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2022 World Conference
on Lung Cancer

AUGUST 6-9, 2022 | VIENNA, AUSTRIA



Non PD1/L1 Immunotherapy Targets and Agents in Advanced NSCLC

Joel Neal, MD, PhD

Associate Professor of Medicine/Oncology
Stanford University, United States of America



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Consulting or Advisory Role: AstraZeneca, Genentech/Roche, Exelixis, Jounce Therapeutics, Takeda Pharmaceuticals, Eli Lilly and Company, Calithera Biosciences, Amgen, Iovance Biotherapeutics, Blueprint Pharmaceuticals, Regeneron Pharmaceuticals, Natera, Sanofi/Regeneron, D2G Oncology, Surface Oncology, Turning Point Therapeutics and Mirati Therapeutics

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Clinical trials with combination immunotherapy



TROPION-Lung02: Initial Results for Datopotamab Deruxtecan Plus Pembrolizumab and Platinum Chemotherapy in Advanced NSCLC



Benjamin Levy,¹ Luis Paz-Ares,² Olivier Rixe,^{3,4} Wu-Chou Su,⁵ Tsung-Ying Yang,⁶ Anthony Tolcher,⁷ Yanyan Lou,⁸ Yoshitaka Zenke,⁹ Panayiotis Savvides,¹⁰ Enriqueta Felip,¹¹ Manuel Domine,¹² Konstantinos Leventakos,¹³ Mariano Provencio Pulla,¹⁴ Marianna Koczywas,¹⁵ Atsushi Horike,¹⁶ Siddhartha Rawat,⁴ Xiangfeng Wu,⁴ Priyanka Basak,⁴ Michael Chisamore,¹⁷ Yasushi Goto¹⁸

Key eligibility

- Advanced/metastatic NSCLC
- Dose confirmation^b: ≤2 lines of prior therapy^c
- Dose expansion
 - ≤1 line of platinum-based CT (cohorts 1 and 2)^c
 - No prior therapy (cohorts 3-6)^c

	Dato-DXd IV Q3W	+	pembro IV Q3W	+	platinum CT IV Q3W	
Cohort 1 (n=20) ^d :	4 mg/kg	+	200 mg	+		} “Doublet”
Cohort 2 (n=20) ^d :	6 mg/kg	+	200 mg	+		
Cohort 3 (n=17) ^d :	4 mg/kg	+	200 mg	+	carboplatin AUC 5	} “Triplet”
Cohort 4 (n=20) ^d :	6 mg/kg	+	200 mg	+	carboplatin AUC 5	
Cohort 5 (n=7) ^d :	4 mg/kg	+	200 mg	+	cisplatin 75 mg/m ²	
Cohort 6 (n=4) ^d :	6 mg/kg	+	200 mg	+	cisplatin 75 mg/m ²	

TROPION-Lung02: Initial Results for Datopotamab Deruxtecán Plus Pembrolizumab and Platinum Chemotherapy in Advanced NSCLC



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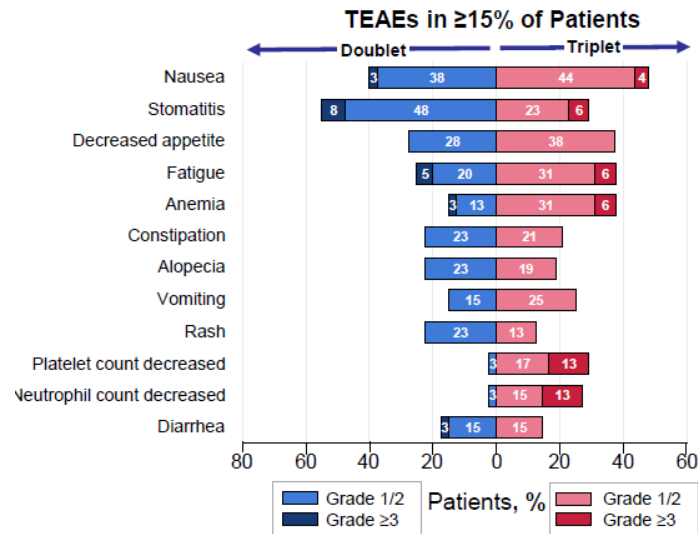
In the overall population:

ORRs (confirmed + pending) of 37% and 41% were seen with doublet (n=38) and triplet (n=37) therapy, respectively; both groups had 84% DCR

BOR With 1L Therapy For Advanced NSCLC^{a,b}

Response, n (%)	Doublet (n=13)	Triplet (n=20)
ORR confirmed + pending	8 (62%)	10 (50%)
CR	0	0
PR confirmed	8 (62%)	7 (35%)
PR pending	0	3 (15%)
SD	5 (39%)	8 (40%)
DCR	13 (100%)	18 (90%)

- As 1L therapy, the doublet and triplet yielded ORRs (confirmed + pending) of 62% and 50%, respectively
- As 2L+ therapy, respective ORRs (confirmed + pending) were 24% and 29%



- The phase 3 TROPION-Lung08 trial (NCT05215340) is evaluating Dato-DXd + pembro vs pembro alone as 1L therapy in advanced/metastatic NSCLC with PD-L1 TPS >50%¹

