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Iniciativa científica de:
GECP
lung cancer research

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Disclosures

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Abstracts

- LBA61: Durvalumab (durva) after sequential chemoradiotherapy (CRT) in patients (pts) with unresectable stage III NSCLC: Final analysis from PACIFIC-6. *Garassino et al.*
- LBA62: Durvalumab after radiotherapy (RT) in patients with unresectable stage III NSCLC ineligible for chemotherapy (CT): Primary results from the DUART study. *Filippi et al.*
- 1292MO: A phase II study of daily carboplatin plus irradiation followed by durvalumab for unresectable III non-small cell lung cancer patients with PS 2 or elderly (≧75 years): NEJ039A. *Ko et al.*

De-escalation strategies

NEJ039A : CRT with daily low-dose Carboplatin

PACIFIC 6 : Sequential RCT

DUART : RT only

- To increase the proportion of pts treated with curative intent
- To increase the proportion of pts treated with ICI
- To allow concurrent Tx with ICI

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LBA61

Durvalumab after sequential chemoradiotherapy in patients with unresectable Stage III NSCLC

Final analysis from PACIFIC-6

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LBA61: Garassino *et. al.*

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- Patients were recruited from 6 countries: Italy (n=39), Spain (30), Germany (18), France (16), UK (12), and USA (2)
- Incidence of AEs (CTCAE v4.03), and the ORR, were summarised with descriptive statistics
- PFS and OS were analysed by Kaplan–Meier method

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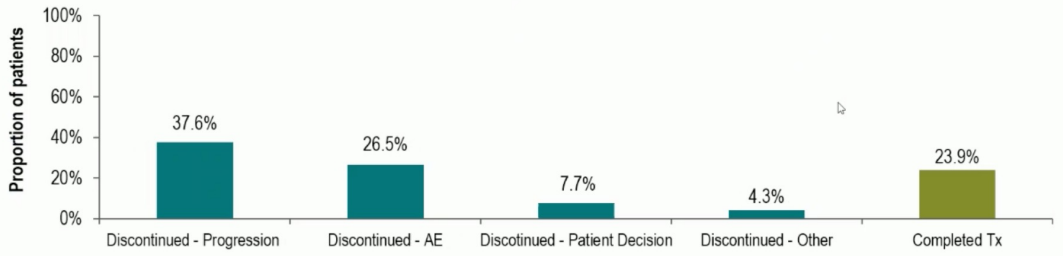
AE, adverse event; CT, chemotherapy; CTCAE, Common Terminology Criteria for Adverse Events; DoR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; IV, intravenous; NSCLC, non-small-cell lung cancer; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PRAE, AE possibly related to study treatment; Q4W, every 4 weeks; RECIST, Response Evaluation Criteria in Solid Tumours; RT, radiotherapy; sCRT, sequential chemoradiotherapy; WHO, World Health Organisation

*Defined as ≥2 cycles of platinum-based CT before RT with ≤6 weeks interval between the last dose of CT and the start of RT. Patients who received no more than 1 cycle of overlapping CT and RT were also eligible. †Or until progression, alternative anticancer therapy, unacceptable toxicity, withdrawal of consent, or another discontinuation criterion is met. ‡As reported by the investigator; PRAE is alternative nomenclature for treatment-related AE and is used here to align with the case report form used to collect investigators' responses.

Patient disposition

- All 117 patients received ≥1 durvalumab infusion – **23.9% of patients completed study Tx**
- Median Tx duration was 41.0 weeks (range: 4–108)* – patients received a median of 9 infusions (range: 1–26)
- No patients remained on study Tx at data cut-off
- PD (37.6%) and AEs (26.5%) were the most common reasons for discontinuing durvalumab



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AE, adverse event; PD, progressive disease; Tx, treatment

Data cutoff: March 20, 2023; median follow-up duration = 126.0 weeks (range: 6–199)
*Includes dose delays; median actual Tx duration (i.e., excluding dose delays) = 36.0 weeks (range: 4–104)

