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Anbenitamab Plus Albumin-Bound Docetaxel ± Carboplatin as Neoadjuvant Therapy in Early or Locally Advanced HER2-Positive Breast Cancer: Randomized, Phase 3, Neo-Healer Trial

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Key takeaway conclusions

Anbenitamab + albumin-bound docetaxel ± carboplatin significantly improved tpCR versus standard THP ± carboplatin in neoadjuvant HER2+ breast cancer, with manageable safety, supporting its potential as a promising new treatment option.

Declaration of interests

- I hereby declare that there are no relevant financial or non-financial conflicts of interest related to this presentation.

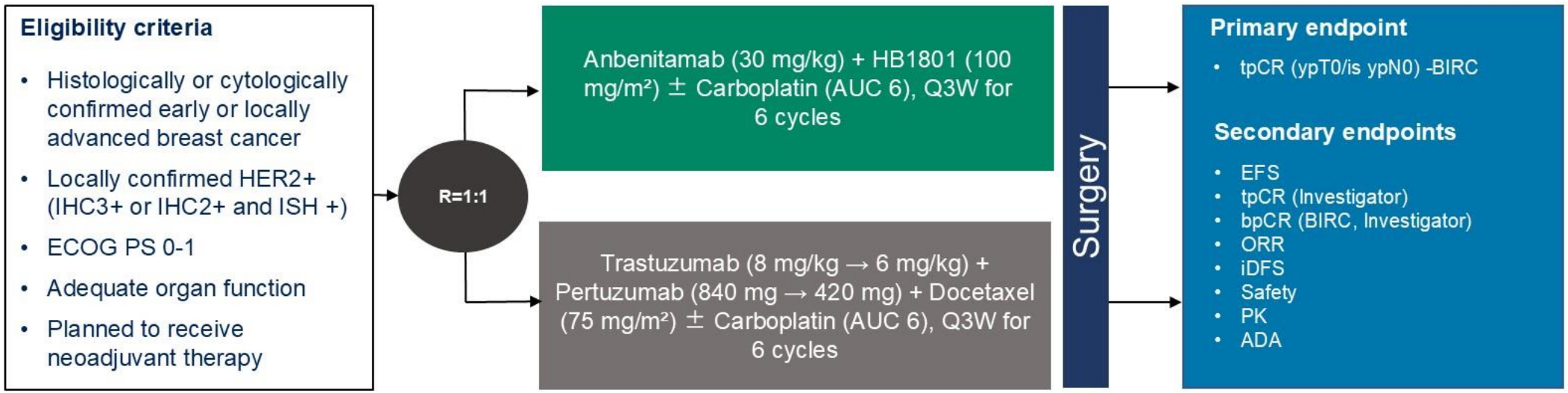
Background

- HER2-positive breast cancer is an aggressive subtype. Neoadjuvant dual HER2 blockade with THP ± carboplatin is the current preferred standard of care for stage II–III disease, with reported pCR rates of 39% to 64%.[1-6]
- The recently approved sequential T-DXd regimen with longer treatment duration and substantial toxicities especially interstitial lung disease. [7]
- Anbenitamab, a novel biparatopic HER2 antibody, combined with docetaxel achieved a tpCR of 56.7% in 30 patients with HER2-positive breast cancer; the posterior probability of tpCR >40% reached 96.7%, showing promising clinical potential.[8-10]
- HB1801 is a novel albumin-bound docetaxel without polysorbate 80 or ethanol. It eliminates high-dose steroid premedication, enables rapid infusion, and shows better tolerability and antitumor activity than conventional docetaxel in breast cancer and other malignancies..[11]
- The Neo-Healer study is a multicenter, randomized phase 3 trial comparing anbenitamab + HB1801 ± carboplatin with standard THP ± carboplatin as neoadjuvant therapy in HER2-positive breast cancer.

1. SCommittee EG, et al. Ann Oncol. 2024;35(2):159-182. 2. Gianni L, et al. Lancet Oncol. 2012;13(1):25-32. 3. Shao Z, et al. JAMA Oncol. 2020;6(3):e193692. 4. Schneeweiss A, et al. Ann Oncol. 2013;24(9):2278-2284. 5. Hurvitz A, et al. Lancet Oncol. 2018;19(1):115-126. 6. National Comprehensive Cancer Network. Breast Cancer (Version 2.2026). 7. Harbeck N, et al. Ann Oncol. 2026;37(2):166-179. 8. Zhang J, et al. Clin Cancer Res. 2022;28(4):618-628. 9. Ma J, et al. Cancer Commun. 2025;45(4):476-485. 10. Ma L, et al. Ann Oncol. 2023;34:S282. 11. Wang Z, et al. J Clin Oncol. 2024;42(16_suppl):e16018.