HUDSON: AN OPEN-LABEL, MULTI-DRUG, BIOMARKER-DIRECTED PHASE 2 STUDY IN NSCLC PATIENTS WHO PROGRESSED ON ANTI-PD-(L)1 THERAPY

Benjamin Besse¹, Mark M. Awad², Patrick M. Forde³, Michael Thomas⁴, Glenwood Goss⁵, Boaz Aronson⁶, Rosalind Hobson⁷, Emma Dean⁷, Jane Peters⁷, Sonia Iyer⁸, James Conway⁶, J. Carl Barrett⁸, Jan Cosaert⁷, Marlene Dressman⁶, Simon T. Barry⁷, John V. Heymach⁹



Combination agent	Mechanism of action	Mechanism of anti-PD-(L)1 resistance targeted	HUDSON biomarkers
Ceralasertib (AZD6738)	ATR inhibitor	Improving tumor immunogenicity and tumor immune microenvironment via DDR pathway inhibition, to sensitize cancer cells to anti-PD-L1/PD-1 therapy ¹	ATM alteration
Olaparib	PARP inhibitor	Alterations to DDR pathways affect anti-PD-(L)1 sensitivity; ² PARP inhibition promotes DDR pathway defects ³	HRRm <i>STK11/LKB1m</i>
Danvatirsen	STAT3 inhibitor	Interferon- γ signalling defects arising from JAK-STAT pathway mutations associated with acquired resistance ⁴	Not applicable
Oleclumab	Anti-CD73 monoclonal antibody	Immunosuppressive tumor immune microenvironment due to production of adenosine, mediated by CD73 ⁵	High CD73 expression

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HUDSON: Phase II multi-arm umbrella study

- Locally advanced or metastatic NSCLC
- Previous platinum-based chemotherapy
- Failure of prior anti-PD-(L)1 immunotherapy
- Suitable for new tumor biopsy / biopsy post-progression on anti-PD-(L)1 therapy
- No targetable alterations in *EGFR*, *ALK*, *ROS1*, *BRAF*, *MET*, or *RET*

Primary endpoint: ORR
Secondary endpoints: DCR, PFS, OS, safety and tolerability

Central molecular screen,[‡] *n* = 255 (Jan 26, 2018–Apr 14, 2021)

Group A: biomarker-matched, *n* = 86

HRRm	Durvalumab + olaparib (PARPi), <i>n</i> = 21
LKB1	Durvalumab + olaparib (PARPi), <i>n</i> = 21
ATM	Durvalumab + ceralasertib (ATRI), <i>n</i> = 21*
ATM	Single-agent ceralasertib (ATRI)*
CD73h	Durvalumab + oleclumab (CD73 mAb), <i>n</i> = 23
HER2e	Durvalumab plus trastuzumab deruxtecan (HER2i) [†]
HER2m	

Group B: biomarker-non-matched, *n* = 169

Primary resistance (disease progression \leq 24 weeks) [§]	Acquired resistance (disease progression >24 weeks) [#]
Durvalumab + olaparib (PARPi), <i>n</i> = 22	Durvalumab + olaparib (PARPi), <i>n</i> = 23
Durvalumab + danvatirsen (STAT3i), <i>n</i> = 23	Durvalumab + danvatirsen (STAT3i), <i>n</i> = 22
Durvalumab + ceralasertib (ATRI), <i>n</i> = 20	Durvalumab + ceralasertib (ATRI), <i>n</i> = 25
Durvalumab + oleclumab (CD73 mAb), <i>n</i> = 9	Durvalumab + oleclumab (CD73 mAb), <i>n</i> = 25
	Durvalumab + cediranib (VEGFi) [†]

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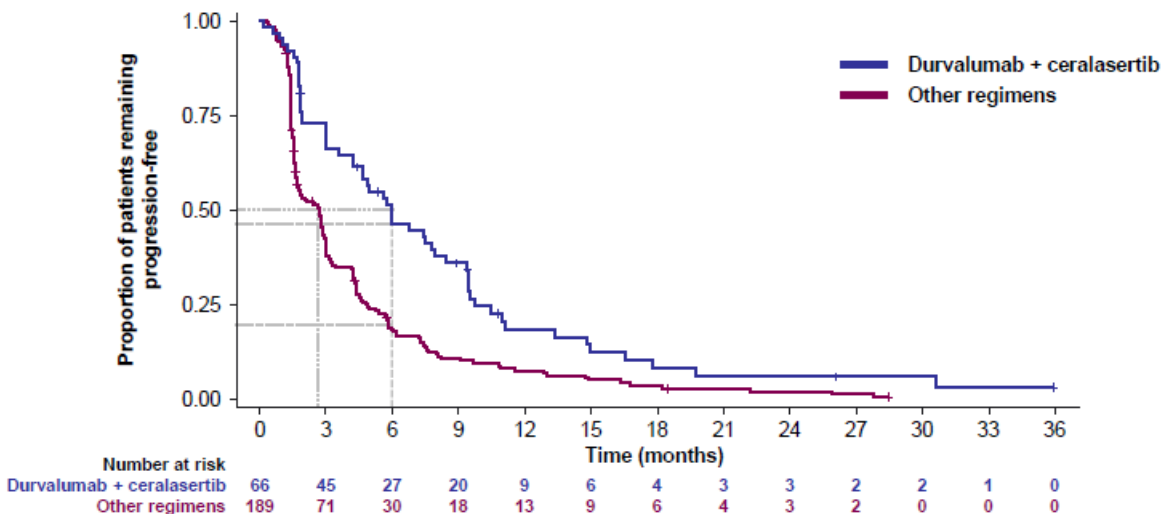
	Durvalumab + ceralasertib n=66	Durvalumab + olaparib n=87	Durvalumab + danvatirsen n=45	Durvalumab + oleclumab n=57
Median treatment duration, months				
Durvalumab*	7.3	3.7	2.8	2.9
Other agent†	6.3	3.2	2.8	2.9
12-week disease control rate, %	60.6	36.8	26.7	29.8
24-week disease control rate, %	42.4	17.2	13.3	15.8
ORR, %	16.7%	4.6%	0%	1.8%

