

THE LANCET Oncology

Supplementary appendix

This appendix formed part of the original submission and has been peer reviewed. We post it as supplied by the authors.

This online publication has been corrected. The corrected version first appeared at [thelancet.com/oncology](https://www.thelancet.com/oncology) on March 31, 2025.

Supplement to: Zdenkowski N, Kuper-Hommel MJ, Niman SM, et al. Timing of nivolumab with neoadjuvant carboplatin and paclitaxel for early triple-negative breast cancer (BCT1902/IBCSG 61-20; Neo-N): a non-comparative, open-label, randomised, phase 2 trial. *Lancet Oncol* 2025; **26**: 367-77.

Supplementary data/Appendix

Figure. Distribution of centrally assessed TILs percentage by PD-L1 status at baseline and pCR status; PD-L1/TIL positive concordant 24/96 (25%); PD-L1+/TIL low 27/96 (28%); PD-L1-/TIL high 8/96 (8%); PD-L1 -/TIL low 37/96 (39%); 12 missing both measurements. The percentage pCR (breast and axilla) and 90% CIs for each of the four subgroups is provided at the bottom of the figure. A dashed horizontal line indicates the cut of value (≥ 30 / <30) for high vs. low TILs

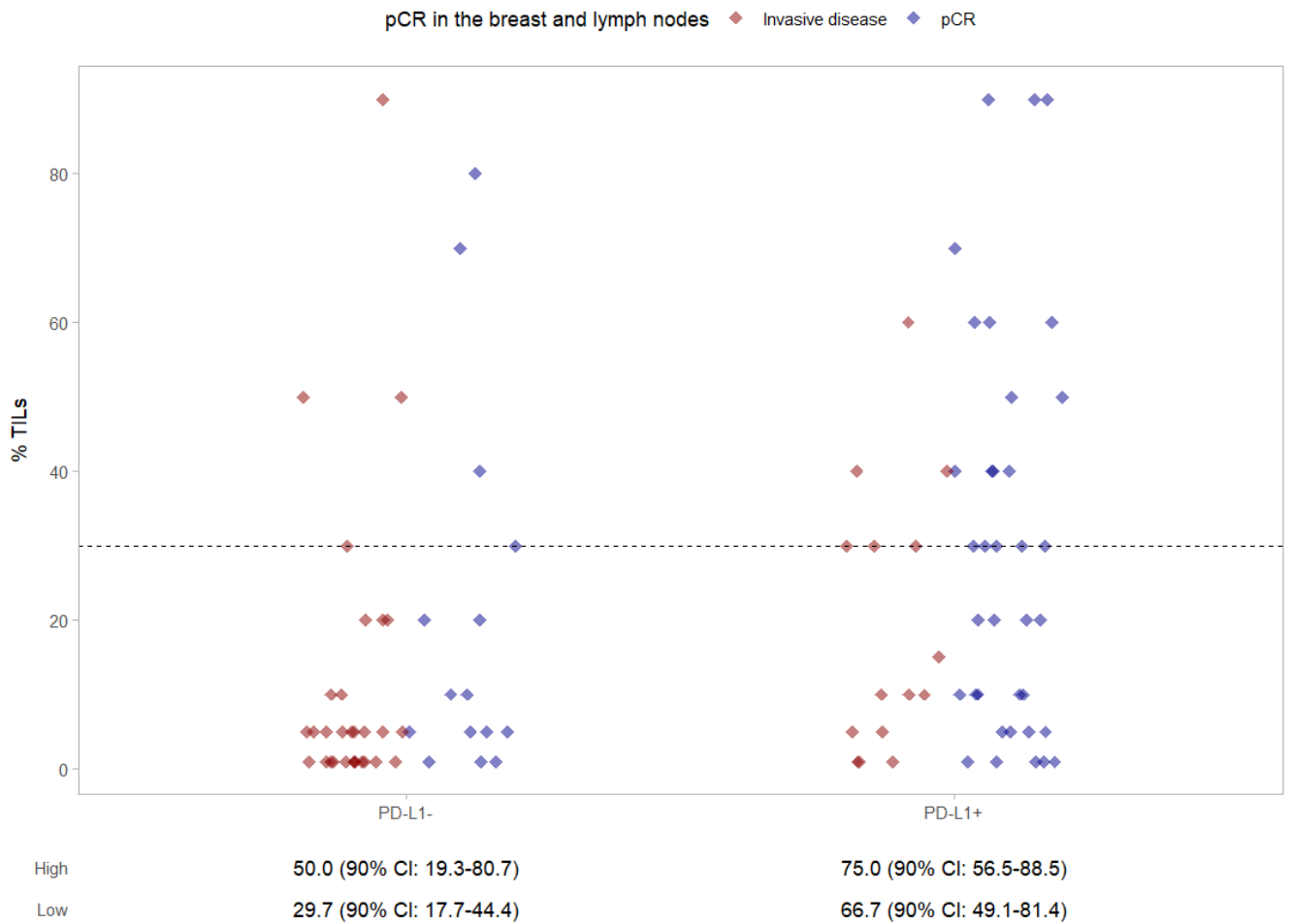


