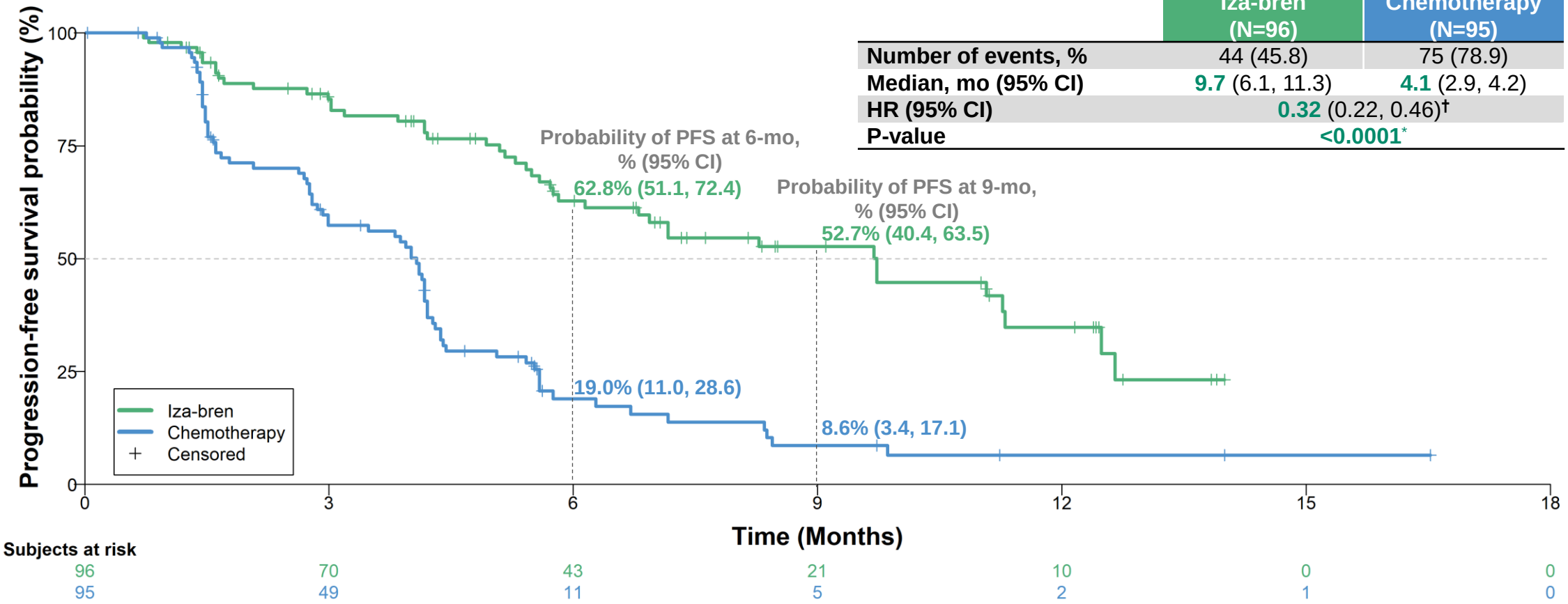
Statistically significant and clinically meaningful improvement in PFS was seen in HER2 IHC 0 patients (median Δ 5.7 mo).

PFS (BICR) was evaluated in IWRS HER2 IHC0 patients from the mITT population. The median duration of follow-up was 8.5 months.
†Based on a unstratified Cox regression model. *One-sided, based on a unstratified log-rank test.

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PFS (BICR) in HER2 Low Population

	Iza-bren (N=96)	Chemotherapy (N=95)
Number of events, %	44 (45.8)	75 (78.9)
Median, mo (95% CI)	**9.7** (6.1, 11.3)	**4.1** (2.9, 4.2)
HR (95% CI)	**0.32** (0.22, 0.46)†	
P-value	**<0.0001***	