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PFS



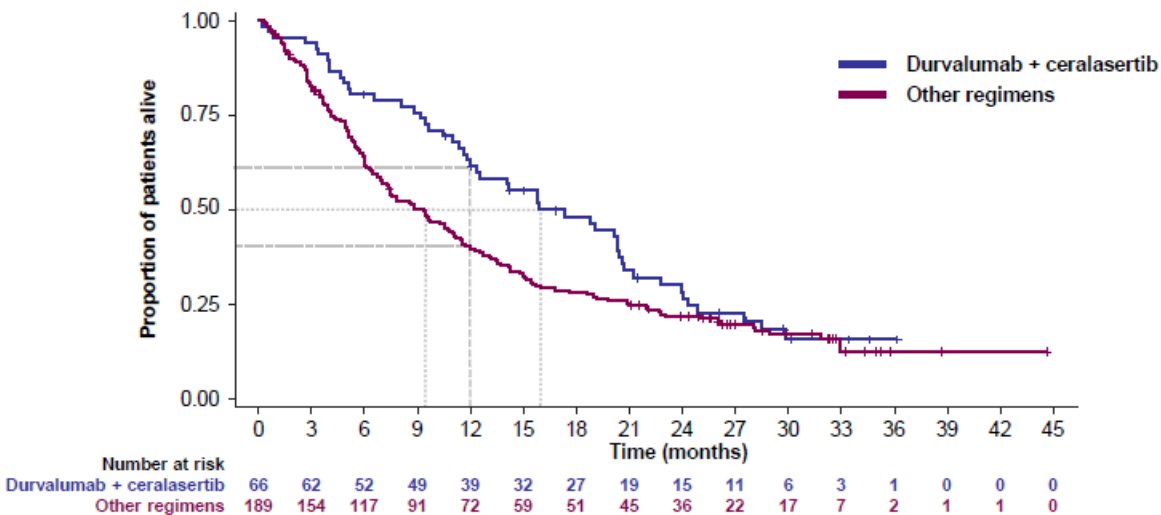
	Durvalumab + ceralasertib. n=66	Other regimens n=189
Median PFS, months (80% CI)	6.0 (4.6–7.5)	2.7 (1.8–2.8)
6-month PFS, % (80% CI)	46.3 (37.9–54.2)	18.0 (14.5–21.9)

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OS



	Durvalumab + ceralasertib. n=66	Other regimens n=189
Median OS, months (80% CI)	15.9 (14.1–20.3)*	9.4 (7.5–10.6)
12-month OS, % (80% CI)	61.6 (53.4–68.8)	39.7 (35.1–44.3)

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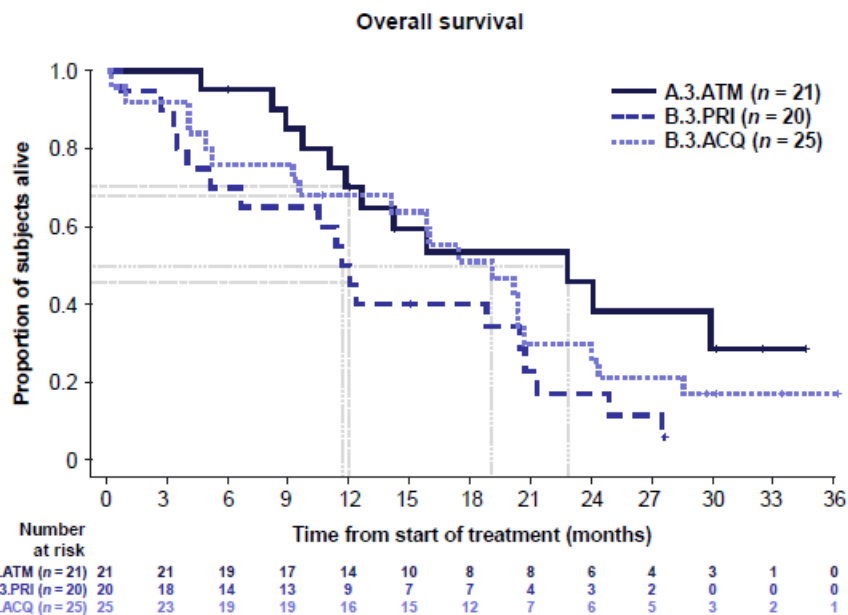


