A randomized phase II study to investigate the addition of PD-L1 antibody MEDI4736 to a taxane-anthracycline containing chemotherapy in triple negative breast cancer (GeparNuevo)

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Primary endpoints

Table1: Primary efficacy endpoint: pCR (ypT0 ypN0) (mITT population)

Parameter	Durvalumab (N=88) N (%)	Placebo (N=86) N (%)	Overall (N=174) N (%)	p-value
No	41 (46.6)	48 (55.8)	89 (51.1)	0.287
Yes	47 (53.4)	38 (44.2)	85 (48.9)	
95% CI	(42.5%, 64.1%)	(33.5%, 55.3%)		
Difference, 95% CI			9.2% (-5.6%, 24.0%)	
80% CI	(46.0%, 60.7%)	(36.9%, 51.7%)		
Difference, 80% CI			9.2% (-0.4%, 18.9%)	

CI=Confidence interval; mITT = modified intent-to-treat; pCR = pathological complete response;

A multivariate logistic regression analysis was performed for the primary efficacy endpoint pCR to report odds ratios (OR) with 95% CI, adjusted for the factors as listed in Figure 1.

Figure 1: Forest plot of pCR (ypT0 ypN0): multivariate logistic regression (mITT population)