Neo-Healer study design

A randomized, controlled, open-label, multicenter phase 3 study (NCT06747338)



Stratification factors:

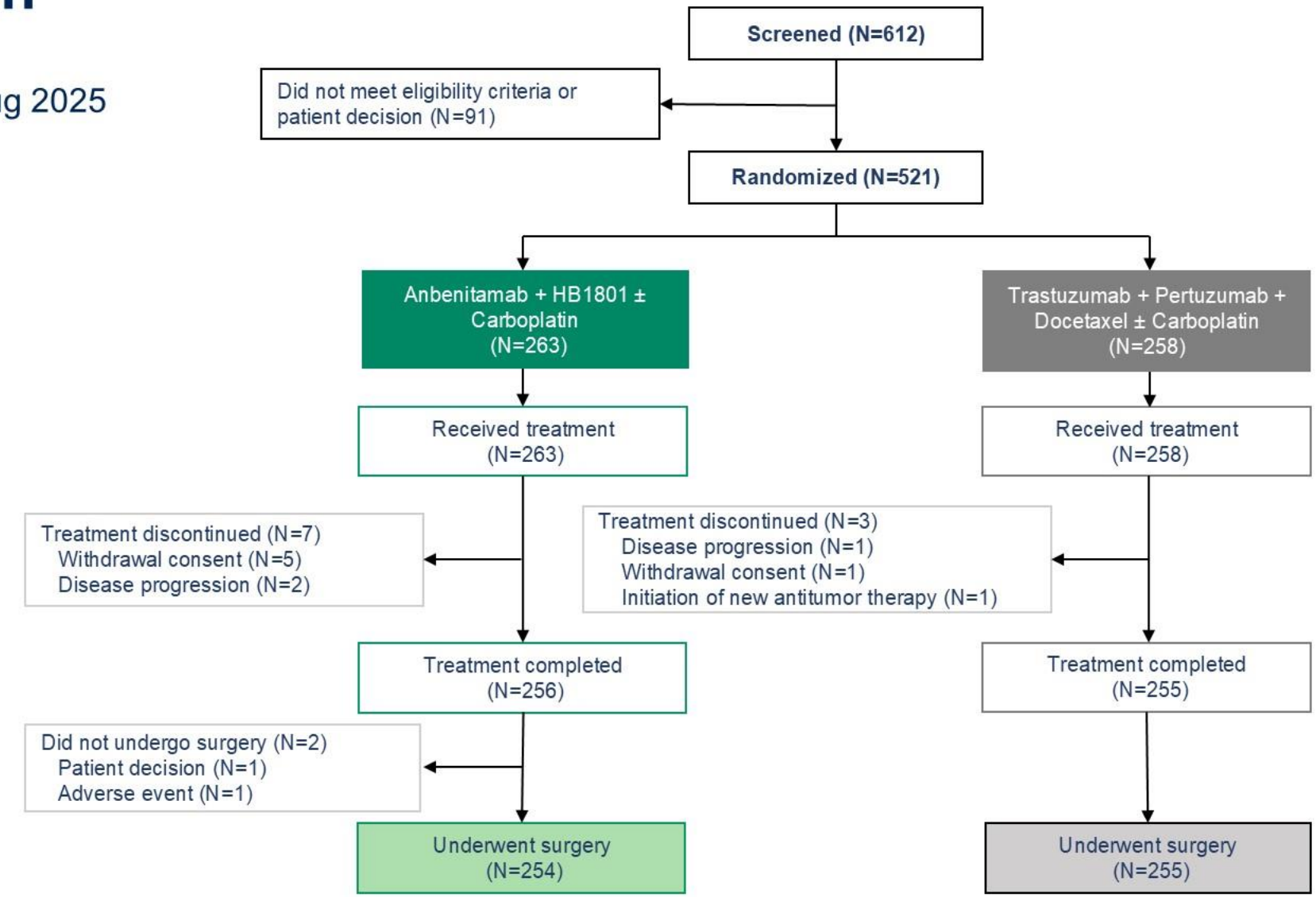
- Clinical stage [Early (T2-3, N0-1, M0) vs. Locally Advanced (T2-3, N2-3, M0; T4, any N, M0)]
- HR status (negative vs. positive)
- Planned use of carboplatin (yes vs. no)

Data cutoff:
January 28, 2026

*Abbreviations: HER2+, Human Epidermal Growth Factor Receptor 2 positive; IHC, Immunohistochemistry; ISH, In Situ Hybridization; ECOG PS, Eastern Cooperative Oncology Group Performance Status; Q3W, Every 3 weeks; AUC, Area Under the Curve; pCR, pathological Complete Response; BIRC, Blinded Independent Review Committee; EFS, Event-Free Survival; INV, investigator; tpCR, total pathological Complete Response; bpCR, breast pathological Complete Response; ORR, Overall Response Rate; iDFS, invasive Disease-Free Survival; PK, Pharmacokinetics; ADA, Anti-Drug Antibody; HR, Hormone receptor