Durvalumab + ceralasertib efficacy – by cohort

	Biomarker-matched (A.3.ATM) n=21	Primary resistance (B.3.PRI) n=20	Acquired resistance (B.3.ACQ) n=25
ORR, %	28.6	15.0	8.0
PR	28.6	15.0	8.0
SD ≥40 days, %	47.6	45.0	64.0
Unconfirmed PR	9.5	0	0
Progression, %	19.0	35.0	24.0
RECIST disease progression	19.0	30.0	16.0
Died	0	5.0	8.0
12-week disease control rate, %	71.4	55.0	56.0
24-week disease control rate, %	57.1	40.0	32.0
Median PFS, months (80% CI)	8.4 (6.0–9.7)	4.9 (1.9–6.8)	4.6 (3.6–6.0)
6-month PFS, %	64.3	41.5	35.2
Median OS, months (80% CI)	22.8* (12.6–29.9)	11.8 (6.6–18.8)	19.1 (14.1–20.3)
12-month OS, %	70.2	45.0	68.0

*Data are still accruing; this median value for OS may change.

ACQ, acquired resistance cohort; ATM, ataxia telangiectasia mutated biomarker-matched cohort; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PR, partial response; PRI, primary resistance cohort; RECIST, Response Evaluation Criteria In Solid Tumours; SD, stable disease



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Safety by regimen

AE category, n (%)	Durvalumab + ceralasertib n=66	Durvalumab + olaparib n=87	Durvalumab + danvatirsen n=45	Durvalumab + oleclumab n=57
Median treatment duration, months				
Durvalumab	7.3	3.7	2.8	2.9
Other agent	6.3	3.2	2.8	2.9
Any TEAE	64 (97.0)	80 (92.0)	43 (95.6)	48 (84.2)
Related to any treatment	52 (78.8)	67 (77.0)	33 (73.3)	34 (59.6)
Any grade ≥3 TEAE	33 (50.0)	47 (54.0)	28 (62.2)	23 (40.4)
Related to any treatment	15 (22.7)	30 (34.5)	17 (37.8)	9 (15.8)
Any TEAE with an outcome of death	2 (3.0)	1 (1.1)	3 (6.7)	1 (1.8)
Any SAE	28 (42.4)	33 (37.9)	20 (44.4)	16 (28.1)
Related to any treatment	8 (12.1)	9 (10.3)	3 (6.7)	4 (7.0)
Any TEAE leading to discontinuation	8 (12.1)	9 (10.3)	10 (22.2)	7 (12.3)
Related to any treatment	5 (7.6)	8 (9.2)	7 (15.6)	3 (5.3)
Most common TRAEs (≥15%*)				
Nausea	34 (51.5)	37 (42.5)	1 (2.2)	4 (7.0)
Vomiting	19 (28.8)	18 (20.7)	2 (4.4)	1 (1.8)
Decreased appetite	15 (22.7)	8 (9.2)	2 (4.4)	4 (7.0)
Anemia	14 (21.2)	22 (25.3)	4 (8.9)	2 (3.5)
Fatigue	11 (16.7)	18 (20.7)	6 (13.3)	8 (14.0)
Diarrhea	10 (15.2)	11 (12.6)	5 (11.1)	7 (12.3)

*In the durvalumab + ceralasertib group. AE, adverse event; SAE, serious adverse event; TEAE, treatment-emergent adverse event; TRAE, treatment-related adverse event.

Nintedanib in combination with nivolumab in pretreated patients with advanced adenocarcinoma of the lung (AIO-TRK-0117/NintNivo - A Phase Ib/II trial)

M. Reck¹, P. Sadjadian², C. Waller³, K. Kambartel⁴, C. Grohe⁵, A. Rittmeyer⁶, A. Sendler⁷, N. Reinmuth⁴, R. Keller⁸, H. von Suchodoletz⁹, M. Maenz⁹, M. Sebastian¹⁰

nintedanib 200 mg bid + nivolumab 240 mg
ORR of 11.3%.

Median progression-free survival was 2.5 months (95% CI: 2.07-3.97 months).

Figure 1: Kaplan-Meier estimate of PFS in Safety Set

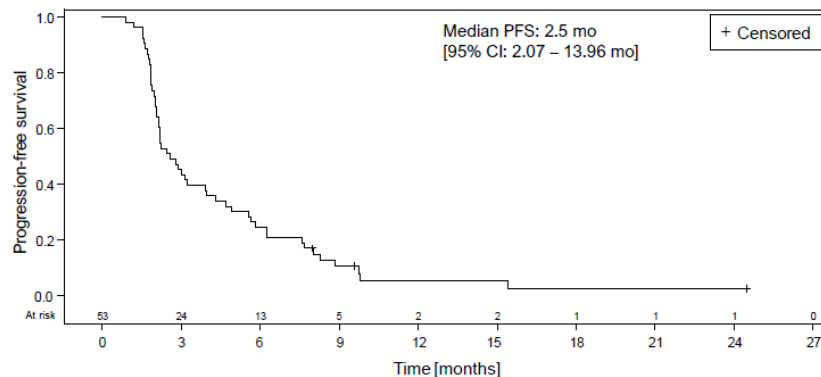


Table 4: Select AEs by number of patients affected, including all AEs reported in >10% of patients; N = 53