Table: Percentage pCR breast and axilla and 90% confidence intervals by subgroups

		N	# pCRs	Estimate	90% LCL	90% UCL
*Overall	All participants	108	57	52.8	44.4	61.0
*Treatment	Nivo lead-in	53	27	50.9	39.0	63.2
	Nivo concurrent	55	30	54.5	42.7	66.2
TILs status	High TILs	36	24	66.7	51.7	79.5
	Low TILs	70	32	45.7	35.5	56.2
PD-L1 status	PD-L1+	51	36	70.6	58.4	80.9
	PD-L1-	45	15	33.3	21.8	46.6
cN status	cN0	90	50	55.6	46.3	64.5
	cN+	18	7	38.9	19.9	60.8
Disease stage	Stage I	37	18	48.6	34.3	63.2
	Stage II/III	71	39	54.9	44.5	65.0

* Confidence intervals for 'all participants' and by treatment cohort are adjusted for the two-stage design, all other confidence intervals are exact binomials.

Table: Percentage pCR breast only and 90% confidence intervals by subgroups

		N	# pCRs breast only	Estimate	90% LCL	90% UCL
Overall	All participants	108	61	56.5	48.1	64.6
Treatment	Nivo lead-in	53	28	52.8	40.7	64.7
	Nivo concurrent	55	33	60.0	48.0	71.1
TILs status	High TILs	36	26	72.2	57.5	84.1
	Low TILs	70	34	48.6	38.2	59.0
PD-L1 status	PD-L1+	51	37	72.5	60.5	82.6
	PD-L1-	45	17	37.8	25.7	51.1
cN status	cN0	90	50	55.6	46.3	64.5
	cN+	18	11	61.1	39.2	80.1
Disease stage	Stage I	37	18	48.6	34.3	63.2
	Stage II/III	71	43	60.6	50.1	70.3

