Lung Cancer UPDATES
ESMO HIGHLIGTHS
20-24 OCTUBRE 2023
Madrid, Spain

Iniciativa científica de:
GECP
lung cancer research

CPCNP enfermedad avanzada sin drivers

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Disclosures

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- No financial disclosures relevant to this presentation

- Other financial relantionships:
  - Advisory Board: Roche, Novartis, Boehringer Ingelheim, Takeda, Sanofi, AstraZeneca
  - Speaker Honoraria: Roche, Merck Sharp & Dohme, Pfizer, Bristol-Myers Squibb, AstraZeneca
  - Travel Grants: Roche, Takeda, Pfizer, Bristol-Myers Squibb, AstraZeneca, Lilly

Abstracts

- LBA64: Overall survival from a phase II randomised double-blind trial (PERLA) of dostarlimab (dostar) + chemotherapy (CT) vs pembrolizumab (pembro) + CT in metastatic non-squamous NSCLC. *Peters et al.*
- 1312MO: Combining the antigen-presenting cell activator eftilagimod alpha (soluble LAG-3) and pembrolizumab: Overall survival data from the first line non-small cell lung carcinoma (NSCLC) cohort of TACTI-002 (phase II). *Carcereny et al.*
- LBA12: Datopotamab deruxtecan (Dato-DXd) vs docetaxel in previously treated advanced/metastatic (adv/met) non-small cell lung cancer (NSCLC): Results of the randomized phase III study TROPION-Lung01. *Lisberg et al.*

LBA64: Peters *et. al.*

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Overall Survival From a Phase II Randomised Double-Blind Trial (PERLA) of Dostarlimab + Chemotherapy vs Pembrolizumab + Chemotherapy in Metastatic Non-Squamous NSCLC

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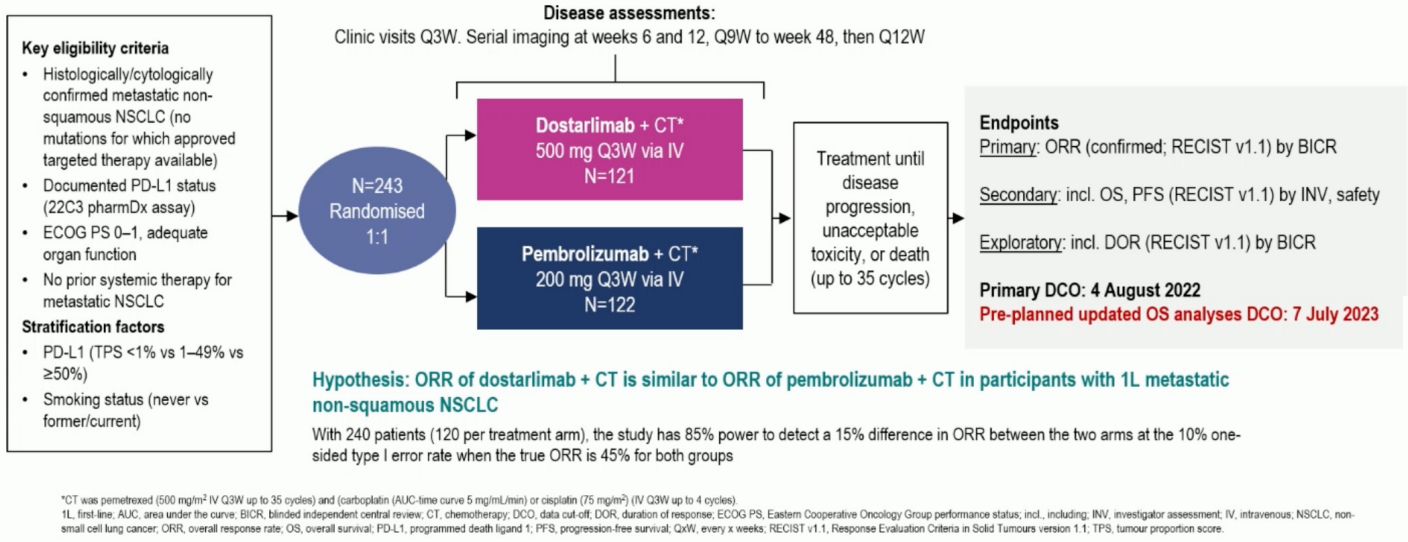
A global, phase II, randomised, double-blind study comparing dostarlimab + CT vs pembrolizumab + CT in patients with 1L metastatic non-squamous NSCLC



Hypothesis: ORR of dostarlimab + CT is similar to ORR of pembrolizumab + CT in participants with 1L metastatic non-squamous NSCLC

With 240 patients (120 per treatment arm), the study has 85% power to detect a 15% difference in ORR between the two arms at the 10% one-sided type I error rate when the true ORR is 45% for both groups

*CT was pemetrexed (500 mg/m² IV Q3W up to 35 cycles) and (carboplatin (AUC-time curve 5 mg/mL/min) or cisplatin (75 mg/m²) (IV Q3W up to 4 cycles).
1L, first-line; AUC, area under the curve; BICR, blinded independent central review; CT, chemotherapy; DCO, data cut-off; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; incl., including; INV, investigator assessment; IV, intravenous; NSCLC, non-small cell lung cancer; ORR, overall response rate; OS, overall survival; PD-L1, programmed death ligand 1; PFS, progression-free survival; QxW, every x weeks; RECIST v1.1, Response Evaluation Criteria in Solid Tumours version 1.1; TPS, tumour proportion score.

