

Supplemental Online Content

Pivot X, Georgievich MA, Shamrai V, et al. Efficacy of HD201 vs referent trastuzumab in patients with ERBB2-positive breast cancer treated in the neoadjuvant setting: a multicenter phase 3 randomized clinical trial. *JAMA Oncol*. Published online March 3, 2022. doi:10.1001/jamaoncol.2021.8171

eTable 1. Concordance analysis of locally versus centrally assessed breast and total pathological complete response (bpCR and tpCR) in the PPS population

eTable 2. Efficacy results in the mFAS and rPPS populations

This supplemental material has been provided by the authors to give readers additional information about their work.

eTable 1. Concordance analysis of locally versus centrally assessed breast and total pathological complete response (bpCR and tpCR) in the PPS population

	Locally assessed tpCR n								
	HD201			Herceptin®			Total		
	Yes	No	Total	Yes	No	Total	Yes	No	Total
Centrally assessed tpCR n									
Yes	83	19	102	92	20	112	175	39	214
No	10	93	103	15	89	104	25	182	207
Total	93	112	205	107	109	216	200	221	421
	Locally assessed bpCR n								
	HD201			Herceptin®			Total		
	Yes	No	Total	Yes	No	Total	Yes	No	Total
Centrally assessed bpCR n									
Yes	110	19	129	107	16	123	217	35	252
No	12	88	100	18	87	105	30	175	205
Total	122	107	229	125	103	228	247	210	457

For tpCR, there was agreement between the 2 assessments for 357 of the 421 subjects with both assessments (84.8%, 95% CI: [81.0%, 88.1%]). The propensity of achieving tpCR based on the local or central assessment was similar (McNemar test: $p=0.080$). The number of patients (n) is provided for each category. For bpCR, there was agreement between the 2 assessments for 392 of the 457 subjects with both assessments (85.8%, 95% CI: [82.2%, 88.8%]). The propensity of achieving bpCR based on the local or central assessment was similar (McNemar test: $p=0.535$). The number of patients (n) is provided for each category.

eTable 2. Efficacy results in the mFAS and rPPS populations

Group	HD201	Herceptin®	Difference	Difference	Ratio	Ratio
mFAS	N =250	N = 252	Unadjusted	Adjusted*	Unadjusted	Adjusted*
Locally Assessed Total Pathological Complete Response (tpCR)						
Responders, n (%)	108 (44.6)	116 (47.3)	-2.7	-1.0	0.94	0.92
95% CI	[38.3; 51.1]	[41.0; 53.8]	[-11.7; 6.2]	[-9.6; 7.7]	[0.78; 1.14]	[0.76; 1.10]
Centrally Assessed Total Pathological Complete Response (tpCR)						
Responders, n (%)	103 (49.5)	112 (50.7)	-1.2	-1.1	0.98	0.97
95% CI	[42.5; 56.5]	[43.9; 57.4]	[-10.6; 8.3]	[-10.2; 8.0]	[0.81; 1.18]	[0.81; 1.16]
Locally Assessed Breast Pathological Complete Response (bpCR)						
Responders, n (%)	127 (52.5)	128 (52.2)	0.2	0.8	1.00	0.97
95% CI	[46.0; 58.9]	[45.8; 58.6]	[-8.7; 9.2]	[-7.9; 9.5]	[0.85; 1.19]	[0.83; 1.14]
Centrally Assessed Breast Pathological Complete Response (bpCR)						
Responders, n (%)	131 (56.2)	125 (52.7)	3.5	3.8	1.07	1.04
95% CI	[49.6; 62.7]	[46.2; 59.2]	[-5.6; 12.6]	[-5.0; 12.7]	[0.90; 1.26]	[0.89; 1.22]
Overall Response at the End of Neoadjuvant Treatment						
Responders, n (%)	220 (88)	218 (86.5)	1.5	1.8	1.02	1.02
95% CI			[-7.3; 10.1]	[-3.9; 7.4]	[0.95%; 1.09]	[0.96; 1.09]
Group	HD201	Herceptin®	Difference	Difference	Ratio	Ratio
rPPS	N =230	N = 233	Unadjusted	Adjusted*	Unadjusted	Adjusted*
Locally Assessed Total Pathological Complete Response (tpCR)						
Responders, n (%)	107 (46.5)	115 (49.4)	-2.8	-1.9	0.94	0.90
95% CI	[39.9; 53.2]	[42.8; 56.0]	[-12.0; 6.4]	[-10.8; 7.0]	[0.78; 1.14]	[0.76; 1.08]
Centrally Assessed Total Pathological Complete Response (tpCR)						
Responders, n (%)	101 (49.8)	109 (51.2)	-1.4	-1.3	0.97	0.96
95% CI	[42.7; 56.8]	[44.3; 58.1]	[-11.0; 8.2]	[-10.6; 7.9]	[0.80; 1.18]	[0.81; 1.15]
Locally Assessed Breast Pathological Complete Response (bpCR)						
Responders, n (%)	122 (53.0)	125 (53.6)	-0.6	-0.3	0.99	0.95%
95% CI	[46.4; 59.6]	[47.0; 60.2]	[-9.8; 8.6]	[-9.2; 8.5]	[0.83; 1.17]	[0.81; 1.12]
Centrally Assessed Breast Pathological Complete Response (bpCR)						

Responders, n (%)	126 (56.5)	120 (53.3)	3.2	3.4	1.06	1.03
95% CI	[49.7; 63.1]	[46.6; 60.0]	[-6.1; 12.6]	[-5.7; 12.4]	[0.90; 1.25]	[0.87; 1.21]

*Adjusted for stratification factors. The effect of the stratification factors was evaluated using an adapted logistic model consisting of a combination of logistic, binomial, and log-binomial regression (referred to as adapted logistic regression). N: number of patients in the population; n: number of patients; (%) percentage of patients.