Figure: Percentage pCR breast only and 90% confidence intervals by subgroups

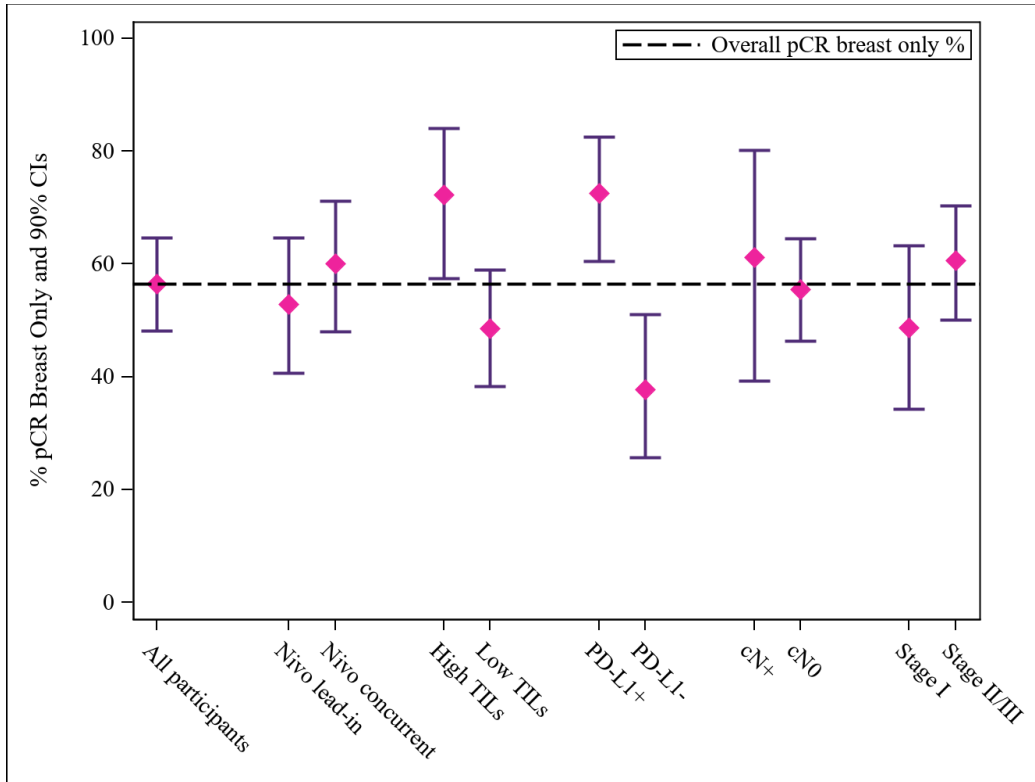


Table: Percentage RCB 0/1 and 90% confidence intervals by subgroups

		N	# RCB 0/1	Estimate	90% LCL	90% UCL
Overall	All participants	108	74	68.5	60.4	75.9
Treatment	Nivo lead-in	53	34	64.2	52.0	75.1
	Nivo concurrent	55	40	72.7	61.2	82.4
TILs status	High TILs	36	27	75.0	60.4	86.3
	Low TILs	70	45	64.3	53.8	73.8
PD-L1 status	PD-L1+	51	40	78.4	66.8	87.4
	PD-L1-	45	26	57.8	44.5	70.3
cN status	cN0	90	66	73.3	64.6	80.9
	cN+	18	8	44.4	24.4	65.9
Disease stage	Stage I	37	25	67.6	52.8	80.1
	Stage II/III	71	49	69.0	58.8	78.0