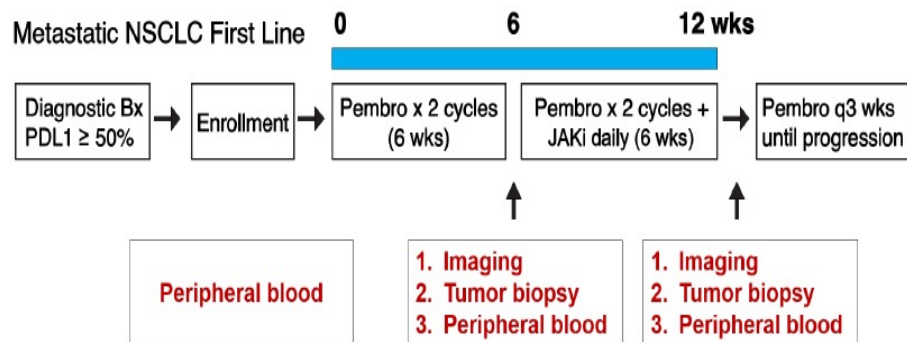
CTCAE Term	All grades n (%)	≥ grade 3 n (%)
Diarrhoea	26 (52.8)	0
Nausea	23 (43.4)	2 (3.8)
Fatigue	13 (24.5)	1 (1.9)
Weight decreased	11 (20.8)	0
GGT increased	10 (18.9)	7 (13.2)
Dyspnoea	9 (17.0)	3 (5.7)
Headache	7 (13.2)	0
Vomiting	6 (11.3)	0
ALT increased	6 (11.3)	2 (3.8)
Drug-induced liver injury	2 (3.8)	2 (3.8)
Hepatotoxicity	2 (3.8)	1 (1.9)
Pneumonitis	4 (7.5)	2 (3.8)

Phase II Study of Pembrolizumab and Itacitinib for First-Line Treatment of Metastatic NSCLC Expressing PD-L1 $\geq 50\%$

Melina E. Marmarelis, Divij Mathew, Joshua Bauml, Wei-Ting Hwang, Jane Zhang, Aditi Singh, Chris D'Avella, Christiana Davis, Darwin Ye, Lova Sun, Christine Ciunci, Nancy Zhang, Charu Aggarwal, Roger B. Cohen, Andy Minn, John Wherry, Corey J. Langer (#754)

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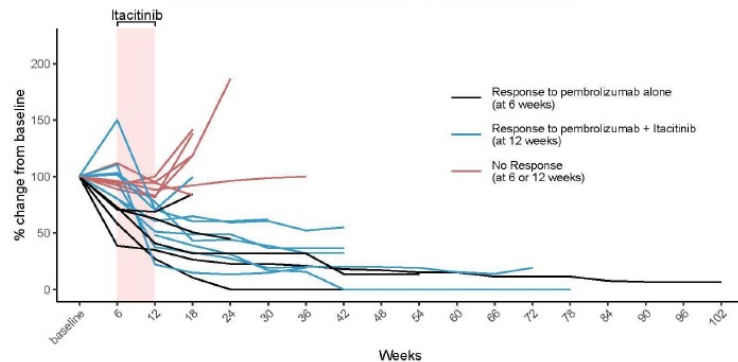
itacitinib (INCB039110; JAK1 inhibitor)



12 week ORR was 62% (13 partial response, 7 stable disease, 1 progressive disease)

Median PFS 23.4 months
OS rate at 12 months: 83%

Spider Plot of Response Status in Patients Treated with Pembrolizumab + Itacitinib



Phase 1: IMU-201 (PD1-Vaxx), a B-Cell Immunotherapy as Monotherapy or in Combination with Atezolizumab, in Adults with Non-Small Cell Lung Cancer

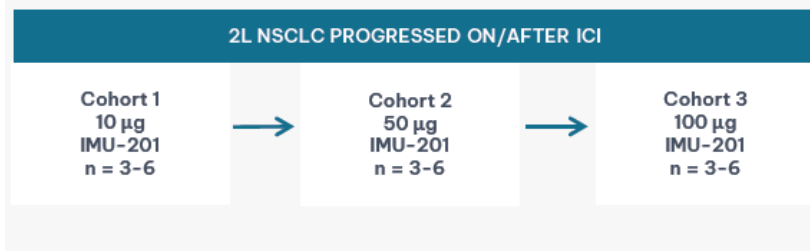
G.E. Richardson¹, J.J. Park², M. Gutierrez³, D.P. Carbone⁴, P. Savvides⁵, P. Kaumaya⁶, T.S. Bekaii-Saab⁷, T.G. Phan⁷, L.M.O. Chong⁸, N. Ede⁹, B. Nixon⁹, N.P. Withana⁹, A.J. Good⁹, M.J. Boyer⁹

¹Gabrin Hospital Malvern, Malvern/AU, ²Macquarie University, North Ryde/AU, ³Hackensack University Medical Center, Hackensack/NJ/USA, ⁴The James Comprehensive Cancer Center, Columbus/OH/USA, ⁵Mayo Clinic Arizona, Phoenix/AZ/USA,

