CLINICAL PRACTICE

LBA1 Neoadjuvant induction with pembrolizumab (Pembro) plus lenvatinib (Len) in resectable early-stage NSCLC impacts the tumor microenvironment (TME): Clinical results including multi-omic deconvolution of the TME from the INNWOP01 study

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Background: Major pathologic responses (MPR) upon neoadjuvant therapy are linked to improved outcome in resectable NSCLC patients. Combined anti-PD-1 and anti-angiogenic therapy may enhance anti-tumor immunity via TME remodeling. We evaluated the efficacy of two neoadjuvant cycles of Pembro plus Len on MPR and correlated therapeutic response with TME alterations assessed by multimodal single-cell and spatial profiling.

Methods: Single-center, phase II study in adults with resectable, early-stage NSCLC (UICC 8th IA2—IIIA). Patients received Pembro plus Len for two induction cycles followed by surgery and adjuvant Pembro. Primary objectives were MPR, feasibility (resection rate, timing), safety and translational multi-omics profiling, including single-cell RNA sequencing, spatial transcriptomics, and multiparametric flow cytometry.

Results: By October 2025, 33 patients were enrolled (median age 66; stages IA2—IIIA). Per-protocol pathology showed MPR in 10/30 (33.3%) and partial pathologic response (≤50% viable) in 14/30 of patients (46.7%). Computed tomography revealed partial response in 20.7% and stable disease in 79.3% pre-surgery. Metabolic response was detected in 51.7% by FDG-PET. Treatment-related adverse events were mostly grade 1—2; all surgeries could be performed by minimal invasive procedures (1 conversion needed). Multi-omics revealed distinct TME remodeling in patients with MPR compared to non-MPR cases, characterized by an expansion of cytotoxic/exhausted T- and B-cells. In non-MPR patients, tumor-associated neutrophils were enriched and adopted a pro-angiogenic, therapy-resistant phenotype.

Conclusions: We report that two cycles of neoadjuvant Pembro plus Len induced MPR in 33.3% of patients, was well tolerated, and enabled timely surgical tumor resection without any safety signals. Multi-omics TME profiling revealed distinct MPR-associated patterns of immune rewiring and suggest novel resistance mechanisms to PD-1/VEGFR inhibition.

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LBA2 The DANTE phase III trial comparing 1 year versus 2 years of anti-PD1 immunotherapy as first-line treatment for metastatic melanoma: Health economics analysis

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Background: First line therapy for patients with metastatic melanoma is an immunotherapy regimen with an anti-PD1 antibody, regardless of tumour BRAF mutation status. Optimal duration of therapy has not been established. We evaluated the long-term cost-utility of reduced treatment duration vs standard of care using data from the UK DANTE clinical trial (ISRCTN15837212).

Methods: In DANTE, 166 adults with unresectable stage III/IV melanoma receiving first line anti-PD1 +/- anti-CTLA-4 therapy who were progression-free after 1 year of treatment were randomised (1:1) to stop treatment, with the option of restarting on progression (Stop), or continue treatment to at least 2 years in the absence of disease progression / toxicity (Control). A partitioned survival model (PSM) was generated to compare the annually discounted (at 3.5%) costs and benefits of Control vs Stop from a UK NHS perspective over a lifetime horizon. Trial-based health state utilities (EQ-5D) plus healthcare resource use with UK-specific unit costs, were used in the model. Incremental cost-effectiveness ratios (ICERs) were calculated and compared against a quality adjusted life year (QALY) threshold value of £20,000. Sensitivity analyses explored uncertainty.

Results: Patients in the Stop arm had 2.13 fewer QALYs but £61,755 less costs versus the Control arm, resulting in an overall ICER of £28,991/QALY. In sensitivity analyses : a) assuming no survival benefit with Control (ΔQALY: -0.29, ΔCost: - £44,674, ICER: £154,531/QALY); b) 50% immunotherapy price reduction (ΔQALY:-2.13, ΔCost:-£33,507, ICER: £15,730/QALY); c) 50% price reduction on immunotherapy and no survival benefit for Control (ΔQALY:-0.29, ΔCost:- £16,427, ICER: £56,821/QALY) — patients in the Stop arm had fewer QALYs and less costs.