Patient disposition

Enrollment: 16 Dec 2024 – 29 Aug 2025
Data cutoff: 28 Jan 2026



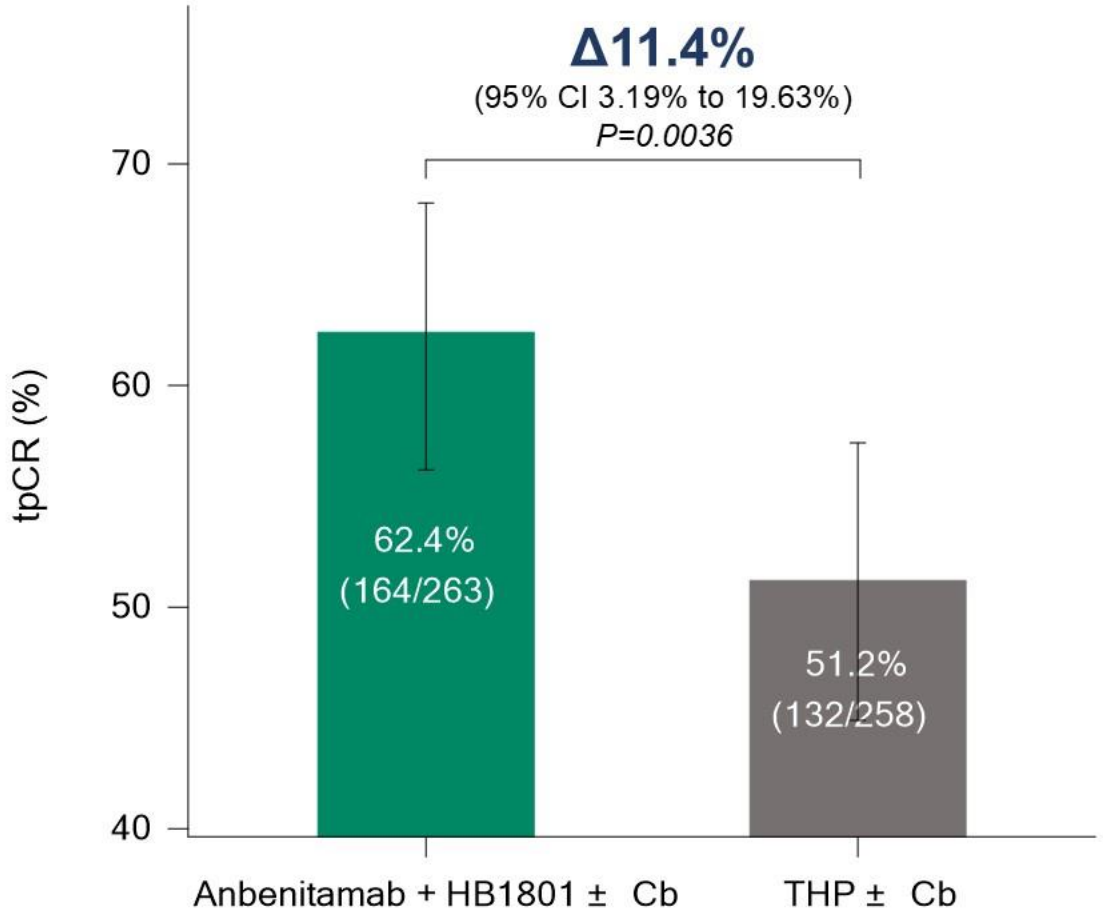
Baseline characteristics

	Anbenitamab + HB1801 ± Carboplatin (N=263)	THP ± Carboplatin (N=258)
Age, years		
Mean (range)	52.0 (23,79)	52.0 (25,72)
ECOG PS*, n (%)		
0	202 (76.8)	211 (81.8)
1	59 (22.4)	47 (18.2)
Disease status, n (%)		
Early	174 (66.2)	168 (65.1)
Locally advanced#	89 (33.8)	90 (34.9)
Clinical tumor stage, n (%)		
T2	207 (78.7)	214 (82.9)
T3	44 (16.7)	37 (14.3)
T4	12 (4.6)	7 (2.7)

	Anbenitamab + HB1801 ± Carboplatin (N=263)	THP ± Carboplatin (N=258)
Clinical nodal stage, n (%)		
N0	69 (26.2)	67 (26.0)
N1	111 (42.2)	104 (40.3)
N2	74 (28.1)	75 (29.1)
N3	9 (3.4)	12 (4.7)
Hormone receptor status, n (%)		
Positive	149 (56.7)	142 (55.0)
Negative	114 (43.3)	116 (45.0)
HER2 status, n (%)		
IHC 2+ and ISH+	28 (10.6)	31 (12.0)
IHC 3+	235 (89.4)	227 (88.0)
Ki67, n (%)		
<30%	60 (22.8)	43 (16.7)
≥30%	203 (77.2)	215 (83.3)
Carboplatin use, n (%)		
Yes	111 (42.2)	112 (43.4)
No	152 (57.8)	146 (56.6)

Cutoff date: January 28, 2026.
*Abbreviations: ECOG PS, Eastern Cooperative Oncology Group Performance Status; HER2, Human Epidermal Growth Factor Receptor 2; IHC, Immunohistochemistry; ISH, In Situ Hybridization; Ki67, Ki-67 proliferation index
#Locally advanced, defined as T2-3, N2-3, M0 or T4, any N, M0.

Primary endpoint: tpCR rates by BIRC assessment (ITT)