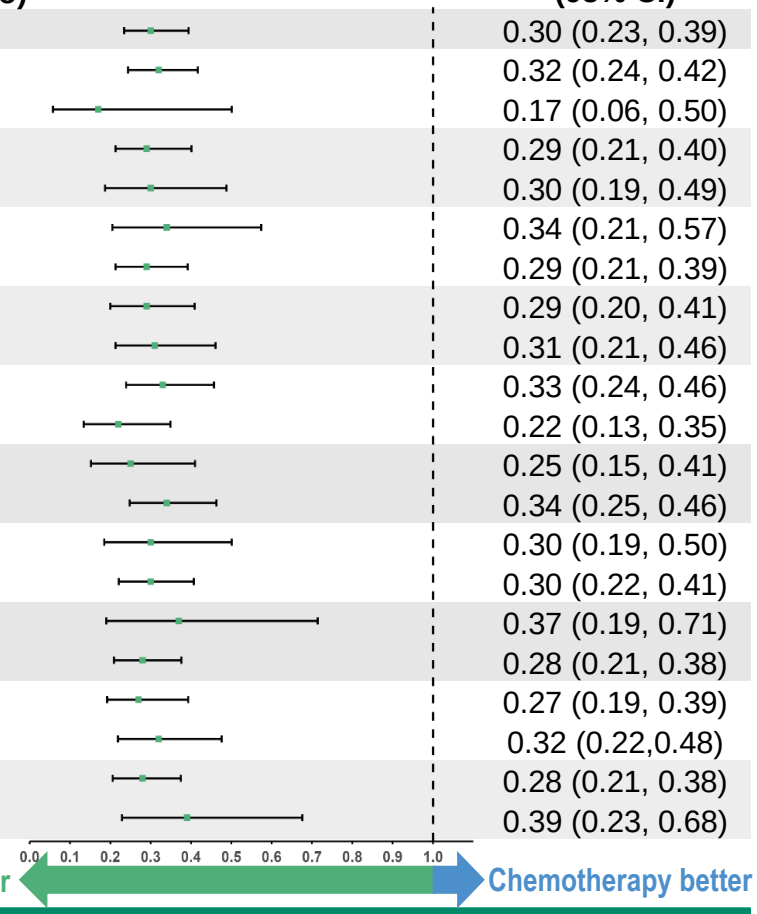
Statistically significant and clinically meaningful improvement in PFS was seen in HER2 low patients (median Δ 5.7 mo).

HER2 Low: defined as HER2 IHC1+ or IHC2+/ISH-.
PFS (BICR) was evaluated in IWRS HER2 IHC1+ or IHC2+/ISH- patients from the mITT population. The median duration of follow-up was 8.5 months.
†Based on a unstratified Cox regression model. *One-sided, based on a unstratified log-rank test.

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Subgroup Analysis of PFS (BICR)

Category	Subgroup	Iza-bren		Chemotherapy		Hazard ratio (95% CI)
		Events/n	mPFS (mo)	Events/n	mPFS (mo)	
All subjects		103/207	8.5	158/205	3.1	0.30 (0.23, 0.39)
Age	<65	96/184	8.2	147/187	3.0	0.32 (0.24, 0.42)
	≥65	7/23	11.3	11/18	4.1	0.17 (0.06, 0.50)
Previous chemotherapy lines	1 Line	67/146	9.7	110/143	3.8	0.29 (0.21, 0.40)
	2 Lines	36/61	6.2	48/62	2.8	0.30 (0.19, 0.49)
Prior anti-PD(L)-1	Yes	29/49	6.9	39/51	2.6	0.34 (0.21, 0.57)
	No	74/158	9.7	119/154	3.5	0.29 (0.21, 0.39)
HER2 expression	IHC0	59/110	8.3	84/111	2.6	0.29 (0.20, 0.41)
	IHC1+ or IHC2+/ISH-	44/97	9.7	74/94	4.0	0.31 (0.21, 0.46)
Was the initial diagnosis of TNBC	Yes	72/130	8.0	91/120	3.0	0.33 (0.24, 0.46)
	No	26/71	11.3	65/83	4.0	0.22 (0.13, 0.35)
Baseline diagnosis liver metastasis	Yes	30/65	9.9	58/72	2.6	0.25 (0.15, 0.41)
	No	73/142	8.2	100/133	3.9	0.34 (0.25, 0.46)
ECOG-PS score	0	25/56	8.3	48/63	2.9	0.30 (0.19, 0.50)
	1	78/151	8.5	110/142	3.5	0.30 (0.22, 0.41)
Was the initial diagnosis of stage IV	Yes	14/31	8.5	26/35	3.0	0.37 (0.19, 0.71)
	No	85/172	8.5	127/165	3.5	0.28 (0.21, 0.38)
Previous radiotherapy	Yes	58/107	8.3	91/113	2.9	0.27 (0.19, 0.39)
	No	45/100	9.7	67/92	3.7	0.32 (0.22,0.48)
Previous (neo)adjuvant chemotherapy	Yes	80/164	8.5	125/161	2.9	0.28 (0.21, 0.38)
	No	23/43	8.0	33/44	3.8	0.39 (0.23, 0.68)