LBA61: Garassino *et. al.*

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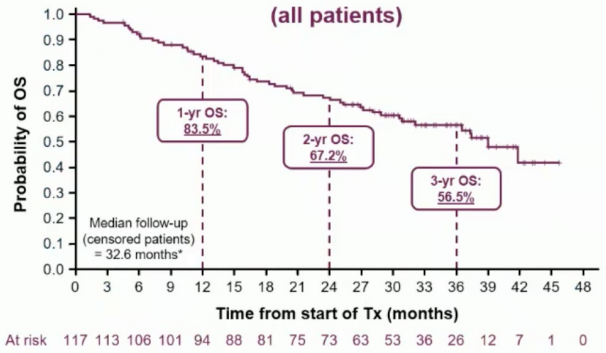
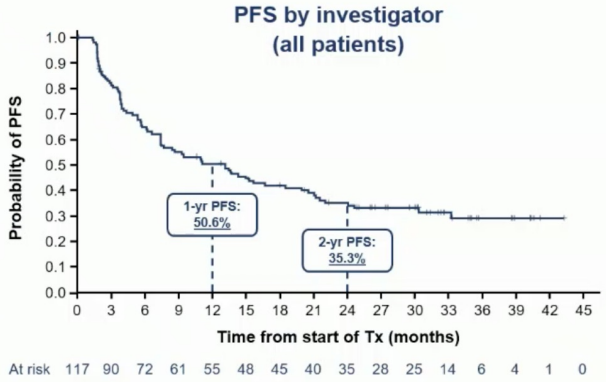
Efficacy





Endpoint		All patients (N=117)	PS 0/1 cohort (n=114)†
OS	Median, months (95% CI)	39.0 (30.6–NC)	39.0 (30.6–NC)
	3-yr rate, % (95% CI)	56.5 (46.4–65.5)	57.2 (46.9–66.2)
PFS by investigator	Median, months (95% CI)	13.1 (7.4–19.9)	13.1 (7.4–19.9)
	2-yr rate, % (95% CI)	35.3 (26.5–44.3)	35.4 (26.4–44.5)
Confirmed ORR by investigator	n (%)	24 (20.5)‡	24 (21.1)‡
	[95% CI]§	[13.6–29.0]	[14.0–29.7]

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CI, confidence interval; ORR, objective response rate; NC, not calculable; OS, overall survival; PFS, progression-free survival; PS, performance status; Tx, treatment; yr, year

*Median follow-up among patients censored for OS / PFS = 32.6 months (range: 4.4–45.7) / 30.2 months (range: 0.0–43.3). †In the PS 0/1 cohort, 47/114 patients (41.2%) had PS 0 and 67/114 (58.8%) had PS 1; outcomes for the PS 2 cohort are not reported due to the small sample size (n=3). ‡An additional 5 patients (4.4%) had unconfirmed responses (all in the PS 0/1 cohort). §CIs calculated using the Clopper–Pearson method.

Adverse events

- 27.4% of patients had all-cause grade 3/4 AEs and 6.0% had grade 3/4 PRAEs*
  - **5 patients (4.3%) had grade 3/4 PRAEs within 6 months (95% CI: 1.4–9.7)†** – primary endpoint‡[1]
    - Events were pneumonitis (n=2), hypothyroidism, adrenal insufficiency, and leukopenia (n=1 each)
- Pneumonitis was the most common PRAE of any grade (17.1%) and grade 3/4 (1.7%)
- 27.4% discontinued Tx due to all-cause AEs
  - 10.3% discontinued due to pneumonitis (all PRAEs), the AE most frequently leading to discontinuation

AE Category (N=117)	All-cause	PRAE*
Any AE, n (%)	111 (94.9)	90 (76.9)
Grade 3/4§	32 (27.4)	7 (6.0)
SAE	32 (27.4)	7 (6.0)
Outcome of death¶	3 (2.6)	1 (0.9)
Leading to Tx discontinuation	32 (27.4)	19 (16.2)
AESI	89 (76.1)	75 (64.1)

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AE, adverse event; AESI, AE of special interest; CI, confidence interval; PRAE, AE possibly related to Tx; SAE, serious AE; Tx, treatment