- Dostarlimab binds to PD-1 at distinct binding sites with different binding orientations from other anti–PD-1s
- Dostarlimab has been shown to significantly improve outcomes in dMMR locally advanced rectal cancer and primary advanced or recurrent endometrial cancer, and is approved in dMMR endometrial cancer and dMMR solid tumours.

Objective: report the pre-planned updated OS results from the PERLA trial of dostarlimab + CT versus pembrolizumab + CT in patients with 1L metastatic, non-squamous NSCLC without known targetable oncogenic driver mutations

Patient Disposition

Results

	Assessed for eligibility (N=352)	
	Randomised (N=243)	
Variable, n (%)	Dostarlimab + CT	Pembrolizumab + CT
Randomised to intervention	**121**	**122**
Received allocated intervention	121	122
Participant status		
Ongoing	**58 (48)**	**41 (34)**
Completed	63 (52)	81 (66)
Completed follow-up*	0	0
Death due to any reason	**59 (49)**	**75 (61)**
Withdrawn	4 (3)	6 (5)
Lost to follow-up	**1 (<1)**	**0**
Discontinued intervention		
Withdrawal by patient	3 (2)	6 (5)
Physician decision	0	0
Other	0	0
Analysed	**121**	**122**

Data cut-off: 7 July 2023; *After 2 years of treatment, follow-up extends up to study closure; Note: imbalances in baseline characteristics are denoted in **bold** text.
CT, chemotherapy.

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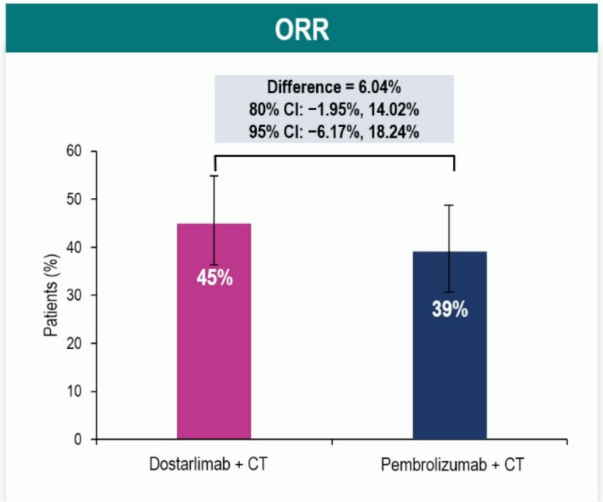
Confirmed ORR by BICR per RECIST v1.1
Results



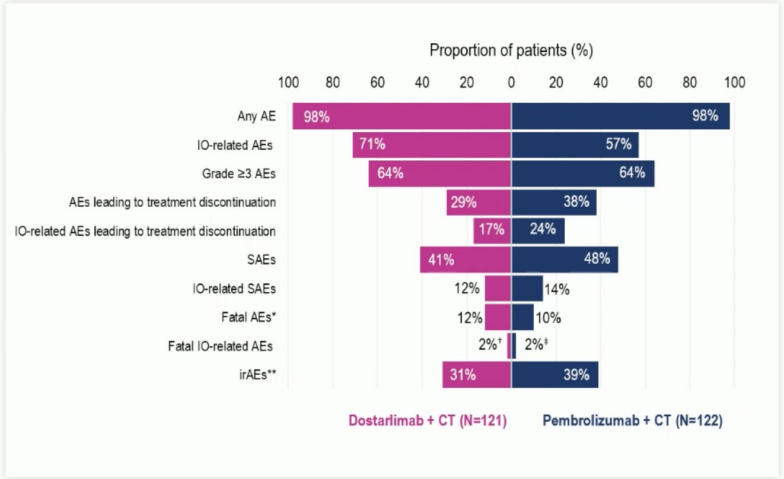
Variable	Dostarlimab + CT (N=121)	Pembrolizumab + CT (N=122)
Best overall response, n (%)		
CR	4 (3)	6 (5)
PR	51 (42)	42 (34)
SD	49 (40)	48 (39)
PD	12 (10)	12 (10)
Not evaluable	0	1 (<1)
Not done	5 (4)	13 (11)
Overall response rate, n (%)		
CR+PR	**55 (45)**	**48 (39)**
95% CI	36.4, 54.8	30.6, 48.6
Median treatment cycles, n (min, max)	13 (1, 35)	7.5 (1, 35)
Median duration of exposure, months (min, max)	9 (0.3, 26.8)	6 (0.2, 25.3)

Safety: Overall Summary of Adverse Events
Results

The proportion of patients experiencing AEs and Grade ≥3 AEs was similar between arms

A numerical trend in favour of dostarlimab was noted as a smaller proportion of patients experienced AEs leading to treatment discontinuation (including IO-related AEs), SAEs and irAEs

The most common IO-related AEs (≥10% in either group) were anaemia, asthenia and rash



*Patients who had a fatal AE recorded and whose death was not recorded as due unequivocally to disease under study; †pneumonitis; immune-related pneumonitis, urosepsis; ‡myelosuppression, respiratory failure; **no new immune-related deaths were observed.
AE, adverse event; CT, chemotherapy; IO, immuno-oncology agent; irAE, immune-related adverse event; SAE, serious adverse event.