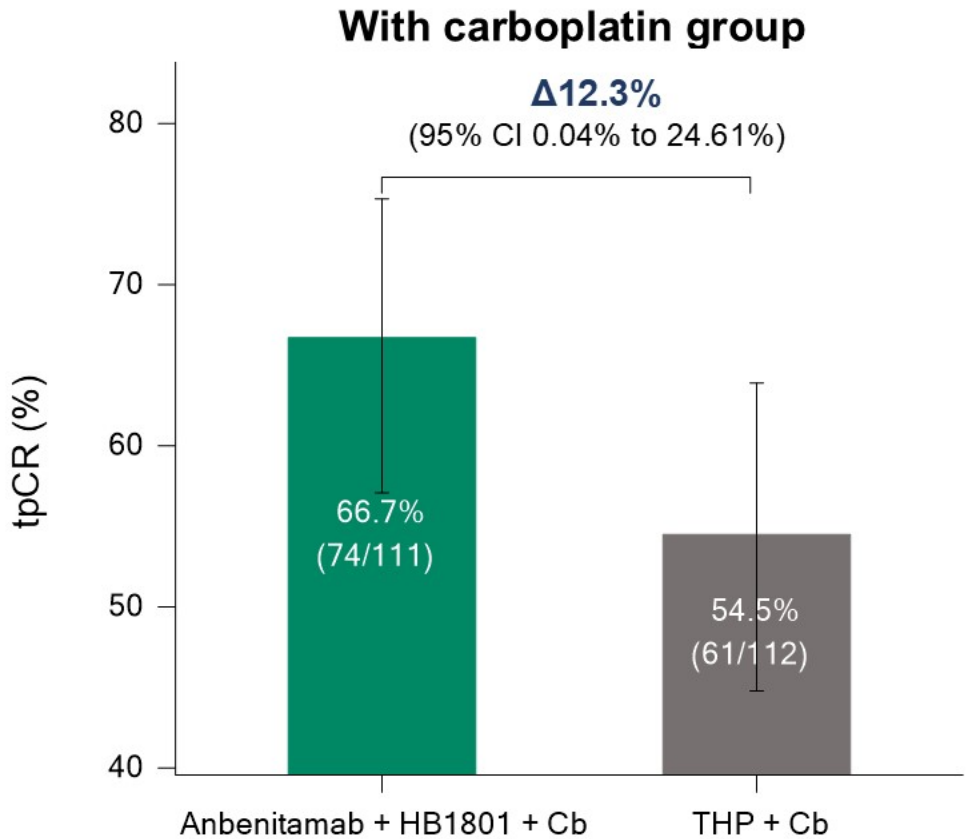


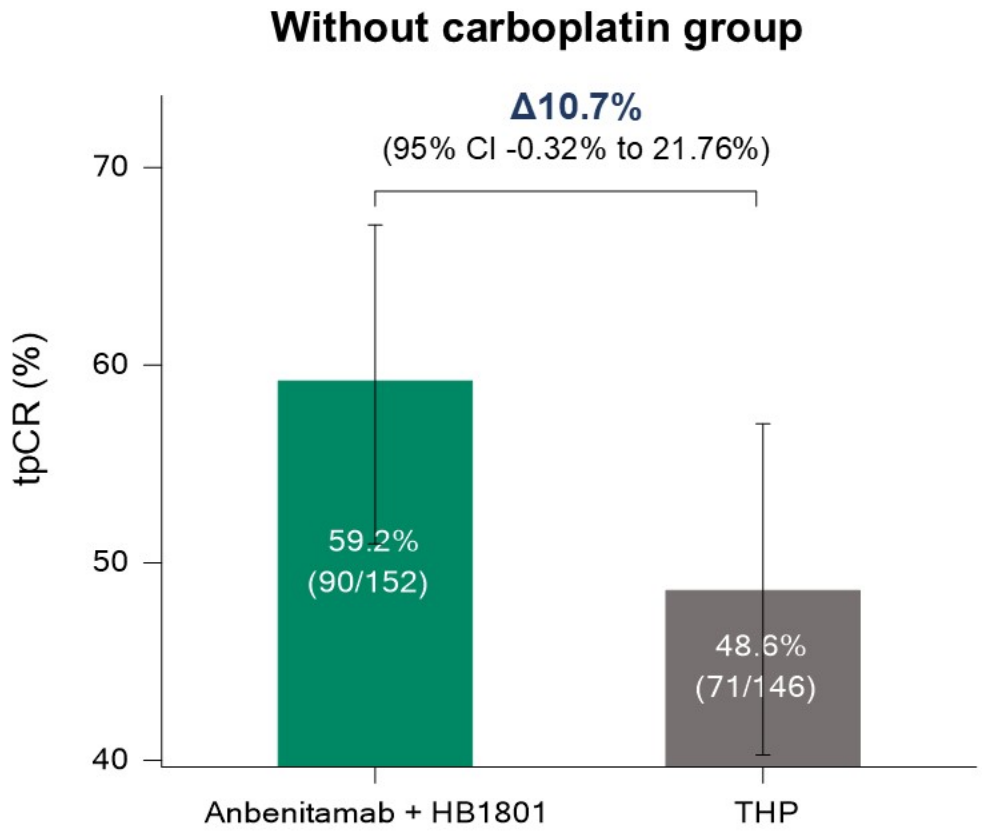
tpCR rates by BIRC assessment (ITT population)

Neoadjuvant anbenitamab + HB1801 ± carboplatin demonstrated a statistically significant and clinically meaningful improvement in BIRC assessed tpCR versus THP ± carboplatin

*Abbreviations: tpCR, total pathological complete response; ITT, intention-to-treat; BIRC, Blinded Independent Review Committee; CI, confidence interval.