*PRAE is alternative nomenclature for Tx-related AE and is used here to align with the case report form used to collect investigators' responses. †CI calculated using the Clopper–Pearson method. ‡Primary endpoint reported previously based on an interim analysis (data cutoff: July 15, 2021).[1] §Two patients had grade 3/4 pneumonitis; both cases were PRAEs. ¶AEs with outcome of death were pneumonitis (n=1; PRAE), cardiac arrest (n=1; not a PRAE), and pulmonary sepsis (n=1; not a PRAE). [1]Garassino MC et al., J Thorac Oncol 2022;17:1415–27.

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Conclusions

- For patients with unresectable, stage III NSCLC, durvalumab after cCRT is a SoC based on the PACIFIC trial; in patients considered unsuitable for cCRT, durvalumab after sCRT maintained a similar safety profile to that seen in PACIFIC[1,2]
  - Only 4.3% of patients had grade 3/4 PRAEs within 6 months, and 6.0% had grade 3/4 PRAEs overall, demonstrating that durvalumab is well tolerated following sCRT
- Encouraging efficacy was seen with durvalumab after sCRT in a frailer population than that enrolled in PACIFIC[1,2]*
  - **mOS = 39.0 months**; >55% of patients were estimated to remain alive at 3 years
  - **mPFS = 13.1 months**; >35% of patients were estimated to remain alive and progression free at 2 years
- Efficacy outcomes compare favourably to historical cohorts treated with sCRT alone,[4,5] and are similar to those observed among patients who received durvalumab after sCRT in the real-world PACIFIC-R study[6,7]
- These findings demonstrate that durvalumab after sCRT is well tolerated and could be a reasonable strategy when cCRT is not possible – **confirmatory phase III data is awaited:**
  - **The ongoing PACIFIC-5 trial is assessing the efficacy and safety of durvalumab after either cCRT or sCRT (NCT03706690)**

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AE, adverse event; c/sCRT, concurrent/sequential chemoradiotherapy; mOS, median overall survival; mPFS, median progression-free survival; PRAE, AE possibly related to treatment; SoC, standard of care; Tx, treatment.

*A higher proportion of patients were aged ≥65 years (65.8% vs 45.2%) and had PS >0 (59.8% vs 50.8%), and a lower proportion had stage IIIA disease (37.6% vs 52.9%) in PACIFIC-6 versus PACIFIC, and nearly all patients in PACIFIC-6 had past/present comorbidities (98.3%).

[1]Antonia SJ, et al., N Engl J Med 2017;377:1919-29; [2]Antonia SJ, et al., N Engl J Med 2018;379:2342-50; [3]Spigel DR et al., J Clin Oncol 2022;40:1301–11; [4]Auperin, et al. J Clin Oncol 2010;28:2181-90; [5]Jazieh, et al. J Thorac Oncol 2021;16:1733-44_(Table S5); [6]Girard N, et al., J Thorac Oncol 2023;18:181-93; [7]Girard N, et al., ESMO-IO 2022; Mini-oral Presentation 58O.