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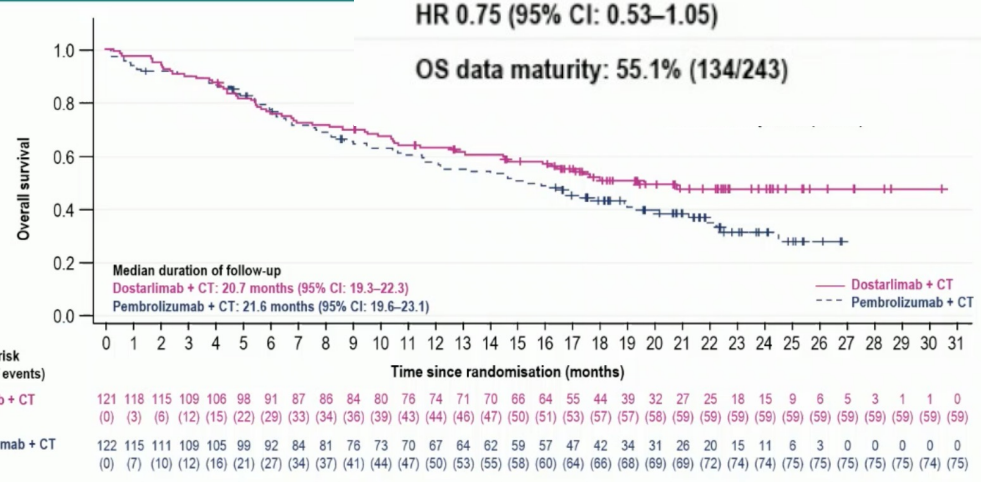
Overall Survival Results

Median OS
Dostarlimab + CT: 19.4 months (95% CI: 14.5–NR)
Pembrolizumab + CT: 15.9 months (95% CI: 11.6–19.3)

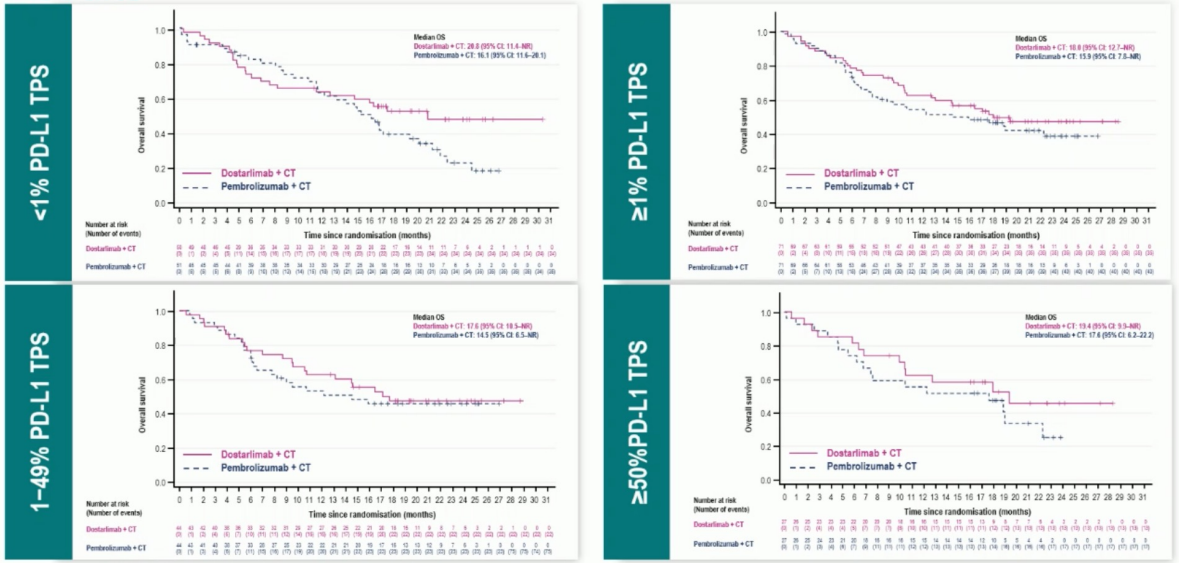
HR 0.75 (95% CI: 0.53–1.05)

OS data maturity: 55.1% (134/243)