Figure: Percentage RCB 0/1 and 90% confidence intervals by subgroups

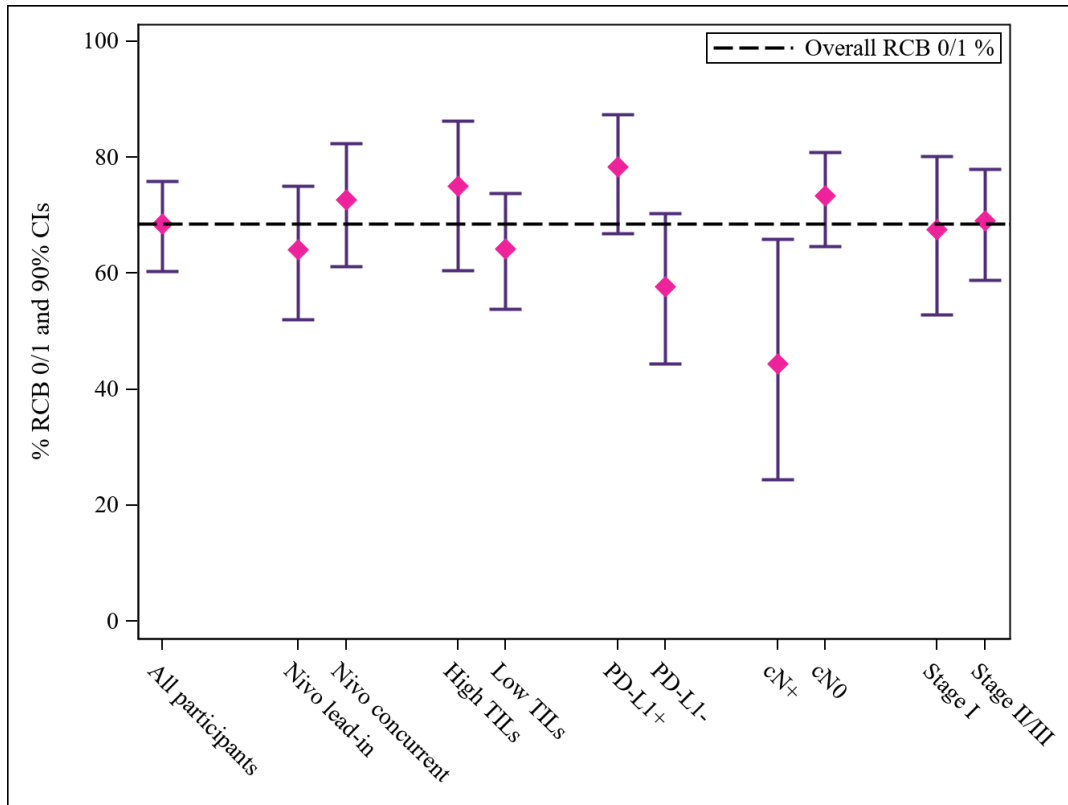


Table: Reasons for discontinuation of all treatment

Treatment cohort	Last cycle of treatment	AE related to treatment suspension
Cohort A (Nivo lead-in)	Cycle 3	Alanine aminotransferase increased
Cohort A (Nivo lead-in)	Cycle 2	Colitis
Cohort A (Nivo lead-in)	Cycle 3	Cholelithiasis
Cohort A (Nivo lead-in)	Cycle 3	COVID-19
Cohort A (Nivo lead-in)	Cycle 3	Pancreatitis
Cohort B (Nivo concurrent)	Cycle 4*	Alanine aminotransferase increased; Aspartate aminotransferase increased
Cohort B (Nivo concurrent)	Cycle 4*	Colitis
Cohort B (Nivo concurrent)	Cycle 4*	Gastritis
Cohort B (Nivo concurrent)	Cycle 4*	Immune Mediated Interstitial Nephritis
Cohort B (Nivo concurrent)	Cycle 1	Infusion related reaction
Cohort B (Nivo concurrent)	Cycle 3	Peripheral sensory neuropathy

Table: Neo-N Listing of SAEs

ID	Treatment	Week from rand to onset	SAE name	Outcome	Relationship to treatment
1902014	Cohort A (Nivo lead-in)	15.0	Acute kidney injury	Resolved	Nivolumab: Definite; Paclitaxel: Unlikely; Carboplatin: Unlikely
1902125	Cohort A (Nivo lead-in)	13.6	Acute kidney injury	Resolved	Nivolumab: Probable; Paclitaxel: Unrelated; Carboplatin: Unlikely
1902087	Cohort A (Nivo lead-in)	12.3	Adrenal insufficiency	Resolved	Unrelated
1902115	Cohort A (Nivo lead-in)	38.7	Adrenal insufficiency	Condition Improved	Nivolumab: Probable; Paclitaxel: Unrelated; Carboplatin: Unrelated
1902100	Cohort A (Nivo lead-in)	26.7	Allergic reaction	Resolved	Unrelated
1902027	Cohort A (Nivo lead-in)	30.7	Anaemia	Resolved	Unrelated
1902115	Cohort A (Nivo lead-in)	18.4	Chest pain - cardiac	Resolved	Unrelated
1902049	Cohort A (Nivo lead-in)	6.9	Colitis	Resolved with sequelae	Nivolumab: Probable; Paclitaxel: Possible; Carboplatin: Possible
1902049	Cohort A (Nivo lead-in)	10.9	Colitis	Resolved with sequelae	Nivolumab: Probable; Paclitaxel: Possible; Carboplatin: Possible
1902124	Cohort A (Nivo lead-in)	23.9	Colitis	Resolved	Nivolumab: Definite; Paclitaxel: Unrelated; Carboplatin: Unrelated
1902049	Cohort A (Nivo lead-in)	19.1	Colonic perforation	Resolved	Nivolumab: Possible; Paclitaxel: Unlikely; Carboplatin: Unrelated