BIRC assessed tpCR by carboplatin subgroup



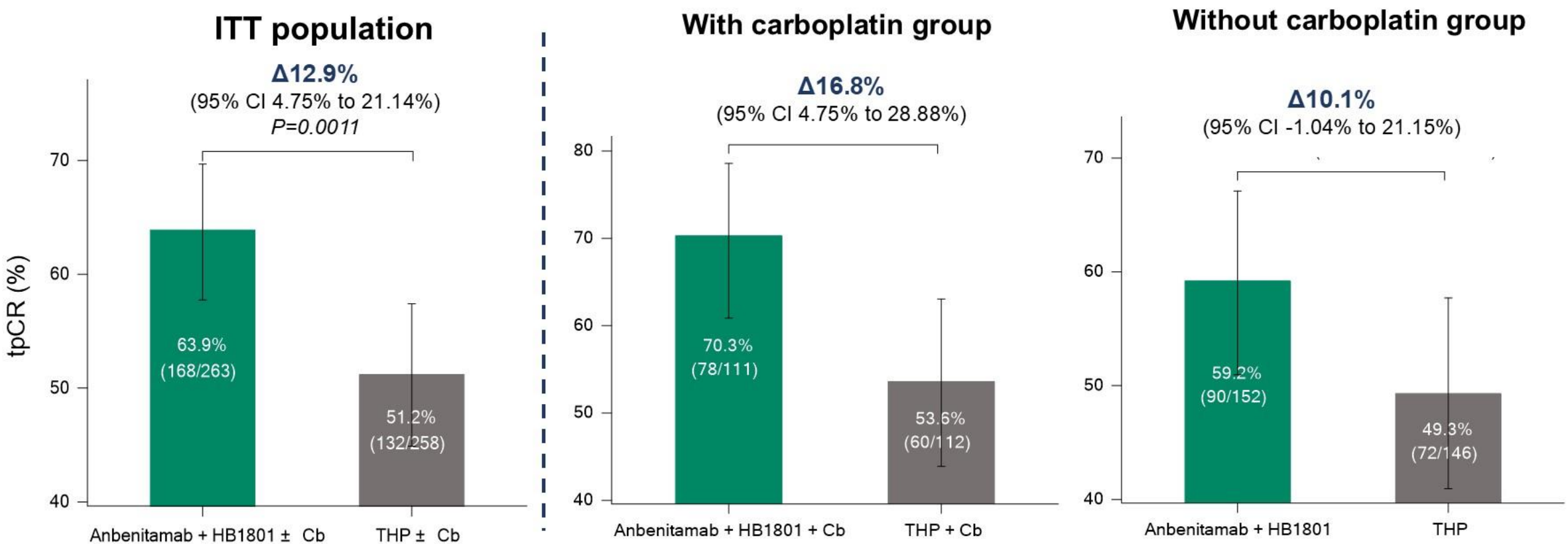


tpCR rates by BIRC assessment (ITT population)

BIRC-assessed tpCR improvement was consistently observed in groups with or without carboplatin use.

* Abbreviations: BIRC, Blinded Independent Review Committee; tpCR, total pathological complete response; Cb, carboplatin; CI, confidence interval.

Secondary endpoint: tpCR rates by investigator assessment (ITT)



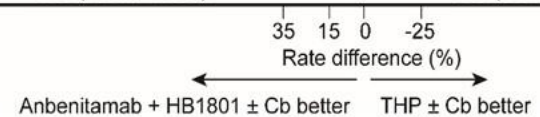
tpCR rates by INV assessment (ITT population)

Investigator-assessed tpCR improvements was observed in the ITT population, as well as groups with or without carboplatin use.

* Abbreviations: INV, Investigator; tpCR, total pathological complete response; ITT, intention-to-treat; Cb, carboplatin;; CI, confidence interval.

Subgroup analysis of BIRC assessed tpCR (ITT)

Subgroup	Anbenitamab + HB1801 ± Cb n/N	Anbenitamab + HB1801 ± Cb tpCR, % (95% CI)	THP ± Cb n/N	THP ± Cb tpCR, % (95% CI)	Rate difference, % (95% CI)
Intent-to-treat Population	**164/263**	**62.4 (56.20, 68.23)**	**132/258**	**51.2 (44.89, 57.41)**	**11.2 (2.69, 19.48)**
Age (years)					
<65	153/242	63.2 (56.81, 69.31)	123/238	51.7 (45.14, 58.18)	11.5 (2.70, 20.14)
≥65	11/21	52.4 (29.78, 74.29)	9/20	45.0 (23.06, 68.47)	7.4 (−21.48, 34.57)
ECOG Performance Status					
0	129/202	63.9 (56.82, 70.49)	103/211	48.8 (41.89, 55.77)	15.0 (5.48, 24.22)
1	34/59	57.6 (44.07, 70.39)	29/47	61.7 (46.38, 75.49)	−4.1 (−21.89, 14.42)
Carboplatin Use					
Yes	74/111	66.7 (57.09, 75.33)	61/112	54.5 (44.78, 63.90)	12.2 (−0.61, 24.46)
No	90/152	59.2 (50.95, 67.10)	71/146	48.6 (40.28, 57.03)	10.6 (−0.72, 21.52)
Hormone Receptor Status					
Positive	77/149	51.7 (43.36, 59.93)	63/142	44.4 (36.04, 52.93)	7.3 (−4.13, 18.48)
Negative	87/114	76.3 (67.44, 83.78)	69/116	59.5 (49.97, 68.50)	16.8 (4.76, 28.23)
Clinical Stage					
Early stage	111/174	63.8 (56.18, 70.93)	87/168	51.8 (43.96, 59.55)	12.0 (1.54, 22.12)
Locally advanced	53/89	59.6 (48.62, 69.83)	45/90	50.0 (39.27, 60.73)	9.6 (−4.95, 23.49)
T Stage					
T2	131/207	63.3 (56.32, 69.86)	109/214	50.9 (44.03, 57.81)	12.4 (2.89, 21.49)
T3–4	33/56	58.9 (44.98, 71.90)	23/44	52.3 (36.69, 67.54)	6.7 (−12.46, 25.29)
N Stage					
N0–1	114/180	63.3 (55.84, 70.38)	88/171	51.5 (43.71, 59.16)	11.9 (1.53, 21.88)
N2–3	50/83	60.2 (48.90, 70.83)	44/87	50.6 (39.64, 61.47)	9.7 (−5.20, 23.92)
HER2 Status					
IHC3+	157/235	66.8 (60.39, 72.80)	128/227	56.4 (49.67, 62.94)	10.4 (1.55, 19.07)
IHC2+ and FISH+	7/28	25.0 (10.69, 44.87)	4/31	12.9 (3.63, 29.83)	12.1 (−8.06, 32.03)
Ki-67					
<30%	32/60	53.3 (40.00, 66.33)	19/43	44.2 (29.08, 60.12)	9.1 (−10.11, 27.42)
≥30%	132/203	65.0 (58.04, 71.57)	113/215	52.6 (45.66, 59.39)	12.5 (3.02, 21.58)