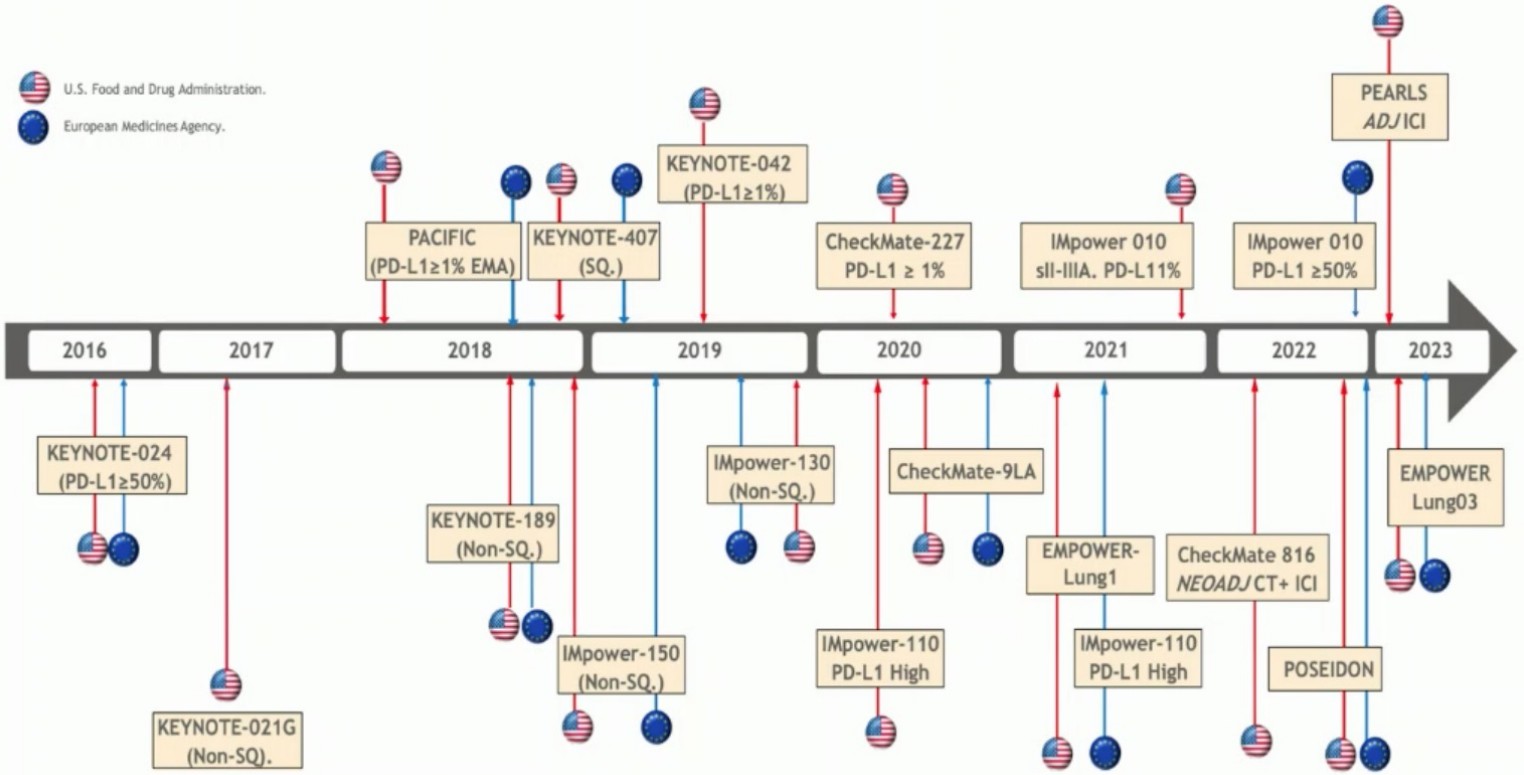


CI, confidence interval; CT, chemotherapy; HR, hazard ratio; NR, not reached; OS, overall survival.

Overall Survival by PD-L1 TPS Status Results



Immune checkpoint inhibitors have revolutionized the treatment of metastatic NSCLC



But most patients will not derive long-term benefit due to either **primary or secundary resistance**

Lizza Hendriks ESMO 2023

1312MO: Carcereny *et. al.*

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Combining the antigen-presenting cell activator eftilagimod alpha (soluble LAG-3) and pembrolizumab: overall survival data from the 1st line non-small cell lung carcinoma cohort of TACTI-002

Phase II study of soluble LAG-3 combined with an anti-PD-1 antibody in 1st line metastatic NSCLC

Carcereny E[1]; Felip E[2]; Majem M[3]; Doger B[4]; Clay T[5]; Bondarenko I[6]; Peguero J[7], Cobo Dols M[8], Forster M[9]; Ursol G[10]; Kalinka E[11]; Garcia Ledo G[12]; Vila Martinez L[13]; Iams W[14]; Krebs MG[15]; Kefas J[16]; Efthymiadis K[17]; Perera S[18]; Mueller C[19]; Triebel F[20]

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1312MO: Carcereny *et. al.*

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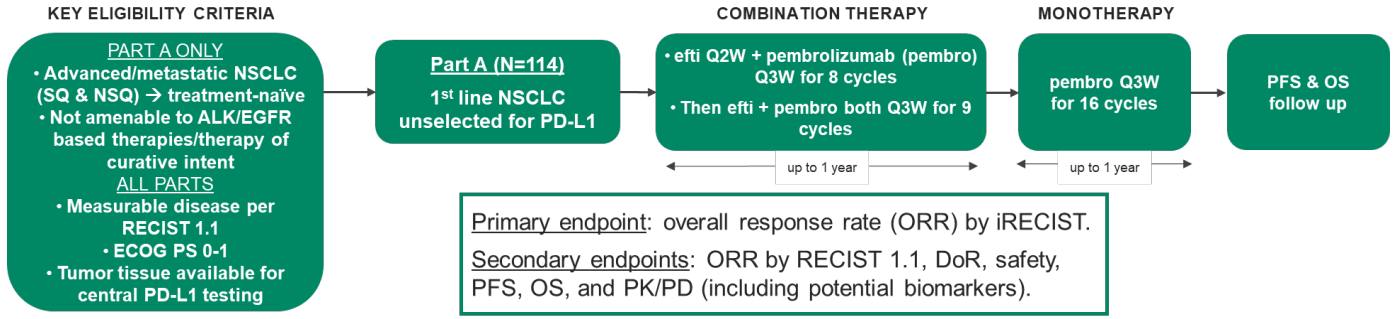
Trial Design

TACTI-002 (Part A)



Note: Pts were recruited according to Simon's optimal two-stage design: during the first stage, 17 pts were recruited; second stage recruitment (n=19) was opened only after the number of responses was above 4. An extension stage (n=78) could be added if there were above 12 responses. In total, 114 pts were enrolled. True response rates sources/assumptions: KN-001 &-042 (KN-001: Lancet Respir Med, 2019; 7(4): 347-357; KN-042: Lancet 2019;393(10183:1819-1830), expecting that ~70% of patients had PD-L1 TPS <50%.