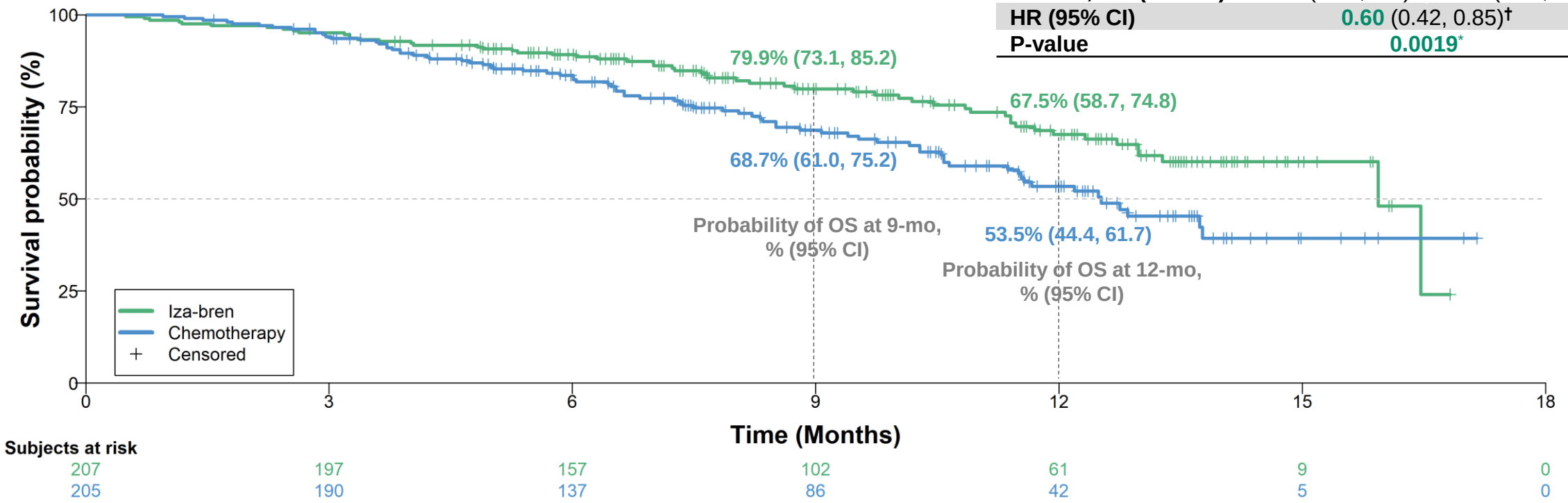


Consistent PFS benefit was seen across the various subgroups.

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OS: Dual Primary Endpoint

	Iza-bren (N=207)	Chemotherapy (N=205)
Number of events, %	56 (27.1)	77 (37.6)
Median, mo (95% CI)	**15.9** (13.3, NR)	**12.5** (11.4, NR)
HR (95% CI)	**0.60** (0.42, 0.85)†	
P-value	**0.0019***	



Iza-bren showed statistically significant and clinically meaningful improvement in OS vs chemotherapy (median Δ 3.4 mo) at pre-specified interim analysis.

OS was evaluated in the mITT population, with a median follow-up duration of 11.0 months. The pre-specified interim analysis was planned upon the observation of 255 BICR-confirmed PFS event, with approximately 175 OS events (70% information fraction) expected at the same time. At the analysis, the actual information fraction was 53.2%. **A P-value of 0.0021 was required for interim analysis superiority.**