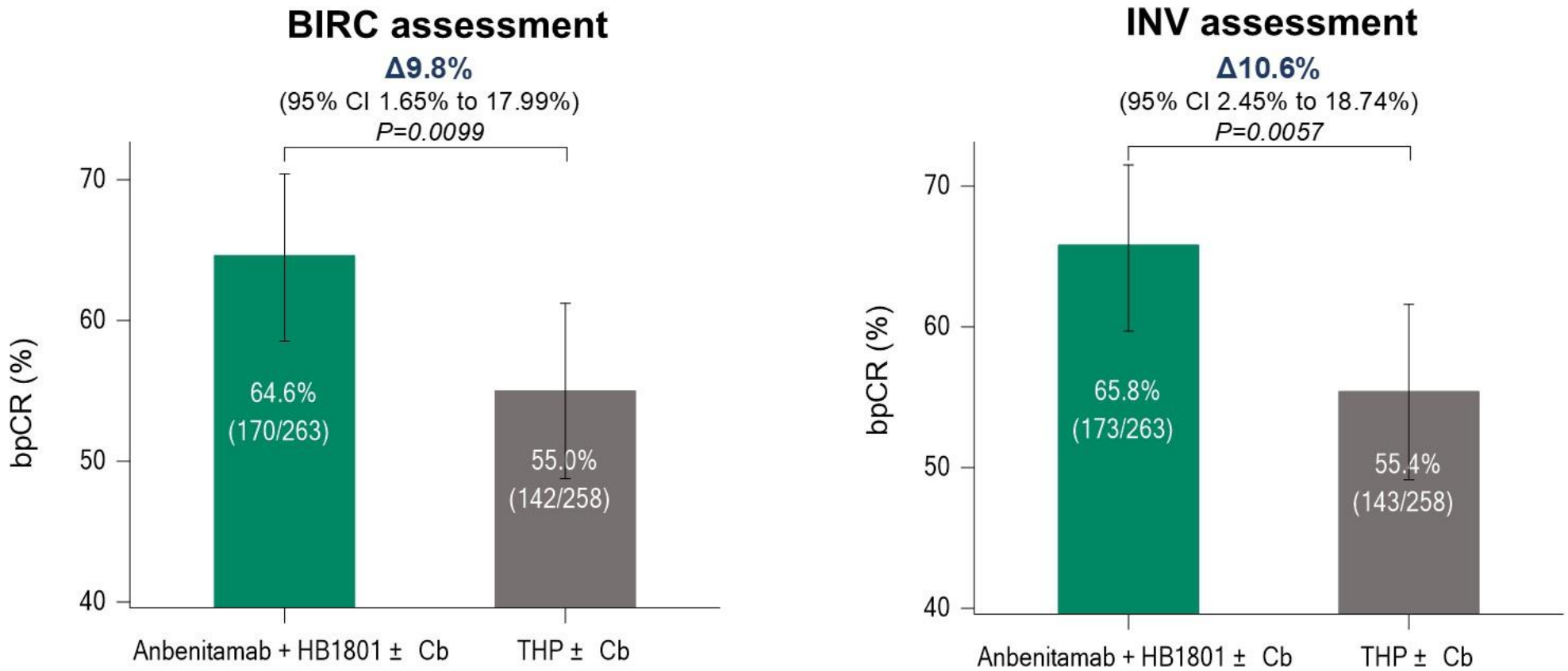


Improvement in BIRC assessed tpCR for anbenitamab + HB1801 ± carboplatin versus THP ± carboplatin was consistent across most prespecified subgroups

Note: The Wilson method was used to estimate the 95% CI of the rate difference between groups for tpCR.

* Abbreviations: tpCR, total pathological complete response; ITT, intention-to-treat; BIRC, Blinded Independent Review Committee; Cb, carboplatin; ECOG, Eastern Cooperative Oncology Group; HER2, human epidermal growth factor receptor 2; CI, confidence interval.

Secondary endpoint：bpCR outcomes by BIRC & INV(ITT)



bpCR rates by BIRC & INV assessment (ITT population)

Neoadjuvant anbenitamab + HB1801 ± carboplatin demonstrated a statistically significant and clinically meaningful improvement in bpCR versus THP ± carboplatin

* Abbreviations: bpCR, breast pathological complete response; BIRC, Blinded Independent Review Committee; INV, Investigator; Cb, carboplatin; RD, risk difference; CI, confidence interval.