- **efti:** a **soluble LAG-3 protein** and **MHC Class II agonist** that leads to a broad anti-cancer immune response, including CD8+ T cell activation & proliferation, through activating antigen presenting cells (APC).
- **Distinct from anti-LAG-3:** efti targets MHC Class II on APCs, unlike LAG-3 antagonists that target T cells.

Baseline parameters		N=114	
Age, median (range), years		67 (44-85)	
Sex, %	Female / Male	26.3 / 73.7	
ECOG PS score, %	0 / 1	37.7 / 62.3	
Smoking status, %	Current or Ex-smoker / Non-smoker	94.7 / 5.3	
Histology, %	Squamous / Non-squamous / Not otherwise specified	35.1 / 63.1 / 1.8	
Metastatic disease, %	Yes / No	99.1 / 0.9	
		Central[1] (N=90)	Central + Local[2] (N=108)
PD-L1 expression TPS, %	<1%	35.6	34.3
	1-49%	42.2	38.9
	≥50%	22.2	26.9
Previous therapy, %	Radiotherapy	33.3	
	Surgery	20.2	
	Systemic therapy for non-met. disease	22.8	

[1] N=90; Central assessment of PD-L1 TPS using Dako IHC 22C3 pharmDx.
[2] N=108; Central assessment as per footnote 1 for 90 pts. For 18 patients, local assessment used predominantly Dako IHC 22C3 pharmDx due to non-evaluable central assessment results.

1312MO: Carcereny *et. al.*

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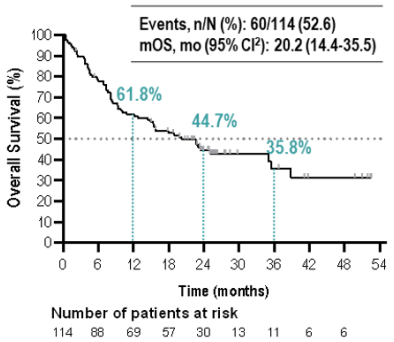
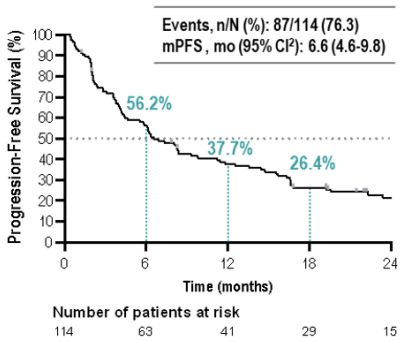
Efficacy - ITT

- Median OS of 20.2 mo in ITT where ~75% of patients had PD-L1 TPS score <50%, including ~35% with PD-L1 TPS of <1%.
- 45/114 (39.5%) received 2nd line therapy → mostly chemotherapy-based (42/45; 93.3%).
- Median DoR of 21.6 mo in the ITT.

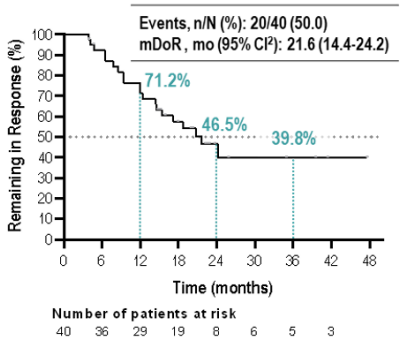
Overall survival, ITT (N=114)



Progression-free survival[1], ITT (N=114)



Duration of response[1], N=40



Efficacy by PD-L1[1]

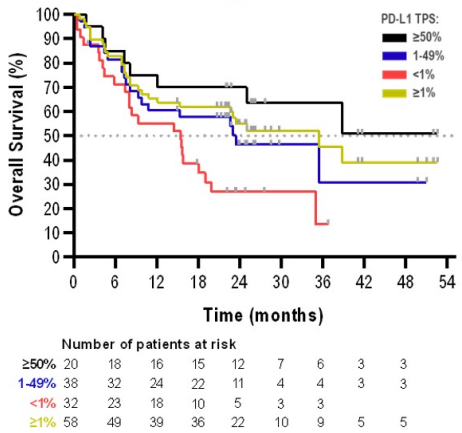
- Promising efficacy (ORR, PFS, OS, DOR) visible across all PD-L1 subgroups[1,2].
- For TPS ≥1%, mOS of 35.5 mo, mPFS[2] of 11.2 mo, mDOR[2] of 24.2 mo.
- For TPS ≥50%, mOS not reached despite long median follow up of 25.1 mo.

Tumor Response by central PD-L1[1], N=90

Efficacy parameter	<1%[1], n (%), N=32	1-49%[1], n (%), N=38	≥50%[1], n (%), N=20	≥1%[1], n (%), N=58
ORR[2,3], % (95% CI)[4]	31.3 (16.1-50.0)	44.7 (28.6-61.7)	55.0 (31.5-76.9)	48.3 (35.0-61.8)
mPFS[2], mo (% events)	4.2 (90.6)	9.3 (71.1)	16.5 (70.0)	11.2 (70.7)
mDoR[2], mo (% events)	20.7 (57.1)	NR (35.7)	18.7 (63.6)	24.2 (48.0)
mOS, mo (% events)	15.5 (71.9)	23.4 (52.6)	NR (40.0)	35.5 (48.3)

[1] N=90; Central assessment of PD-L1 TPS using Dako IHC 22C3 pharmDx; [2] iRECIST; [3] unconfirmed; [4] calculated using Clopper Pearson method; NR: not reached.
Note: results for PD-L1 central + local (N=108) were as follows (<1% / 1-49% / ≥50% / ≥1%):
mOS, mo: 14.4 / 23.4 / 38.8 / 35.5; mPFS[2]: 4.2 / 8.3 / 16.3 / 9.8; mDoR[2]: 20.7 / 21.6 / 18.7 / 21.6.