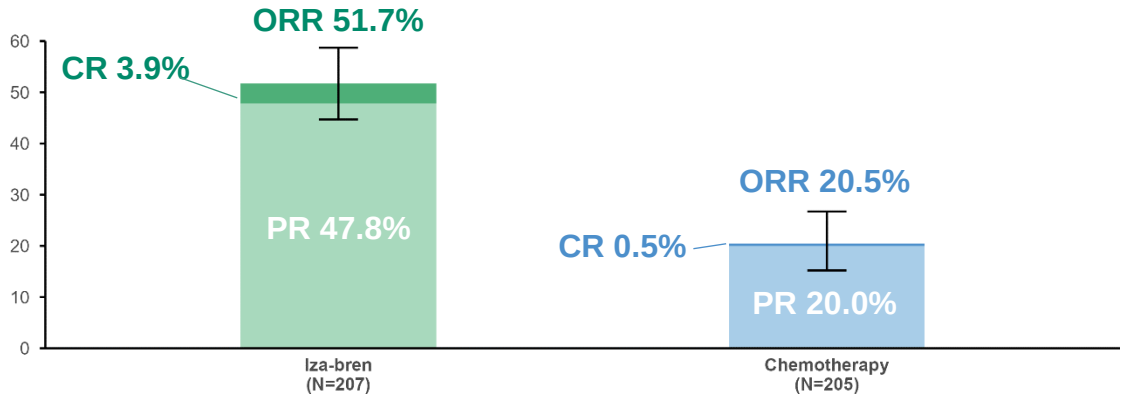
Similar results were observed for OS in the ITT population, with 56 events in the iza-bren arm and 77 events in the chemotherapy arm. The hazard ratio (95% CI) was 0.60 (0.42, 0.85).

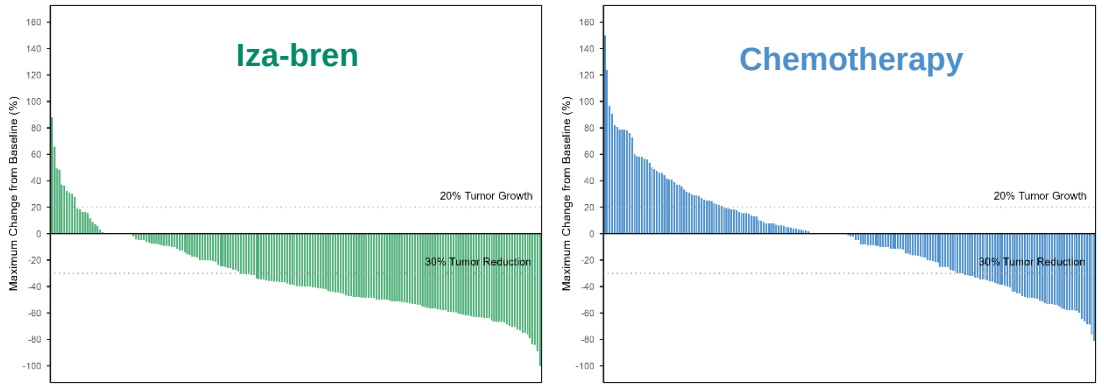
†Based on a stratified Cox regression model. *One-sided, based on a stratified log-rank test.

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ORR (BICR): Secondary Endpoint

	Iza-bren (N=207)	Chemotherapy (N=205)
Confirmed ORR, % (95% CI)	**51.7** (44.7, 58.7)	**20.5** (15.2, 26.7)
Odds ratio (95% CI)	**4.3** (2.8, 6.7)	
Best overall response, n (%)		
CR	8 (3.9)	1 (0.5)
PR	99 (47.8)	41 (20.0)
DCR, n (%)	172 (83.1)	121 (59.0)
CBR, n (%)	133 (64.3)	64 (31.2)
Median DoR, mo (95% CI)	8.3 (8.1, 11.0)	4.0 (2.9, 5.2)



