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Table 4 Key ongoing studies of immunotherapy in early stage NSCLC

Trial (NCT identifier)	Phase	Stage	A/NA	Other key selection criteria*	Agent	Estimated enrollment	Primary endpoint
ANVIL (ALCHEMIST trial) (NCT02595944)	III	IB–IIIA	A	EGFR-, ALK-; PD-L1 tested	Nivolumab vs. observation	714	OS, DFS
PEARLS/ KEYNOTE-091 (NCT02504372)	III	IB–IIIA	A	PD-L1 tested	Pembrolizumab vs. placebo	1,080	DFS
NCT02273375	III	IB–IIIA	A	–	Durvalumab vs. placebo	1,360	DFS
IMpower010 (NCT02486718)	III	IB–IIIA	A	–	Atezolizumab vs. best supportive care	1,127	DFS
NCT03447769	III	II–IIIA, resected IIIB	A	–	Canakinumab vs. placebo	1,500	DFS
NCT03148327	I	I	A	Medically-inoperable (or surgery refused)	Phase 1: Durvalumab + SBRT; Phase 2: SBRT alone vs. durvalumab + SBRT	105	PFS
CheckMate 816 (NCT02998528)	III	IB–IIIA	NA	–	3 arms: (I) Nivolumab + ipilimumab; (II) Nivolumab + platinum doublet chemotherapy; (III) Platinum doublet chemotherapy alone	642	Event-free survival; pathological complete response
IMpower030 (NCT03456063)	III	II–IIIA, select IIIB	NA	–	Neoadjuvant atezolizumab (or placebo) + platinum-based chemotherapy ×4 cycles, then adjuvant atezolizumab (or placebo) ×16 cycles	302	Major pathologic response (% with ≤10% residual viable tumor at time of resection)
KEYNOTE-671 (NCT03425643)	III	IIB–IIIA	NA	–	Platinum doublet chemotherapy + pembrolizumab/placebo (×4 cycles neoadjuvant + 13 cycles adjuvant)	786	Event-free survival
TOP1501** (NCT02259621)	II	IB–IIA	NA	–	Pembrolizumab then surgery followed by adjuvant chemotherapy + pembrolizumab	32	Surgical feasibility rate
NEOSTAR (NCT03158129)	II	I–IIIA	NA	–	3 arms: (I) nivolumab; (II) nivolumab + ipilimumab; (III) nivolumab + platinum doublet chemotherapy	66	Major pathologic response (% w ≤10% residual viable tumor at time of resection)
NCT03081689**	II	IIIA	NA	–	Nivolumab + platinum doublet chemotherapy	46	Progression free survival
IONESCO** (NCT03030131)	II	IB–II	NA	No prior neoadjuvant chemotherapy or radiotherapy	Durvalumab ×3 cycles	81	Percentage of surgical resection R0
LCMC3** (NCT02927301)	II	IB–IIA, selected IIB resectable	NA	–	Atezolizumab ×2 cycles then adjuvant atezolizumab for 12 months	180	Major pathologic response
PRINCEPS (NCT02994576)	II	IB–IIIA	NA	–	Atezolizumab ×1	60	Rate of patients without major toxicities or morbidities from treatment to 1 month after surgery
NCT02716038**	II	IB–IIIA	NA	–	Atezolizumab + platinum doublet chemotherapy	60	DFS
NCT02904954	II	I–IIIA	NA	–	Arm 1: Durvalumab ×2 cycles; Arm 2: Durvalumab ×2 cycles + SBRT	–	–
NCT02572843**	II	IIIA	NA	–	Durvalumab ×3 cycles following cisplatin/docetaxel ×2 cycles, then adjuvant durvalumab ×1 yr (following radiotherapy in subset with incomplete resection)	–	Event-free survival at 12 months

*, for the adjuvant studies when not specifically indicated, routine adjuvant chemotherapy permitted prior to study entry; **, indicates single-arm study. NSCLC, non-small cell lung cancer; DFS, disease-free survival; EGFR, epidermal growth factor receptor; ALK, anaplastic lymphoma kinase; PD-L1, programmed death-ligand 1; OS, overall survival; PFS, progression-free survival; SBRT, stereotactic body radiation therapy.



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