Secondary endpoint：ORR rates by INV assessment (ITT)

	Anbenitamab + HB1801 ± Carboplatin (N=263)	THP ± Carboplatin (N=258)
Confirmed BOR，n (%)		
CR	34 (12.9)	34 (13.2)
PR	214 (81.4)	204 (79.1)
SD	11 (4.2)	20 (7.8)
PD	1 (0.4)	0
NE	3 (1.1)	0
No post-baseline tumor assessment	1 (0.4)	0
SD duration less than 42 days	2 (0.8)	0
Preoperative ORR，n (%)	248 (94.3)	238 (92.2)
95% CI[1]	(90.77, 96.77)	(88.28, 95.20)
Rate Difference[2]	2.1 (-2.06, 6.33)	

Investigator-assessed confirmed ORR was 94.3% (248/263) in Anbenitamab + HB1801 ± carboplatin versus 92.2% (238/258) in THP ± carboplatin

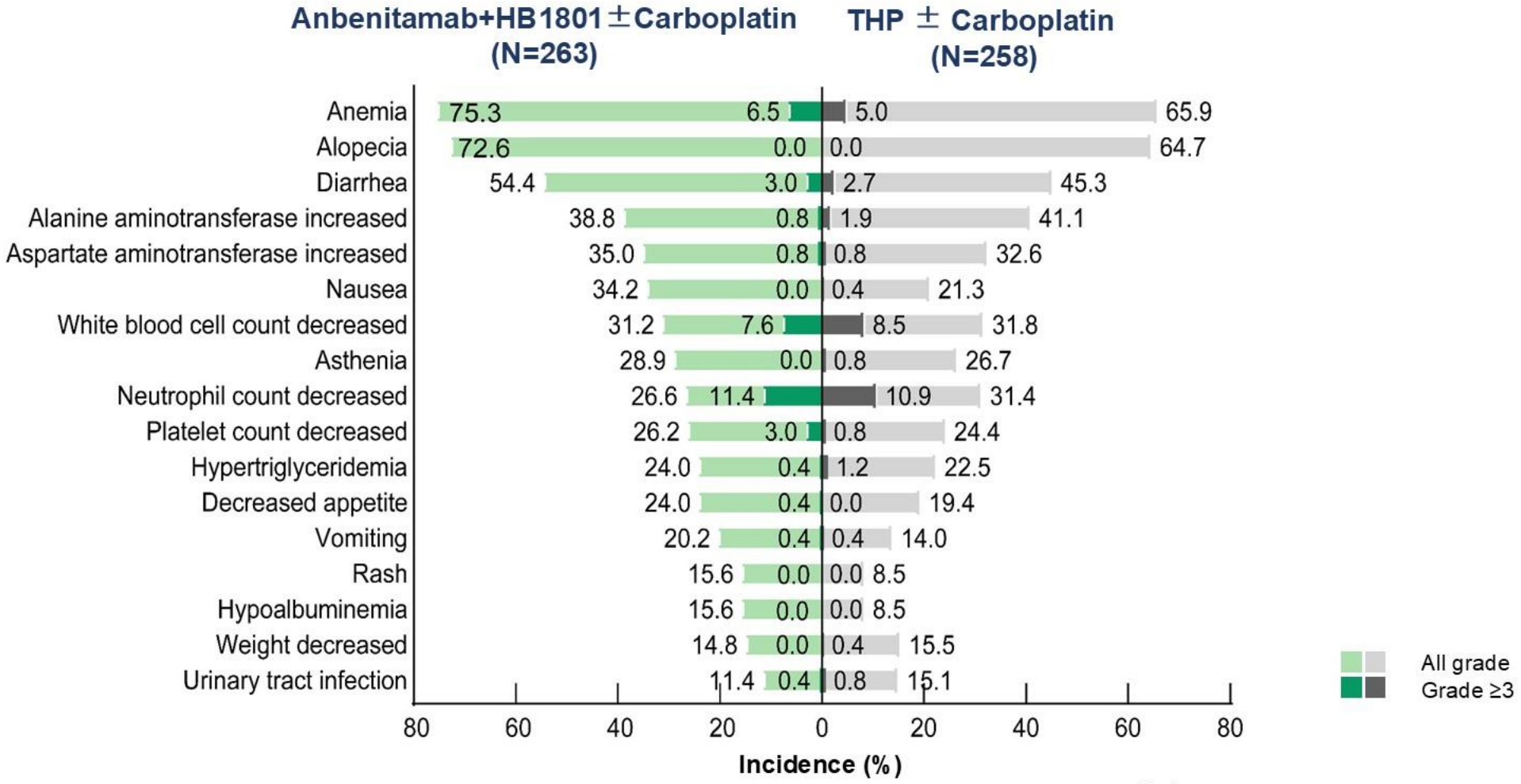
Note：Percentages are calculated based on the intent-to-treat analysis set.
Overall Response Rate (ORR) is defined as the proportion of subjects with a Best Overall Response (BOR) of complete response (CR) or partial response (PR).
[1] The 95% confidence interval for the rate is calculated using the Clopper–Pearson method.
[2] The rate difference and its 95% confidence interval are calculated using the stratified Cochran–Mantel–Haenszel method, with stratification variables being the randomization factors collected in the IWRS system.
Abbreviations: ORR, Overall Response Rate; ITT, Intent-to-Treat; INV, Investigator; BOR, Best Overall Response; CR, Complete Response; PR, Partial Response; SD, Stable Disease; PD, Progressive Disease; NE, Not Evaluable; CI, Confidence Interval.