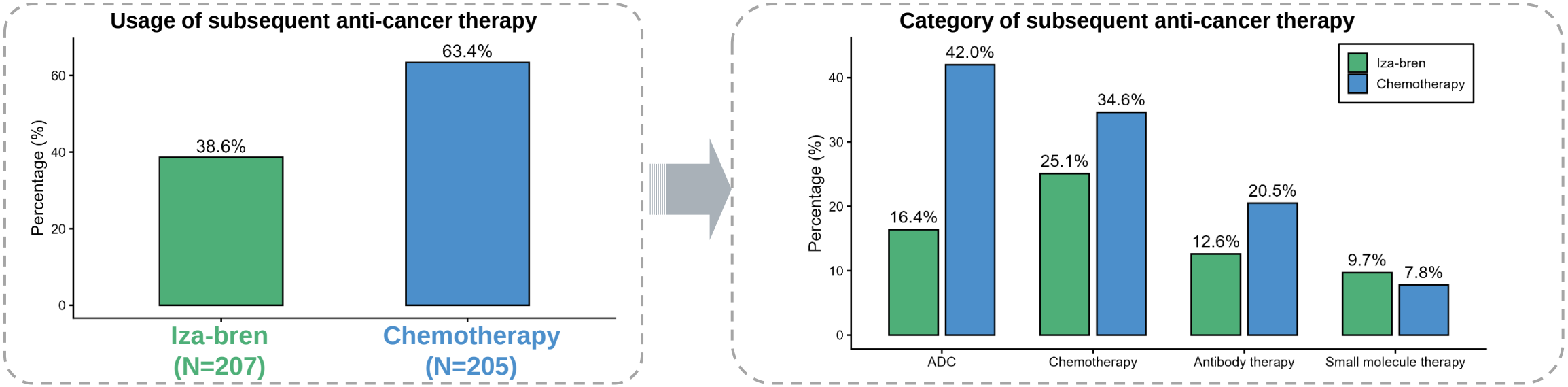


CR, complete response; **PR**, partial response; **CBR**, clinical benefit rate
ORR (BICR) was evaluated based on mITT population. ORs were calculated using the stratified Mantel-Haenszel method.
In the iza-bren arm, 77.3% of patients (160/207) had tumor shrinkage and the median (range) shrinkage (%) was -44.6 (-100, -2.3); in the chemotherapy arm, 48.8% of patients (100/205) had tumor shrinkage and the median (range) shrinkage (%) was -32.0 (-81.1, -1.4).

The confirmed objective response rate assessed by BICR was 51.7% with iza-bren and 20.5% with TPC.

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Subsequent Anti-cancer Therapy After Progression



- More patients in the chemotherapy arm (63.4%), compared to the iza-bren arm (38.6%), received at least one subsequent anti-cancer therapy.
- Iza-bren showed a statistically significant and clinically meaningful improvement in OS vs. chemotherapy, despite more patients receiving subsequent therapies in the chemotherapy arm, including 42.0% with an ADC.

Note: Data for the new anti-cancer drug therapy were presented.

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Safety Summary

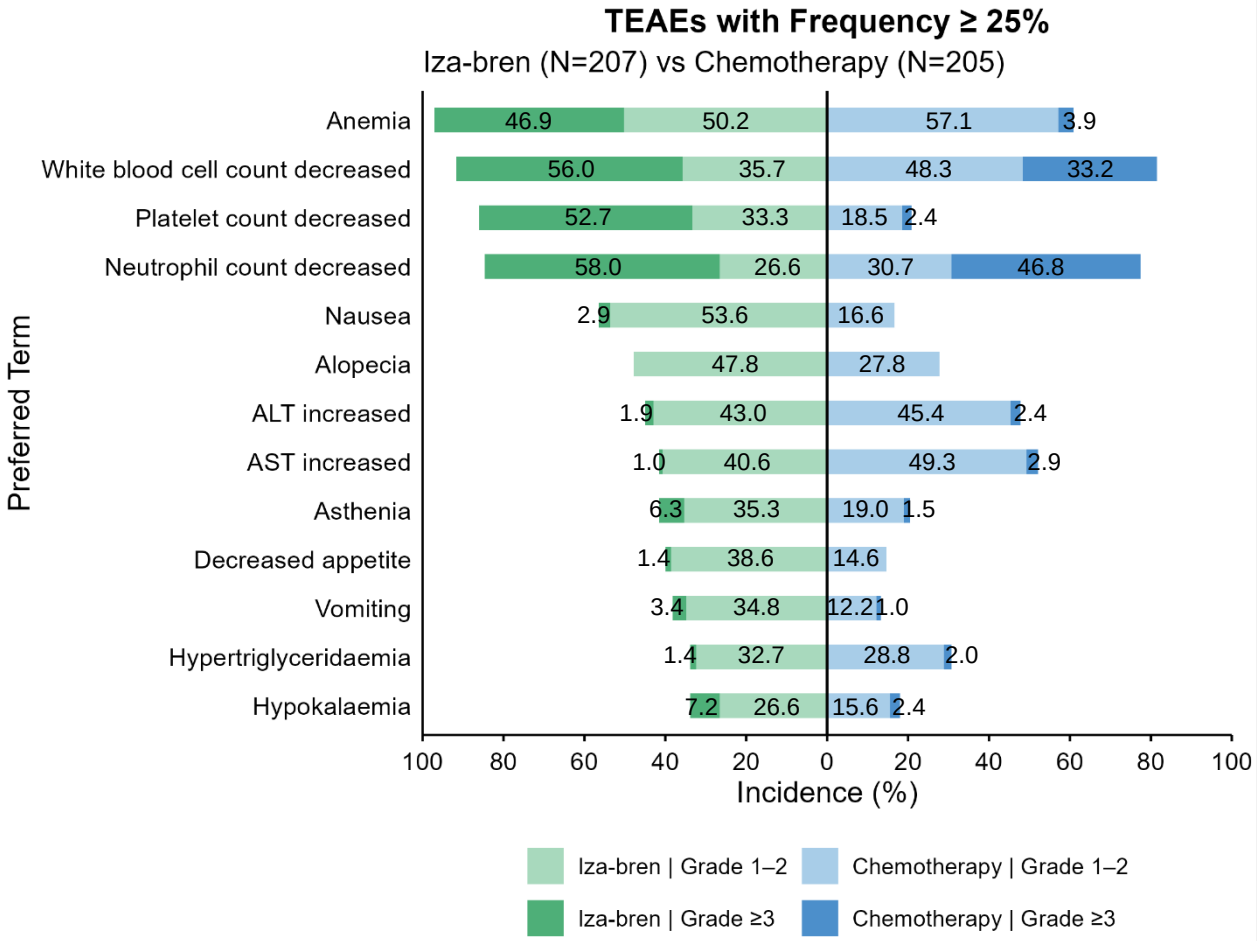
	Iza-bren (N=207)	Chemotherapy (N=205)
TEAEs, n (%)	207 (100)	202 (98.5)
≥Grade 3 TEAEs, n (%)	184 (88.9)	129 (62.9)
SAEs, n (%)	91 (44.0)	39 (19.0)
TEAEs leading to death, n (%)	6 (2.9)	2 (1.0)
TEAEs leading to treatment discontinuation, n (%)	4 (1.9)	1 (0.5)
TEAEs leading to dose reduction, n (%)	131 (63.3)	23 (11.2)
TEAEs leading to dose interruption, n (%)	131 (63.3)	72 (35.1)