ID	Treatment	Week from rand to onset	SAE name	Outcome	Relationship to treatment
1902027	Cohort A (Nivo lead-in)	24.1	Febrile neutropenia	Resolved	Unrelated
1902027	Cohort A (Nivo lead-in)	26.3	Febrile neutropenia	Resolved	Unrelated
1902066	Cohort A (Nivo lead-in)	37.3	Febrile neutropenia	Resolved	Unrelated
1902071	Cohort A (Nivo lead-in)	24.6	Febrile neutropenia	Resolved	Unrelated
1902079	Cohort A (Nivo lead-in)	28.6	Febrile neutropenia	Resolved	Unrelated
1902103	Cohort A (Nivo lead-in)	31.0	Febrile neutropenia	Resolved	Unrelated
1902065	Cohort A (Nivo lead-in)	8.6	Fever	Resolved	Nivolumab: Unlikely; Paclitaxel: Unrelated; Carboplatin: Unrelated
1902071	Cohort A (Nivo lead-in)	10.1	Fever	Resolved	Unrelated
1902071	Cohort A (Nivo lead-in)	36.0	Fever	Resolved	Unrelated
1902044	Cohort A (Nivo lead-in)	11.9	Hepatobiliary disorders Other (Cholelithiasis)	Resolved	Unrelated
1902066	Cohort A (Nivo lead-in)	39.3	Hypophysitis	Resolved with sequelae	Nivolumab: Definite; Paclitaxel: Unrelated; Carboplatin: Unrelated
1902044	Cohort A (Nivo lead-in)	26.3	Infections and infestations - Other (Bacillus cereus Bacteraemia)	Resolved	Unrelated
1902066	Cohort A (Nivo lead-in)	39.3	Myocarditis	Resolved	Nivolumab: Definite; Paclitaxel: Unrelated; Carboplatin: Unrelated
1902027	Cohort A (Nivo lead-in)	9.1	Pancreatitis	Resolved	Unrelated

ID	Treatment	Week from rand to onset	SAE name	Outcome	Relationship to treatment
1902087	Cohort A (Nivo lead-in)	13.1	Paresthesia	Resolved	Nivolumab: Unrelated; Paclitaxel: Possible; Carboplatin: Unrelated
1902003	Cohort A (Nivo lead-in)	10.9	Pneumonitis	Resolved	Nivolumab: Possible; Paclitaxel: Unlikely; Carboplatin: Unrelated
1902063	Cohort A (Nivo lead-in)	48.0	Pneumonitis	Resolved	Nivolumab: Unlikely; Paclitaxel: Unrelated; Carboplatin: Unrelated
1902108	Cohort A (Nivo lead-in)	10.1	Sepsis	Resolved	Nivolumab: Unrelated; Paclitaxel: Possible; Carboplatin: Possible
1902087	Cohort A (Nivo lead-in)	5.6	Skin infection	Resolved	Unrelated
1902003	Cohort A (Nivo lead-in)	10.9	Thromboembolic event	Resolved	Nivolumab: Unrelated; Paclitaxel: Possible; Carboplatin: Possible
1902102	Cohort A (Nivo lead-in)	20.7	Thromboembolic event	Resolved	Unrelated
1902103	Cohort A (Nivo lead-in)	26.9	Urinary tract infection	Resolved	Unrelated
1902107	Cohort B (Nivo concurrent)	27.9	Adrenal insufficiency	Resolved	Nivolumab: Definite; Paclitaxel: Unrelated; Carboplatin: Unrelated
1902099	Cohort B (Nivo concurrent)	15.3	Anaemia	Resolved	Nivolumab: Unrelated; Paclitaxel: Probable; Carboplatin: Probable

ID	Treatment	Week from rand to onset	SAE name	Outcome	Relationship to treatment
1902017	Cohort B (Nivo concurrent)	5.7	Anaemia	Resolved	Nivolumab: Unrelated; Paclitaxel: Definite; Carboplatin: Definite
1902017	Cohort B (Nivo concurrent)	10.0	Anaemia	Resolved	Nivolumab: Unrelated; Paclitaxel: Probable; Carboplatin: Probable
1902032	Cohort B (Nivo concurrent)	12.1	Anaemia	Resolved	Nivolumab: Unrelated; Paclitaxel: Definite; Carboplatin: Definite
1902054	Cohort B (Nivo concurrent)	11.7	Anaemia	Resolved	Nivolumab: N/A; Paclitaxel: Definite; Carboplatin: Definite
1902082	Cohort B (Nivo concurrent)	6.6	Anaemia	Resolved with sequelae	Nivolumab: Unrelated; Paclitaxel: Definite; Carboplatin: Definite
1902011	Cohort B (Nivo concurrent)	5.3	Atrial fibrillation	Resolved	Unrelated
1902043	Cohort B (Nivo concurrent)	25.1	CPK increased	Resolved	Nivolumab: Probable; Paclitaxel: Unrelated; Carboplatin: Unrelated
1902072	Cohort B (Nivo concurrent)	15.4	Colitis	Resolved	Unrelated
1902072	Cohort B (Nivo concurrent)	17.3	Colitis	Resolved	Unrelated
1902121	Cohort B (Nivo concurrent)	1.6	Colitis	Resolved	Nivolumab: Probable; Paclitaxel: Unlikely; Carboplatin: Unrelated