Overall safety summary

n (%)	Anbenitamab + HB1801 ± Carboplatin			THP ± Carboplatin		
	Without carboplatin (N=152)	With carboplatin (N=111)	Overall (N=263)	Without carboplatin (N=146)	With carboplatin (N=112)	Overall (N=258)
Any grade TEAEs	149 (98.0)	110 (99.1)	259 (98.5)	143 (97.9)	112 (100)	255 (98.8)
Grade ≥ 3	39 (25.7)	38 (34.2)	77 (29.3)	39 (26.7)	34 (30.4)	73 (28.3)
Serious TEAEs	18 (11.8)	12 (10.8)	30 (11.4)	16 (11.0)	7 (6.3)	23 (8.9)
Death due to TEAEs	0	0	0	0	0	0
TEAEs leading to interruption of any study drug	8 (5.3)	7 (6.3)	15 (5.7)	11 (7.5)	8 (7.1)	19 (7.4)
TEAEs leading to interruption of Anbenitamab/ Trastuzumab& Pertuzumab	8 (5.3)	7 (6.3)	15 (5.7)	11 (7.5)	8 (7.1)	19 (7.4)
TEAEs leading to interruption of HB1801/ Docetaxel	7 (4.6)	6 (5.4)	13 (4.9)	8 (5.5)	6 (5.4)	14 (5.4)
TEAEs leading to interruption of Cb	-	4 (3.6)	4 (1.5)	-	3 (2.7)	3 (1.2)
TEAEs leading to discontinuation of any study drug	3 (2.0)	10 (9.0)	13 (4.9)	1 (0.7)	8 (7.1)	9 (3.5)
TEAEs leading to discontinuation of Anbenitamab/ Trastuzumab& Pertuzumab	1 (0.7)	0	1 (0.4)	0	0	0
TEAEs leading to discontinuation of HB1801/ Docetaxel	3 (2.0)	0	3 (1.1)	1 (0.7)	0	1 (0.4)
TEAEs leading to discontinuation of Cb	-	10 (9.0)	10 (3.8)	-	8 (7.1)	8 (3.1)
TEAEs leading to dose reduction of any study drug	12 (7.9)	28 (25.2)	40 (15.2)	8 (5.5)	30 (26.8)	38 (14.7)
TEAEs leading to dose reduction of HB1801/ Docetaxel	12 (7.9)	10 (9.0)	22 (8.4)	8 (5.5)	6 (5.4)	14 (5.4)
TEAEs leading to dose reduction of Cb	-	26 (23.4)	26 (9.9)	-	29 (25.9)	29 (11.2)

The safety profile of the anbenitamab + HB1801 ± carboplatin was similar to that of THP ± carboplatin

TEAEs in at least 15% of patients



The safety profile of anbenitamab + HB1801 ± carboplatin were favorable

TEAEs leading to discontinuation (≥2 patients)

n (%)	Anbenitamab+HB1801± Carboplatin (N=263)				THP ± Carboplatin (N=258)				
	Anbenitamab	HB1801	Carboplatin	Any	Trastuzumab	Pertuzumab	Docetaxel	Carboplatin	Any
TEAE leading to discontinuation of any study drug	1 (0.4)	3 (1.1)	10 (3.8)	13 (4.9)	0	0	1 (0.4)	8 (3.1)	9 (3.5)
Platelet count decreased	0	0	2 (0.8)	2 (0.8)	0	0	0	5 (1.9)	5 (1.9)
Asthenia	0	0	2 (0.8)	2 (0.8)	0	0	0	2 (0.8)	2 (0.8)
Anemia	0	0	2 (0.8)	2 (0.8)	0	0	1 (0.4)	2 (0.8)	3 (1.2)
Gastrointestinal disorders	0	1 (0.4)	1 (0.4)	2 (0.8)	0	0	0	0	0

- **TEAEs leading to discontinuation occurred in 4.9% and 3.5% of patients in the Anbenitamab + HB1801 ± carboplatin and THP ± carboplatin groups, respectively.**
- **The most common events leading to discontinuation were primarily carboplatin-related toxicities.**

Conclusions

- **Neoadjuvant anbenitamab and HB1801 ± carboplatin significantly improved tpCR rate compared with the standard therapy with a well-tolerated safety profile**.
  - BIRC-assessed tpCR rate was significantly higher in anbenitamab and HB1801 ± carboplatin group (62.4% vs. 51.2%; absolute difference 11.4%, 95%CI, 3.2 to 19.6; *P*=0.0036).
  - The tpCR benefit was consistent across all predefined subgroups, including HR-positive/negative, early/locally advanced disease, and with/without carboplatin.
  - Benefits of anbenitamab and HB1801 ± carboplatin group were also observed in tpCR (INV assessed), bpCR (BIRC and INV assessed) and ORR (INV assessed).
  - Grade ≥3 TRAEs were comparable between the two groups (29.3% vs. 28.3%), with no treatment-related deaths reported.

Anbenitamab + HB1801 ± carboplatin could provide a promising neoadjuvant treatment option for patients with early-stage HER2-positive breast cancer.

Lay summary

- This study tests a new treatment before surgery for HER2-positive early or locally advanced breast cancer.
- The new treatment helped more patients have no cancer left after surgery, with similar safety to standard of care.

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