TEAE: Treatment-emergent adverse event.
Safety data based on the safety analysis set.

- Iza-bren had a manageable safety profile. Most AEs were effectively managed by dose modification and standard supportive care.
- The treatment discontinuation rate due to TEAEs was low (1.9%) in the iza-bren arm.
- Median (range) number of treatment cycles:
  - Iza-bren: 8 (1, 24)
  - Chemotherapy: 4 (1, 23)

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TEAEs in >25% of Patients



- The most frequent Grade ≥3 TEAEs in the iza-bren arm were hematologic and were effectively managed by standard supportive care.
- In the iza-bren arm, median time to resolution of Grade 3 or 4 neutropenia was 4 days. Most patients had only 1 episode. G-CSF was not mandatory in this study.
- Febrile neutropenia occurred in 5.3% (n=11) of patients in the iza-bren arm vs. 0.5% in the control arm. Grade ≥ 3 infection rates were 6.8% in the iza-bren arm vs. 5.4% in the control arm.
- Per investigator's assessment, all-grade ILD were reported in 3 (1.4%) patients in the iza-bren arm, including 1 case of Grade 1 and 2 cases of Grade 2.
- Per independent ILD adjudication committee, only 1 (0.5%) case of Grade 2 ILD occurred in the iza-bren arm.
- No new safety signals were observed.

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Conclusions

- This study has met both dual primary endpoints of PFS by BICR and OS at the pre-specified interim analysis.
- Iza-bren has demonstrated a statistically significant and clinically meaningful improvement in both PFS and OS compared with chemotherapy, with a manageable safety profile in pre-treated TNBC patients.
  - Median PFS by BICR was 8.5 months for iza-bren versus 3.1 months for chemotherapy. Iza-bren reduced the risk of progression or death by 71% (HR=0.29, p<0.0001).
  - Median OS was 15.9 months for iza-bren versus 12.5 months for chemotherapy. Iza-bren reduced the risk of death by 40% (HR=0.60, p=0.0019).
    - OS with longer follow-up will be reported in the future.
  - Confirmed ORR was significantly higher in the iza-bren arm (51.7%) vs. chemotherapy arm (20.5%).
  - Rate of treatment discontinuation due to TEAEs was low with iza-bren (1.9%).
  - Rate of adjudicated ILD was 0.5% (1 case only, Grade 2) in the iza-bren arm.
- Results from this phase III study support iza-bren as a new standard of care for patients with pre-treated metastatic TNBC.

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