Conclusions: Base case results suggest that stopping therapy may be optimal. However, QALYs losses may not be acceptable clinically, while uncertainty surrounds the point estimates. Additional analyses using follow-up from real world data will help improve certainty in model extrapolations.

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Interests, Institutional, Research Grant, trial funding to previous employer (HARE40 trial): Biontech; Financial Interests, Institutional, Coordinating PI, research conducted in my clinical center: Scan ell; Financial Interests, Institutional, Local PI, conduct of clinical trial: Grey Wolf; Financial Interests, Institutional, Coordinating PI, conduct of clinical trial: Corbus. M. Payne: Financial Interests, Personal, Advisory Board, clinical advisor for advisory board: BMS; Financial Interests, Personal, Invited Speaker, Invited speaker: BMS; Financial Interests, Personal, Invited Speaker, Speaker at educational event: Loreal; Financial Interests, Personal, Advisory Board, Advisory board: Sun Pharma; Financial Interests, Personal, Full or part-time Employment, Clinical Reference Group advisor: Genesis; Financial Interests, Personal, Royalties, Royalties from the OUP Oncology Handbook: Oxford University Press; Non-Financial Interests, Personal, Other, Received funding towards conference fess and travel for ESMO 2022: Pierre Fabre; Non-Financial Interests, Personal, Other, Received financial support for conference attendance 2023: Pierre Fabre; Non-Financial Interests, Personal, Other, Received financial support for conference attendance 2024: Pierre Fabre; Non-Financial Interests, Personal, Advisory Role, Chair of Medical Advisory Group of charity (vountary): Melanoma Focus. A. Waterston: Financial Interests, Personal, Invited Speaker, chair educational event: BMS; Financial Interests, Personal, Invited Speaker, Chair educational event: MSD; Financial Interests, Institutional, Local PI, local PI on research trial: BMS; Financial Interests, Institutional, Local PI, local PI on adjuvant trial: MSD; Financial Interests, Institutional, Other, co investigator on trials: Immunocore; Non-Financial Interests, Personal, Principal Investigator: BMS, MSD; Non-Financial Interests, Personal, Member, UK organisation for medical oncologists: Association of Cancer Physicians. P.G. Corrie: Financial Interests, Personal, Advisory Board: Merck Sharpe & Dohme, Scancell, Astellas, SUN Pharma, Viatris, Iovance Biotherapeutics; Financial Interests, Personal, Invited Speaker: Pierre Fabre, Merck Sharpe & Dohme, Novartis; Financial Interests, Personal, Other, Consultancy: Microbiotica; Financial Interests, Institutional, Local PI: Bristol Myers Squibb, Novartis, AstraZeneca, Merck Sharpe and Dohme, Pfizer, Immunocore, Scancell; Financial Interests, Institutional, Research Grant: Pierre Fabre; Financial Interests, Institutional, Coordinating PI, Free drug supply for academic multi centre trial: Merck Sharpe & Dohme; Financial Interests, Institutional, Coordinating PI: Microbiotica. S. Danson: Financial Interests, Personal, Other, Consultancy: Greywolf Therapeutics, Orion; Financial Interests, Personal, Advisory Board, MTH1 development advisory board: Oxcia; Financial Interests, Personal, Full or part-time Employment, Co-Clinical Lead for the UK Vaccine Innovation Pathway: NIHR; Financial Interests, Institutional, Coordinating PI, Dante lead: NIHR; Financial Interests, Institutional, Coordinating PI, Fortitude co-ordinating PI for the UK: Amgen; Financial Interests, Institutional, Research Grant, Ecmc lead: Cancer Research UK; Financial Interests, Institutional, Local PI, Local PI for the MSD-Anti-PD1 study: MSD; Financial Interests, Institutional, Local PI, Local PI for the TEADES study: Orion; Non-Financial Interests, Personal, Leadership Role, Lion steering group chair: NIHR; Non-Financial Interests, Personal, Proprietary Information, Have received prescribing information for immunotherapy to inform a project proposal: BMS. All other authors have declared no conflicts of interest.