⁶The Ohio State Wexner Medical Centre, Columbus/OH/USA, ⁷Govan Institute of Medical Research, Darlington/AU, ⁸Imugene Limited, Sydney/AU, ⁹Chris O'Brien Lifecare Hospital, Camperdown/AU

Correspondence: Prof. Michael Boyer <Michael.Boyer@lh.org.au>

Induces the production of anti-PD-1 antibodies using a peptide epitope designed to stimulate **polyclonal** antibodies against PD-1

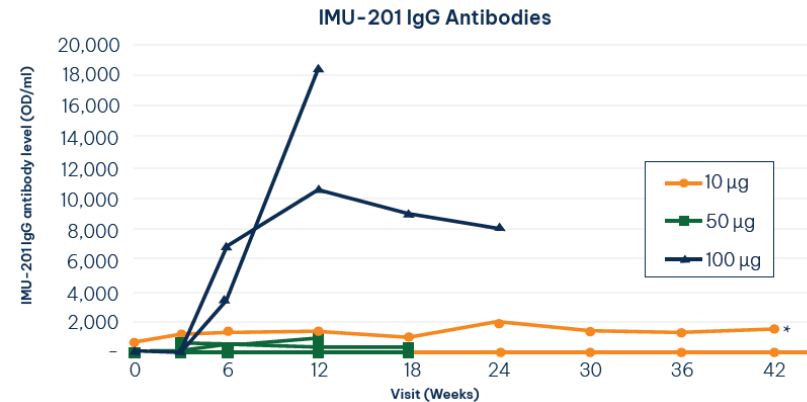


mOBD = monotherapy optimal biological dose

cOBD = combination optimal biological dose

Later: atezo combinations

Figure 2: IMU-201 Antibody Development in Phase 1



Tumor Response Results

- Four patients were in the 10 µg/dose cohort, 6 patients in 50 µg/dose cohort, and 4 patients in the 100 µg/dose cohort
- In the 10 µg/dose cohort, one patient achieved a CR
- In the 50 µg/dose cohort, two patients achieved SD
- In the 100 µg/dose cohort, one patient achieved PR and two patients achieved SD
- Three patients remain on study

Durvalumab + olaparib versus durvalumab alone as maintenance therapy in metastatic NSCLC: outcomes from the phase 2 ORION study

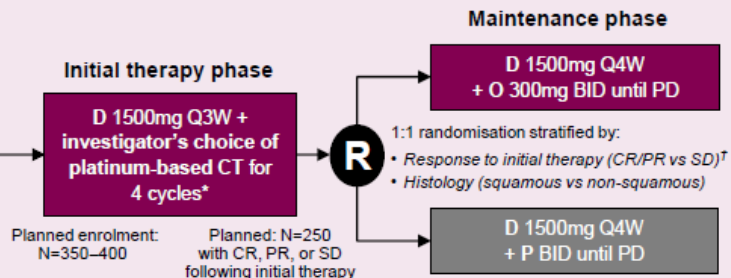
Myung-Ju Ahn,¹ Igor Bondarenko,² Ewa Kalinka,³ Byoung Chul Cho,⁴ Shunichi Sugawara,⁵ Gabriella Galfy,⁶ Byoung Yong Shim,⁷ Nikolay Kislov,⁸ Rajnish Nagarkar,⁹ Ingel Demedts,¹⁰ Steven J. M. Gans,¹¹ Dolores Mendoza Oliva,¹² Ross Stewart,¹³ Zhongwu Lai,¹⁴ Lucy Mcparland,¹³ Xiaojin Shi,¹⁵ Maen Hussein¹⁶



Figure 1: Study design

Key eligibility criteria:

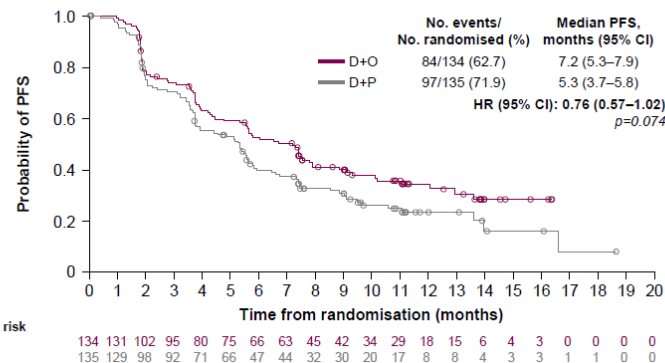
- Aged ≥18 years
- Documented mNSCLC not amenable to curative surgery or radiation
- 1L (no prior treatment for metastatic disease)
- ECOG PS 0/1
- EGFR/ALK wildtype
- RECIST v1.1 evaluable



*Permitted CT regimens were nab-paclitaxel+carboplatin or gemcitabine+carboplatin/cisplatin for squamous NSCLC and nab-paclitaxel+carboplatin or pemetrexed for non-squamous NSCLC; pemetrexed maintenance was not allowed. †Obtained at the last visit prior to randomisation (Cycle 4 scan) during the initial therapy phase

Figure 2: Investigator-assessed PFS (maintenance phase)