ID	Treatment	Week from rand to onset	SAE name	Outcome	Relationship to treatment
1902032	Cohort B (Nivo concurrent)	1.0	Constipation	Resolved	Nivolumab: Unrelated; Paclitaxel: Unrelated; Carboplatin: Possible
1902121	Cohort B (Nivo concurrent)	8.9	Dehydration	Resolved	Nivolumab: Unlikely; Paclitaxel: Probable; Carboplatin: Probable
1902023	Cohort B (Nivo concurrent)	45.3	Esophagitis	Resolved	Nivolumab: Possible; Paclitaxel: Unrelated; Carboplatin: Unrelated
1902018	Cohort B (Nivo concurrent)	24.6	Febrile neutropenia	Resolved	Unrelated
1902032	Cohort B (Nivo concurrent)	12.1	Febrile neutropenia	Resolved	Nivolumab: Unrelated; Paclitaxel: Definite; Carboplatin: Definite
1902082	Cohort B (Nivo concurrent)	6.6	Febrile neutropenia	Resolved	Nivolumab: Unrelated; Paclitaxel: Definite; Carboplatin: Definite
1902017	Cohort B (Nivo concurrent)	3.4	Fever	Resolved	Nivolumab: Possible; Paclitaxel: Probable; Carboplatin: Unlikely
1902031	Cohort B (Nivo concurrent)	2.3	Fever	Resolved	Nivolumab: Possible; Paclitaxel: Probable; Carboplatin: Unrelated
1902054	Cohort B (Nivo concurrent)	5.9	Fever	Resolved	Nivolumab: Unlikely; Paclitaxel: Unlikely; Carboplatin: Unrelated
1902054	Cohort B (Nivo concurrent)	6.6	Fever	Resolved	Nivolumab: Unlikely; Paclitaxel: Unlikely; Carboplatin: Unrelated

ID	Treatment	Week from rand to onset	SAE name	Outcome	Relationship to treatment
1902072	Cohort B (Nivo concurrent)	2.7	Fever	Resolved	Nivolumab: Possible; Paclitaxel: Unlikely; Carboplatin: Unrelated
1902075	Cohort B (Nivo concurrent)	10.3	Fever	Resolved	Nivolumab: Unlikely; Paclitaxel: Unlikely; Carboplatin: Unlikely
1902082	Cohort B (Nivo concurrent)	3.6	Fever	Resolved	Unrelated
1902093	Cohort B (Nivo concurrent)	4.6	Fever	Resolved	Nivolumab: Possible; Paclitaxel: Unlikely; Carboplatin: Unlikely
1902119	Cohort B (Nivo concurrent)	33.9	Fever	Resolved	Unrelated
1902119	Cohort B (Nivo concurrent)	35.6	Fever	Resolved	Unrelated
1902122	Cohort B (Nivo concurrent)	23.3	Hematoma	Resolved	Unrelated
1902095	Cohort B (Nivo concurrent)	26.7	Hyperglycemia	Resolved with sequelae	Nivolumab: Probable; Paclitaxel: Unrelated; Carboplatin: Unrelated
1902127	Cohort B (Nivo concurrent)	15.4	Hyperthyroidism	Resolved	Nivolumab: Probable; Paclitaxel: Unrelated; Carboplatin: Unrelated
1902090	Cohort B (Nivo concurrent)	15.6	Hypomagnesemia	Resolved	Nivolumab: Unrelated; Paclitaxel: Probable; Carboplatin: Possible
1902007	Cohort B (Nivo concurrent)	52.1	Hyponatremia	Resolved	Nivolumab: Possible; Paclitaxel: Unrelated; Carboplatin: Unrelated