LBA62: Filippi *et. al.*

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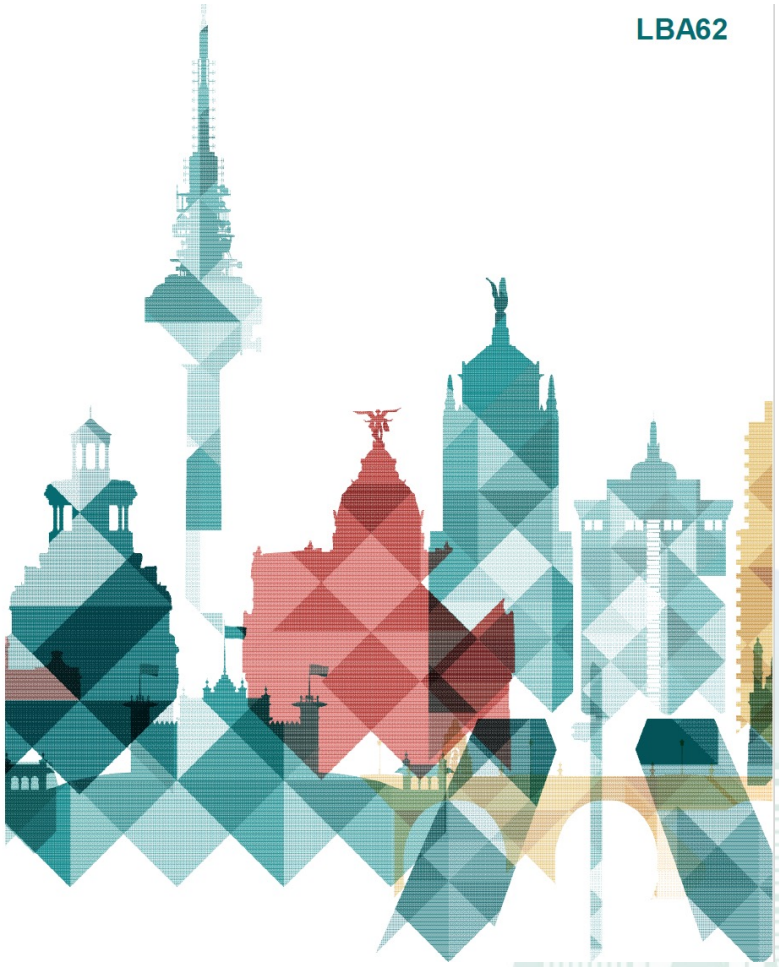

Durvalumab after Radiotherapy in Patients with Unresectable Stage III NSCLC Ineligible for Chemotherapy

Primary Results from the DUART Study

Andrea R. Filippi,[1] Maria Rosario García Campelo,[2] Jean-Baptiste Paoli,[3] Dariusz Kowalski,[4] Chiara Bennati,[5] Paolo Borghetti,[6] Diego Cortinovis,[7] Angelo Delmonte,[8] Carlo Genova,[9] Sylvie Van Hulst,[10] Robert Mroz,[11] Sergiusz Nawrocki,[12] Ivan Toledano,[13] Giuseppe Tonini,[14] Ignacio Diaz Perez,[15] Nefeli Georgoulia,[15] Kayhan Foroutanpour,[15] Rafał Dziadziuszko[16]

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LBA62: Filippi *et. al.*

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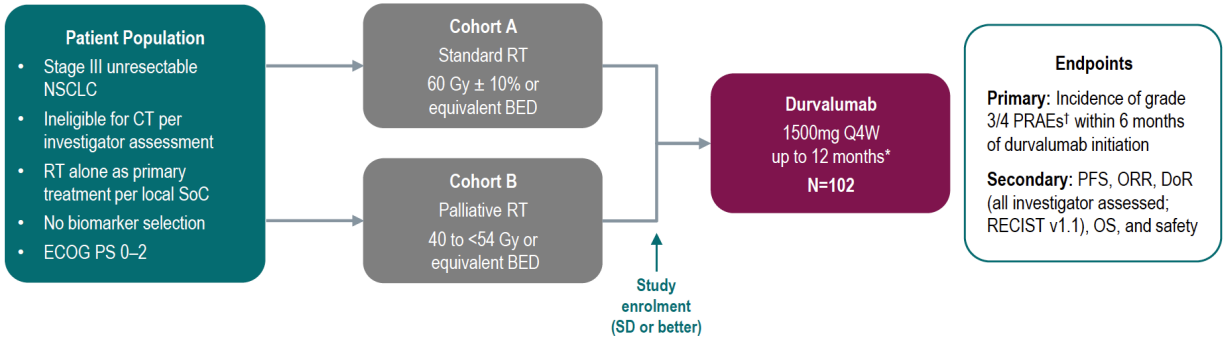
A phase 2, open-label, multicentre, international study



- RT must have been completed within 6 weeks (42 days) prior to the first dose of durvalumab
- The incidence of AEs (CTCAE v5.0) and ORR were summarised with descriptive statistics
- PFS and OS were analysed using the Kaplan-Meier method to estimate medians, landmark rates, and associated 95% CIs