A) ITT population



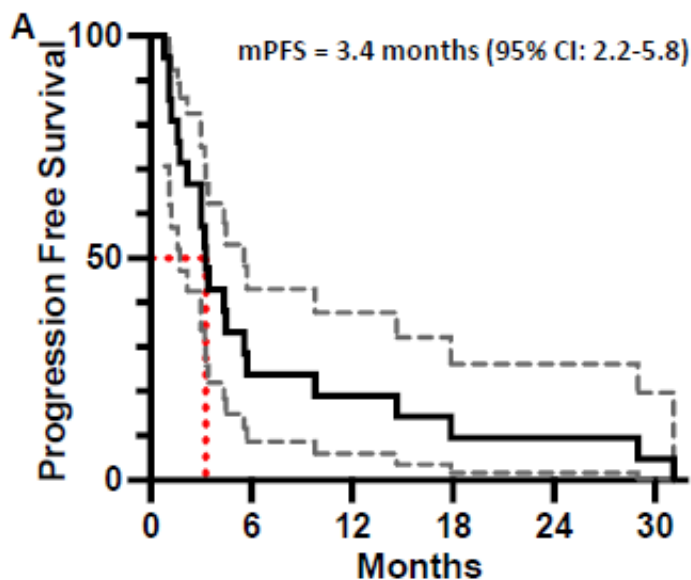
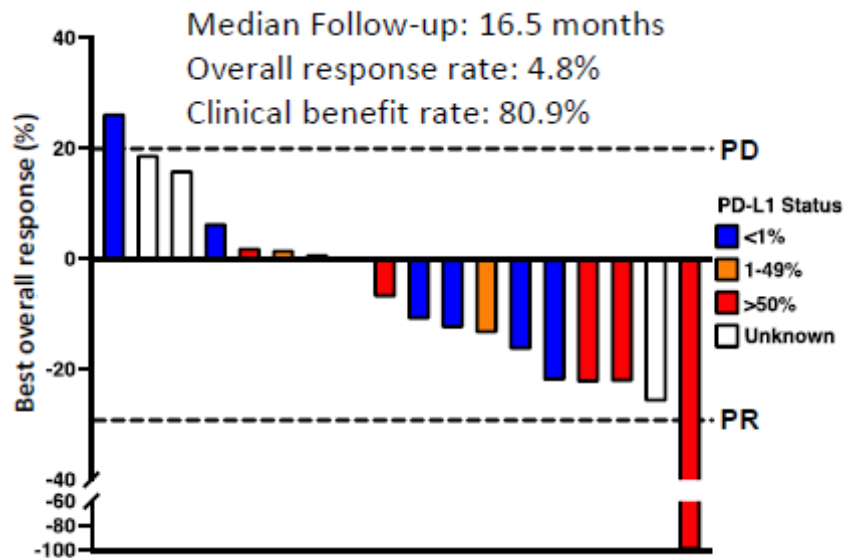
Maintenance D+O did not significantly improve PFS versus D alone (HR: 0.76; 95% CI: 0.57–1.02; $p=0.074$).

A phase II study of Ramucirumab, an anti-VEGFR-2 antibody, and Atezolizumab, an anti-PD-L1 antibody, after progression on any immune checkpoint blocker in NSCLC (RamAtezo-1)

Brett H. Herzog, Saiama N. Waqar, Siddhartha Devarakonda, Jeffrey P. Ward, Ramaswamy Govindan, Daniel Morgensztern

Treatment

- Ramucirumab 10 mg/kg IV every 21 days
- Atezolizumab 1,200 mg IV every 21 days



Overall response rate was 4.8% and did not meet the primary endpoint

Durvalumab ± tremelimumab + chemotherapy in first-line metastatic NSCLC: outcomes by tumour PD-L1 expression in POSEIDON

Edward B. Garon,¹ Byoung Chul Cho,² Alexander Luft,³ Jorge Alatorre-Alexander,⁴ Sarayut Lucien Geater,⁵ Sang-We Kim,⁶ Grygorii Ursol,⁷ Maen Hussein,⁸ Farah Louise Lim,⁹ Cheng-Ta Yang,¹⁰ Luiz Henrique Araujo,¹¹ Haruhiro Saito,¹² Niels Reinmuth,¹³ Milena Kohlmann,¹⁴ Xiaojin Shi,¹⁴ Helen Mann,¹⁵ Solange Peters,¹⁶ Tony S. Mok,¹⁷ Melissa L. Johnson¹⁸

- In the phase 3 POSEIDON study involving patients with mNSCLC, first-line T+D+CT significantly improved both PFS (HR, 0.72; 95% CI, 0.60–0.86; p=0.0003) and OS (0.77; 0.65–0.92; p=0.0030) vs CT.¹