ID	Treatment	Week from rand to onset	SAE name	Outcome	Relationship to treatment
1902104	Cohort B (Nivo concurrent)	20.3	Hypophysitis	Resolved	Nivolumab: Probable; Paclitaxel: Unrelated; Carboplatin: Unrelated
1902104	Cohort B (Nivo concurrent)	23.0	Hypophysitis	Resolved	Nivolumab: Probable; Paclitaxel: Unrelated; Carboplatin: Unrelated
1902017	Cohort B (Nivo concurrent)	14.0	Hypothyroidism	Resolved	Nivolumab: Probable; Paclitaxel: Unrelated; Carboplatin: Unrelated
1902072	Cohort B (Nivo concurrent)	24.0	Immune system disorders - Other(Immune Mediated Interstitial Nephritis)	Resolved	Nivolumab: Definite; Paclitaxel: Unrelated; Carboplatin: Unrelated
1902072	Cohort B (Nivo concurrent)	10.4	Immune system disorders - Other(Immune related Interstitial nephritis)	Resolved	Nivolumab: Definite; Paclitaxel: Unrelated; Carboplatin: Unrelated
1902122	Cohort B (Nivo concurrent)	1.1	Infusion related reaction	Resolved	Nivolumab: Unrelated; Paclitaxel: Definite; Carboplatin: Unrelated
1902127	Cohort B (Nivo concurrent)	3.9	Infusion related reaction	Resolved	Nivolumab: Unrelated; Paclitaxel: Definite; Carboplatin: Unrelated
1902045	Cohort B (Nivo concurrent)	18.3	Lung infection	Resolved	Nivolumab: Possible; Paclitaxel: Unrelated; Carboplatin: Unrelated
1902045	Cohort B (Nivo concurrent)	26.6	Lung infection	Resolved	Nivolumab: Possible; Paclitaxel: Unrelated; Carboplatin: Unrelated

ID	Treatment	Week from rand to onset	SAE name	Outcome	Relationship to treatment
1902072	Cohort B (Nivo concurrent)	10.4	Lung infection	Resolved	Nivolumab: Possible; Paclitaxel: Unlikely; Carboplatin: Unrelated
1902075	Cohort B (Nivo concurrent)	3.6	Lung infection	Resolved	Unrelated
1902075	Cohort B (Nivo concurrent)	23.3	Lung infection	Resolved	Unrelated
1902122	Cohort B (Nivo concurrent)	29.0	Myasthenia gravis	Resolved	Nivolumab: Definite; Paclitaxel: Unrelated; Carboplatin: Unrelated
1902122	Cohort B (Nivo concurrent)	29.0	Myocarditis	Resolved	Nivolumab: Definite; Paclitaxel: Unrelated; Carboplatin: Unrelated
1902122	Cohort B (Nivo concurrent)	29.0	Myositis	Resolved	Nivolumab: Definite; Paclitaxel: Unrelated; Carboplatin: Unrelated
1902024	Cohort B (Nivo concurrent)	84.3	Pleural effusion	Resolved with sequelae	Unrelated
1902024	Cohort B (Nivo concurrent)	87.4	Pleural effusion	Resolved with sequelae	Unrelated
1902006	Cohort B (Nivo concurrent)	8.7	Rash maculo-papular	Resolved with sequelae	Nivolumab: Definite; Paclitaxel: Unrelated; Carboplatin: Possible
1902078	Cohort B (Nivo concurrent)	1.9	Rash maculo-papular	Resolved	Nivolumab: Probable; Paclitaxel: Possible; Carboplatin: Unlikely
1902127	Cohort B (Nivo concurrent)	2.9	Rash maculo-papular	Resolved	Nivolumab: Probable; Paclitaxel: Probable; Carboplatin: Unrelated

ID	Treatment	Week from rand to onset	SAE name	Outcome	Relationship to treatment
1902072	Cohort B (Nivo concurrent)	66.9	Renal calculi	Resolved	Unrelated
1902092	Cohort B (Nivo concurrent)	22.7	Skin infection	Resolved	Unrelated
1902052	Cohort B (Nivo concurrent)	3.0	Stroke	Resolved	Unrelated
1902019	Cohort B (Nivo concurrent)	14.3	Thromboembolic event	Resolved	Nivolumab: Unrelated; Paclitaxel: Possible; Carboplatin: Possible
1902122	Cohort B (Nivo concurrent)	6.0	Thromboembolic event	Resolved	Nivolumab: Unrelated; Paclitaxel: Probable; Carboplatin: Probable
1902122	Cohort B (Nivo concurrent)	17.1	Thromboembolic event	Resolved	Nivolumab: Unlikely; Paclitaxel: Possible; Carboplatin: Possible
1902075	Cohort B (Nivo concurrent)	6.1	Urinary tract infection	Resolved	Unrelated
1902073	Cohort B (Nivo concurrent)	14.1	Wound infection	Resolved	Unrelated
1902099	Cohort B (Nivo concurrent)	22.1	Wound infection	Resolved	Unrelated

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