Overall survival by central PD-L1[1]



ASCO 22
favourable tox profile: 11% grade ≥3 TRAE

Felip et al

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Datopotamab deruxtecan (Dato-DXd) vs docetaxel in previously treated advanced/metastatic (adv/met) non-small cell lung cancer (NSCLC): Results of the randomized phase 3 study TROPION-Lung01

Myung-Ju Ahn,[1,*] Aaron Lisberg,[2,4,5] Luis Paz-Ares,[3] Robin Cornelissen,[6] Nicolas Girard,[7] Elvire Pons-Tostivint,[8] David Vicente Baz,[7] Shunichi Sugawara,[9] Manuel Angel Cobo,[9] Maurice Pérol,[10] Céline Mascaux,[11] Elena Poddubskaya,[12] Satoru Kitazono,[13] Hidetoshi Hayashi,[14] Jacob Sands,[15] Richard Hall,[16] Yong Zhang,[17] Hong Zebger-Gong,[18] Deise Uema,[17] Isamu Okamoto[19]

*Equal contribution as first author. †Indicates presenting author.

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LBA12: Lisberg *et. al.*

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TROPION-Lung01 Study Design

Randomized, Phase 3, Open-Label, Global Study (NCT04656652)

Key Eligibility Criteria

- NSCLC (stage IIIB, IIIC, or IV)
- ECOG PS of 0 or 1
- No prior docetaxel
  - **Without actionable genomic alterations**[a]
    - 1 or 2 prior lines, including platinum CT and anti–PD-(L)1 mAb therapy
  - **With actionable genomic alterations**
    - Positive for *EGFR*, *ALK*, *NTRK*, *BRAF*, *ROS1*, *MET* exon 14 skipping, or *RET*
    - 1 or 2 prior approved targeted therapies + platinum-based CT, and ≤1 anti–PD-(L)1 mAb

R 1:1

- **Dato-DXd** 6 mg/kg Q3W (N=299)
- **Docetaxel** 75 mg/m^2 Q3W (N=305)

Dual Primary Endpoints
- PFS by BICR
- OS

Secondary Endpoints
- ORR by BICR
- DOR by BICR
- Safety

Stratified by: histology,[b] actionable genomic alteration,[c] anti–PD-(L)1 mAb included in most recent prior therapy, geography[d]

Enrollment period: 19 February 2021 to 7 November 2022.
BICR, blinded independent central review; CT, chemotherapy; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; mAb, monoclonal antibody; NSCLC, non-small cell lung cancer; ORR, objective response rate; OS, overall survival; PD-(L)1, programmed cell death 1 (ligand 1); PFS, progression-free survival; Q3W, every 3 weeks; R, randomized.
[a]Patients with *KRAS* mutations in the absence of known actionable genomic alterations are eligible; must meet prior therapy requirements for patients without actionable genomic alterations. [b]Squamous vs non-squamous. [c]Presence vs absence. [d]United States/Japan/Western Europe vs rest of world.

- **Dato-DXd** is a **TROP2-directed ADC** that selectively delivers a potent topoisomerase I inhibitor payload directly into tumor cells[1]
- **Promising antitumor activity** was seen with Dato-DXd in patients with adv/met NSCLC in the phase 1 TROPION-PanTumor01 trial (26% ORR)[1]

Demographics and Baseline Characteristics

Characteristic		Dato-DXd N=299	Docetaxel N=305
Age, median (range), years		63 (26-84)	64 (24-88)
Male, n (%)		183 (61)	210 (69)
Race, n (%)	Asian	119 (40)	120 (39)
	White	123 (41)	126 (41)
	Black or African American	6 (2)	4 (1)
	Other[a]	51 (17)	55 (18)
ECOG PS, n (%)	0	89 (30)	94 (31)
	1	210 (70)	211 (69)
Histology, n (%)	Non-squamous	234 (78)	234 (77)
	Squamous	65 (22)	71 (23)

Characteristic		Dato-DXd N=299	Docetaxel N=305
Current or former smoker, n (%)		238 (80)	251 (82)
Actionable genomic alterations, n (%)	Present	50 (17)	51 (17)
	EGFR mutation	39 (13)	45 (15)
Brain metastasis at baseline, n (%)[b]		50 (17)	47 (15)
Prior lines of therapy, n (%)	1	167 (56)	174 (57)
	2	108 (36)	102 (33)
	≥3	22 (7)	28 (9)
Previous systemic therapy, n (%)[c]	Platinum containing	297 (99)	305 (100)
	Anti–PD-(L)1	263 (88)	268 (88)
	Targeted	46 (15)	50 (16)

ECOG PS, Eastern Cooperative Oncology Group performance status; PD-(L)1, programmed cell death 1 (ligand 1).
[a]Race data missing for 8 patients in each arm. [b]Patients who are no longer symptomatic and who require no treatment with corticosteroids and anticonvulsants and have recovered from acute toxic effects of radiation are eligible. [c]In the Dato-DXd arm, 2 patients did not receive prior treatment with a platinum-containing therapy and 1 patient with actionable genomic alterations did not receive previous targeted therapy, deviating from the protocol.