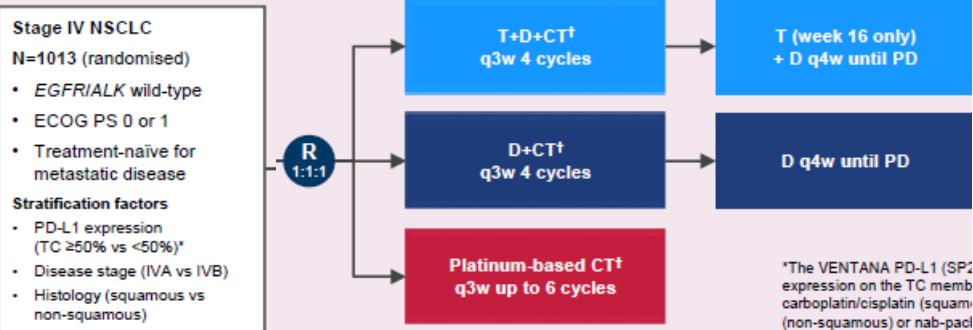
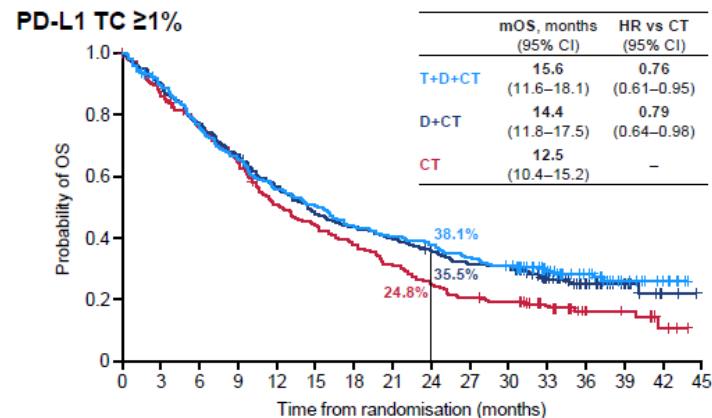
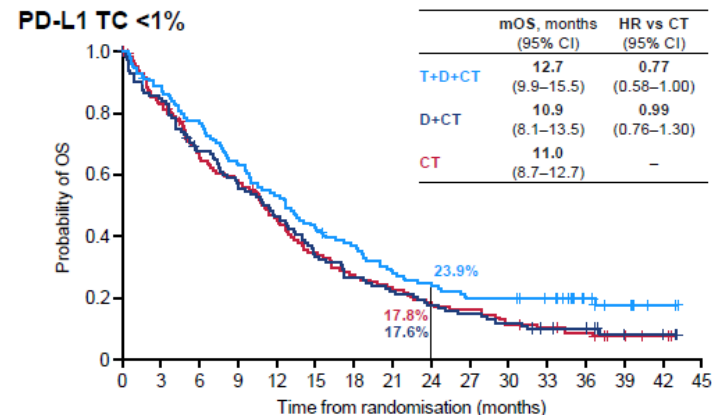


Figure 2. OS by PD-L1 expression



No. at risk

	213	188	160	138	117	106	92	85	80	71	64	43	30	13	6	0
T+D+CT	213	188	160	138	117	106	92	85	80	71	64	43	30	13	6	0
D+CT	224	202	174	150	126	106	97	88	78	69	68	42	26	12	3	0
CT	207	178	154	132	103	89	77	63	50	42	38	26	12	9	3	0



The Use of Medical Cannabis Concomitantly with Immune-Check Point Inhibitors among NSCLC Patients: A Sigh of Relief?



Barliz Waissengrin, Yasmin Leshem, Marwa Taya, David Meiri, Ofer

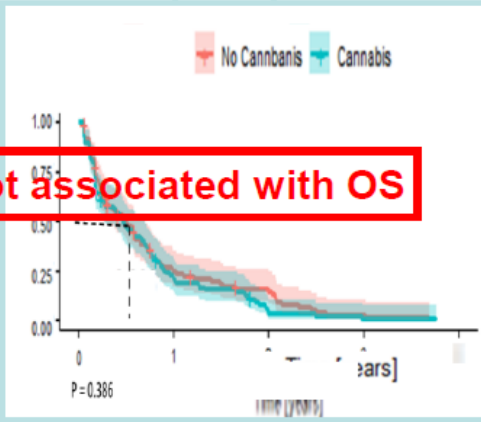
Merimsky, Sivan Shamai, Tami Rubinak, Ido Wolf

Cannabis in the clinic

Demographic

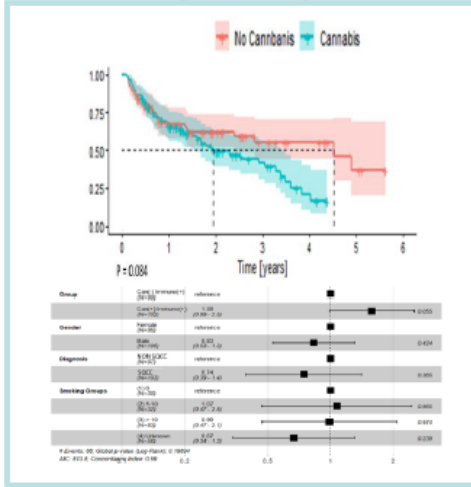
N	Without cannabis (99)	Cannabis licensed (102)	P value
Age	74	68	0.003
Female	34	72	0.0002
Smoking	81	90	0.39
Non SQCC	51	46	0.3

TTP



P= 0.386

OS



P= 0.084



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Take Home Messages

- Immunotherapy appears tolerable in combination with multiple different agents
- Emerging combinations of anti-PD1/PDL1 drugs with TROP-2 ADCs, and ATR, PARP, JAK, and VEGFR inhibitors - but no hints these will change practice in the near future.