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BED, biologically effective dose; CI, confidence interval; CTCAE v5.0, Common Terminology Criteria for Adverse Events version 5.0; DoR, duration of response; ECOG, Eastern Cooperative Oncology Group; Gy, Gray (unit of ionizing radiation); NSCLC, non-small-cell lung cancer; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PRAE, adverse event possibly related to treatment; PS, performance status; Q4W, every 4 weeks; RECIST v1.1, Response Evaluation Criteria in Solid Tumours version 1.1; SD, stable disease.

*Or until disease progression, unacceptable toxicity or consent withdrawal.
†PRAE is alternative nomenclature for a treatment-related adverse event and is used here to align with the case report form used to collect investigators' responses.

Baseline Characteristics (N=102)

- All patients had past/present medical conditions, mostly vascular (76.5%), metabolic (53.9%), respiratory (53.9%), or cardiac (52.0%) disorders

Characteristic		Cohort A (standard RT; n=59)	Cohort B (palliative RT; n=43)	Total (N=102)
Age	Median (range), years	78.0 (43–87)	80.0 (56–87)	79.0 (43–87)
	≥75 years, %	59.3	72.1	64.7
Sex, %	Male	69.5	74.4	71.6
	Female	30.5	25.6	28.4
Race, %*	White	94.5	95.0	94.7
	Other	1.8	0	1.1
	Unknown	3.6	5.0	4.2
ECOG PS, %*	0	27.6	7.0	18.8
	1	70.7	76.7	73.3
	2	1.7	16.3	7.9
Disease stage, %†	IIIA	61.0	60.5	60.8
	IIIB	33.9	30.2	32.4
	IIIC	5.1	7.0	5.9
PD-L1 expression, %*	TC <1%	44.2	45.2	44.6
	TC ≥1%	53.5	48.4	51.4
Smoking status, %	Current	23.7	16.3	20.6
	Former	64.4	72.1	67.6
	Never	11.9	11.6	11.8

ECOG, Eastern Cooperative Oncology Group; PD-L1, programmed cell death-ligand; PS, performance status; TC, tumour cell

*Percentages were calculated based on the number of patients with non-missing data in the safety analysis set; data were missing for 7 / 1 / 28 patients in the race / ECOG PS / PD-L1 expression categories, respectively. †Disease substage was missing for 1 patient in Cohort B.

Patient Disposition

- All patients received ≥1 dose of durvalumab
- As of 30 March 2023, median total Tx duration was 30.6 weeks (range: 0.3–56.0),* and Tx was ongoing in 21 (20.6%) patients
- In total, 58.8% (Cohort A, 57.6%; Cohort B, 60.5%) had discontinued Tx
  - The most common reasons for discontinuation were AEs (22.5%) and PD (17.6%)

	Cohort A (standard RT; n=59)	Cohort B (palliative RT; n=43)	Total (N=102)
Ongoing study Tx, %	18.6	23.3	20.6
Discontinued study Tx, %	57.6	60.5	58.8
AE	23.7	20.9	22.5
PD	16.9	18.6	17.6
Other†	13.6	16.3	14.7
Patient decision	3.4	4.7	3.9
Completed study Tx, %‡	23.7	16.3	20.6

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AE, adverse event; PD, progressive disease; Tx, treatment.

*Includes dose delays; median actual treatment duration (i.e., excluding dose delays) = 28.4 weeks (range: 0.3–52.0).
†Includes patients who discontinued Tx due to development of study-specific discontinuation criteria (Cohort A, n=4; Cohort B, n=2), death (Cohort A, n=3; Cohort B, n=4) or 'other' reasons (Cohort A, n=1; Cohort B, n=1).
‡Includes patients who 'completed' Tx or for whom the maximum cycle of immunotherapy was reached.