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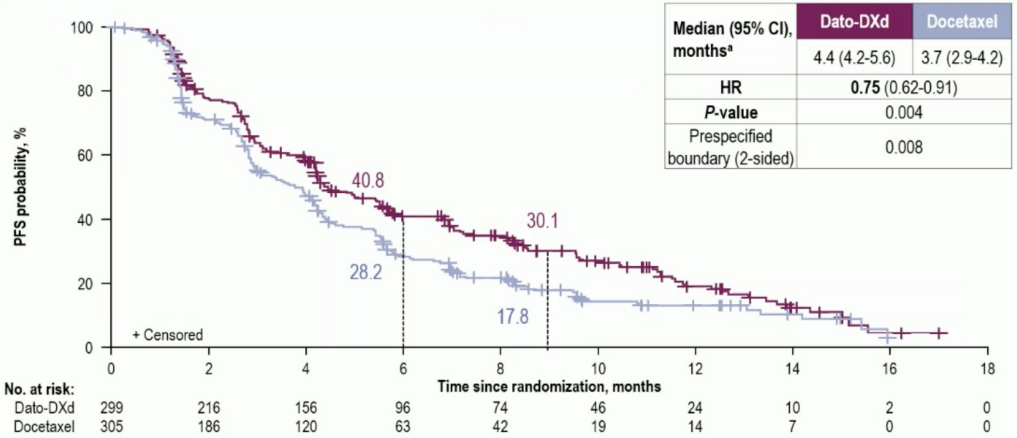
Progression-Free Survival: ITT

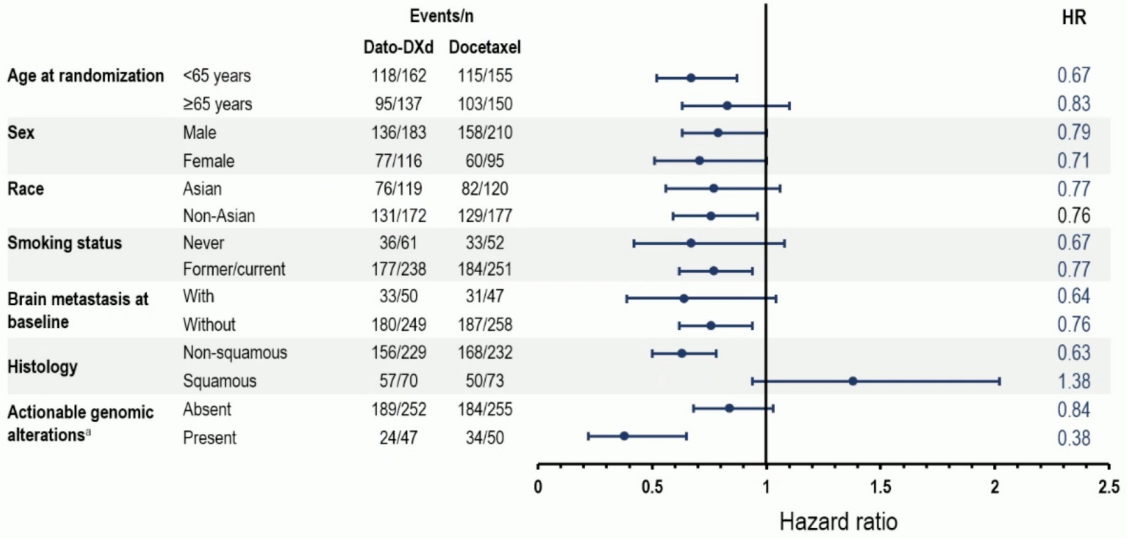


Median (95% CI), months[a]	Dato-DXd	Docetaxel
	4.4 (4.2-5.6)	3.7 (2.9-4.2)
HR	**0.75** (0.62-0.91)	
P-value	0.004	
Prespecified boundary (2-sided)	0.008	

	Dato-DXd	Docetaxel
ORR (95% CI), %[b]	**26.4** (21.5-31.8)	**12.8** (9.3-17.1)
DOR (95% CI), mo	**7.1** (5.6-10.9)	**5.6** (5.4-8.1)

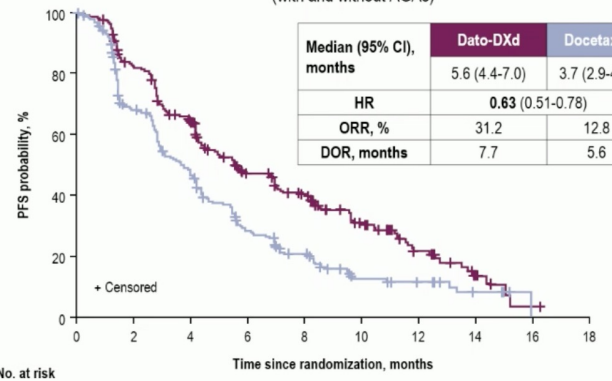
CR, complete response; DOR, duration of response; HR, hazard ratio; ITT, intention to treat; ORR, objective response rate; PFS, progression-free survival; PR, partial response.
[a]Median PFS follow-up was 10.9 (95% CI, 9.8-12.5) and 9.6 (95% CI, 8.2-11.9) months for Dato-DXd and docetaxel, respectively. [b]Included 4 CRs and 75 PRs for Dato-DXd and 39 PRs for docetaxel.