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123MO Survival outcomes in POD1UM-303/InterAACT-2: A phase III study of retifanlimab (R) + carboplatin-paclitaxel (CP) in first-line (1L) advanced squamous anal cancer (SCAC)

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Background: Primary results from POD1UM-303 have been published (Rao S, Lancet. 2025; 405(10495): 2144-2152). The study met the primary endpoint of progression-free survival (PFS) (hazard ratio [HR] 0.63 [95% CI 0.47, 0.84]; p=0.0006), with a safety profile consistent with PD-(L)1 + chemotherapy regimens. Mature survival data are now available.

Methods: 308 patients (pts) were randomized (1:1) across Europe, Australia, Japan, and the US to blinded R or placebo (P) for up to one year, with 6 cycles of CP. Crossover to R monotherapy was permitted for pts assigned to the P arm after independent blinded verification of progressive disease. The primary endpoint was PFS; overall survival (OS), objective response rate (ORR), and duration of response (DOR) were secondary endpoints. OS (key secondary endpoint) was analyzed once ≥165 events had occurred.

Results: After planned follow-up (data cutoff, 01 Aug 2025), 172 OS events were recorded, 94 in the P arm (n=154) and 78 in the R arm (n=154). Half (n=77) of the pts in the P + CP arm crossed over to R monotherapy. Median OS was 32.8 mo for R + CP vs 22.2 mo with P + CP (HR 0.75 [95% CI 0.55,1.01]; p=0.03). When adjusted for crossover, results strongly favored the addition of R to CP (HR 0.63 [95% CI 0.47, 0.86]; p=0.002). All predefined subgroups benefited from R, aside from possibly tumor PD-L1 <1%, locally recurrent disease, and HIV+ pts, though CIs for all these comparisons were wide (Table). Per previously reported results, PFS (HR 0.62 [95% CI 0.47, 0.81]; P=0.0002), ORR (56.6% vs 44.8%), and median DOR (14.7 vs 7.2 mo) all favored R + CP. Safety was consistent with previous reports of this study and other PD-(L)1 studies.

Conclusions: Retifanlimab provided meaningful clinical benefit when added to 1L chemotherapy for advanced SCAC and is a new therapeutic option for this rare and difficult to treat disease.

Table: 123MO Overall survival subgroup analysis

Subgroup	R (n=154)	P (n=154)	R vs P HR (95% CI)
Age group, years			
<65	96	100	0.86 (0.58, 1.27)
≥65	58	54	0.58 (0.35, 0.96)
Gender			
Male	50	36	0.79 (0.45, 1.37)
Female	104	118	0.73 (0.50, 1.05)
PD-L1 Expression			
<1%*	14	14	1.49 (0.60, 3.71)
≥1%	140	140	0.69 (0.50, 0.95)
Liver metastases			
Yes	56	56	0.60 (0.37, 0.99)
No	98	98	0.86 (0.59, 1.27)
HPV status			
Positive	29	28	0.74 (0.35, 1.56)
Negative*	125	126	0.76 (0.55, 1.07)
ECOG PS			
0*	83	86	0.62 (0.39, 0.99)
≥1	71	68	0.79 (0.53, 1.19)
HIV status			
Positive	6	5	1.66 (0.27, 10.02)
Negative*	148	149	0.74 (0.54, 1.00)
Extent disease			
Locally recurrent	23	24	1.23 (0.62, 2.45)
Metastatic*	131	130	0.68 (0.49, 0.96)

*Includes unknown and/or missing

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