LBA62: Filippi *et. al.*

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Efficacy

Objective Response Rate

Endpoint	Cohort A (standard RT; n=59)	Cohort B (palliative RT; n=43)	Total (N=102)
Confirmed ORR*, % (95% CI)†	28.8 (17.8–42.1)	23.3 (11.8–38.6)	26.5 (18.2–36.1)
Response status, n (%)			
Complete response	0	0	0
Partial response	17 (28.8)	10 (23.3)	27 (26.5)
Stable disease	25 (42.4)	22 (51.2)	47 (46.1)
Progression	10 (16.9)	6 (14.0)	16 (15.7)
RECIST v1.1 progression	6 (10.2)	5 (11.6)	11 (10.8)
Death	4 (6.8)	1 (2.3)	5 (4.9)
Not evaluable	7 (11.9)	5 (11.6)	12 (11.8)

- The confirmed ORR was 26.5% and 46.1% of patients had stable disease

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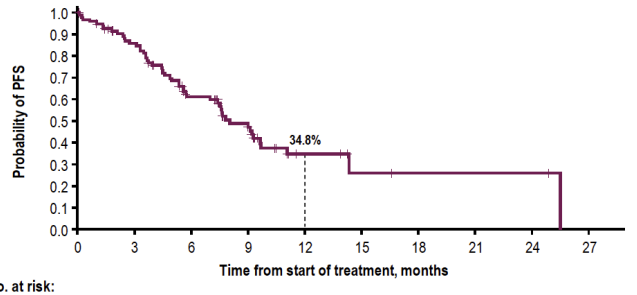
CI, confidence interval; ORR, objective response rate; RECIST v1.1, Response Evaluation Criteria in Solid Tumours version 1.1

*An additional 7 patients (6.9%) had unconfirmed responses (3 [5.1%] in Cohort A and 4 [9.3%] in Cohort B).
†CI calculated using the Clopper-Pearson method.

PFS

	Cohort A (standard RT)	Cohort B (palliative RT)	Total
No. events / no. patients (%)	26/59 (44.1)	25/43 (58.1)	51/102 (50.0)
Median PFS (95% CI)*, months	9.0 (5.6–NC)	7.6 (5.3–11.0)	8.0 (7.0–9.7)
12-month PFS rate (95% CI)†, %	40.2 (23.6–56.3)	29.3 (13.8–46.7)	34.8 (23.0–46.9)



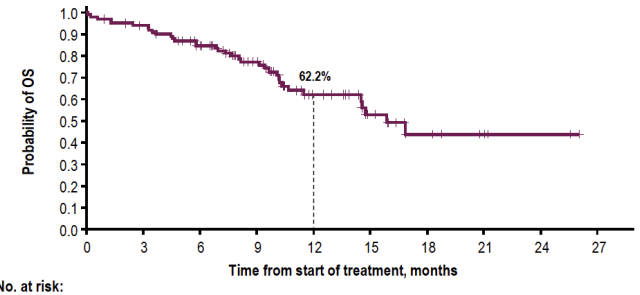
No. at risk:

Total	102	76	47	28	9	3	2	2	2	0

Median follow-up (range) for patients censored for PFS: 7.4 months (0.0–24.9).

OS

	Cohort A (standard RT)	Cohort B (palliative RT)	Total
No. events / no. patients (%)	16/59 (27.1)	19/43 (44.2)	35/102 (34.3)
Median OS (95% CI)*, months	NC (14.5–NC)	14.8 (10.1–NC)	15.9 (11.5–NC)
12-month OS rate (95% CI)†, %	67.0 (50.1–79.2)	56.3 (37.3–71.6)	62.2 (49.8–72.4)



No. at risk:

Total	102	93	78	54	27	15	7	4	2	0

Median follow-up (range) for patients censored for OS: 9.9 months (0.9–26.0).