PFS in Key Subgroups



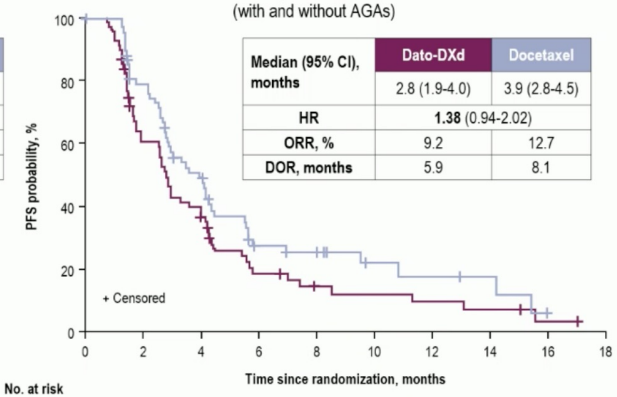
PFS by Histology

Non-squamous
(with and without AGAs)



Median (95% CI), months	Dato-DXd	Docetaxel
	5.6 (4.4-7.0)	3.7 (2.9-4.2)
HR	**0.63** (0.51-0.78)	
ORR, %	31.2	12.8
DOR, months	7.7	5.6

Squamous
(with and without AGAs)



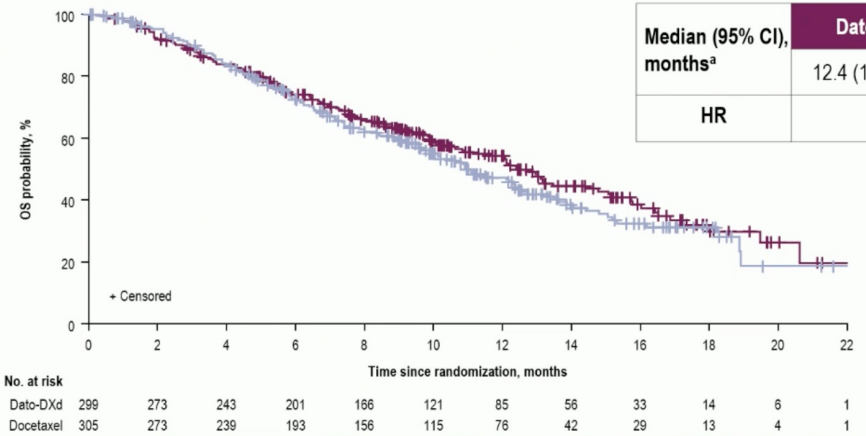
Median (95% CI), months	Dato-DXd	Docetaxel
	2.8 (1.9-4.0)	3.9 (2.8-4.5)
HR	**1.38** (0.94-2.02)	
ORR, %	9.2	12.7
DOR, months	5.9	8.1

PFS HR for non-squamous without AGAs: 0.71 (0.56, 0.91)

LBA12: Lisberg *et. al.*

Iniciativa científica de: GECP lung cancer research

Interim Overall Survival: ITT



Median (95% CI), months[a]	Dato-DXd	Docetaxel
	12.4 (10.8-14.8)	11.0 (9.8-12.5)
HR	**0.90** (0.72-1.13)	

Information fraction at interim analysis (events/total events required): **74%.**

Non-squamous HR (95% CI): **0.77** (0.59-1.01); **Squamous HR** (95% CI): **1.32** (0.87-2.00)

Trial is continuing to final OS analysis

HR, hazard ratio; ITT, intention to treat; OS, overall survival.
[a]Median OS follow-up was 11.8 (95% CI, 11.3-12.7) and 11.7 (95% CI, 10.9-12.9) months for Dato-DXd and docetaxel, respectively.

TRAEs Occurring in ≥10% of Patients

System organ class Preferred term, n (%)	Dato-DXd N=297		Docetaxel N=290	
	Any grade	Grade ≥3	Any grade	Grade ≥3
Blood and lymphatic system				
Anemia	43 (15)	11 (4)	59 (20)	11 (4)
Neutropenia[a]	12 (4)	2 (1)	76 (26)	68 (23)
Gastrointestinal				
Stomatitis	140 (47)	19 (6)	45 (16)	3 (1)
Nausea	100 (34)	7 (2)	48 (17)	3 (1)
Vomiting	38 (13)	3 (1)	22 (8)	1 (0.3)
Constipation	29 (10)	0	30 (10)	0
Diarrhea	28 (9)	1 (0.3)	55 (19)	4 (1)
General				
Asthenia	55 (19)	8 (3)	55 (19)	5 (2)
Fatigue	34 (11)	2 (1)	40 (14)	6 (2)
Metabolism and nutrition				
Decreased appetite	68 (23)	1 (0.3)	45 (16)	1 (0.3)
Skin and subcutaneous				
Alopecia	95 (32)	0	101 (35)	1 (0.3)[b]
Rash	36 (12)	0	18 (6)	0
Pruritus	30 (10)	0	12 (4)	0

TRAE, treatment-related adverse event.
[a]This category includes the preferred terms "neutropenia" and "neutrophil count decreased". [b]Includes an event incorrectly reported as grade 3. [c]7% vs 0.3% for Docetaxel and Dato-DXd, respectively

- Stomatitis and nausea were the most frequent TRAEs seen with Dato-DXd and were predominantly grade 1 or 2
- Hematologic toxicities, including neutropenia and febrile neutropenia[c], were more common with docetaxel
- No new safety signals were observed with Dato-DXd

Lung Cancer UPDATES
ESMO HIGHLIGTHS
20-24 OCTUBRE 2023
Madrid, Spain

Iniciativa científica de:
GECP
lung cancer research

CPCNP enfermedad avanzada sin drivers

Ivana Sullivan, MD, PhD

Hospital Sant Pau e Instituto Oncológico Dr. Rosell