AEs Summary

- **Grade 3/4 PRAEs* within 6 months (primary endpoint): 9.8% (95% CI: 4.8–17.3)†**
  - Cohort A: 11.9% (95% CI: 4.9–22.9)†
  - Cohort B: 7.0% (95% CI:1.5–19.1)†
- 9.8% had PRAEs leading to discontinuation, most commonly pneumonitis (3.9% of all patients)

	All-cause AEs			PRAEs*		
	Cohort A (standard RT; n=59)	Cohort B (palliative RT; n=43)	Total (N=102)	Cohort A (standard RT; n=59)	Cohort B (palliative RT; n=43)	Total (N=102)
Any AE, n (%)	56 (94.9)	43 (100)	99 (97.1)	40 (67.8)	21 (48.8)	61 (59.8)
Grade 3/4	25 (42.4)	15 (34.9)	40 (39.2)	9 (15.3)	3 (7.0)	12 (11.8)
Within 6 months	—	—	—	7 (11.9)	3 (7.0)	10 (9.8)
SAE	25 (42.4)	13 (30.2)	38 (37.3)	7 (11.9)	2 (4.7)	9 (8.8)
Outcome of death‡	5 (8.5)	2 (4.7)	7 (6.9)	1 (1.7)	0	1 (1.0)
Leading to Tx discontinuation	11 (18.6)	7 (16.3)	18 (17.6)	7 (11.9)	3 (7.0)	10 (9.8)
Leading to Tx interruption	31 (52.5)	17 (39.5)	48 (47.1)	8 (13.6)	5 (11.6)	13 (12.7)
AESI	26 (44.1)	15 (34.9)	41 (40.2)	21 (35.6)	9 (20.9)	30 (29.4)
imAE	23 (39.0)	13 (30.2)	36 (35.3)	22 (37.3)	12 (27.9)	34 (33.3)

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AE, adverse event; AESI, adverse event of special interest; CI, confidence interval; imAE, immune-mediated adverse event; PRAE, adverse event possibly related to treatment; SAE, serious adverse event; Tx, treatment

*PRAE is alternative nomenclature for a treatment-related AE and is used here to align with the case report form used to collect investigators' responses.
†CI calculated using the Clopper-Pearson method.
‡PRAE with outcome of death was pneumonitis (n=1) in Cohort A.

Conclusions

- Durvalumab following thoracic RT had a similar safety profile to that observed with durvalumab after cCRT in the PACIFIC trial and showed encouraging preliminary efficacy in this frailer and older population that are ineligible for CT[1,2]*
- Only 10 of 102 patients (9.8%) had grade 3/4 PRAEs within 6 months of starting Tx (primary endpoint), demonstrating that RT followed by consolidation durvalumab is well-tolerated in patients who are ineligible for CT, including patients with PS 2
- Median PFS was 8.0 months and ~35% of patients were alive and progression free at 1 year after starting durvalumab
  - Median PFS was numerically higher in the 60 Gy cohort (9.0 months), with ~40% alive and progression free at 1 year after starting durvalumab
- Median OS was 15.9 months and ~62% of patients were alive at 1 year after starting durvalumab
  - Notwithstanding changes in modern RT techniques, this compares favourably to historical cohorts treated with RT alone, in which patients experienced a median survival of approximately 8–14 months[3–6]
- **The combination of thoracic RT followed by durvalumab provides a novel option for this common subset of elderly and more fragile patients**

*In the durvalumab arm of the PACIFIC trial, median age was 64 years (range: 31–84) and 49.2% / 50.4% / 0% of patients had PS 0 / 1 / 2, respectively.[1,2]
c, concurrent; CRT, chemoradiotherapy; Gy, Gray (unit of ionization); OS, overall survival; PFS, progression-free survival; PRAE, adverse event possibly related to treatment; PS, performance status.

1. Antonia SJ, et al. N Engl J Med 2017;377:1919–29; 2. Antonia SJ, et al. N Engl J Med 2018;379:2342–50; 3. Provencio M, et al. J Thoracic Dis 2011;3:197–204; 4. Dillman RO, et al. J Natl Cancer Inst 1996;88:1210–5; 5. Sause WT, et al. J Natl Cancer Inst 1995;87:198–205; 6. Davidoff AJ, et al. J Thorac Oncol 2011;6:934–41.

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Iniciativa científica de: GECP lung cancer research

MADRID 2023 ESMO congress

A phase II study of daily carboplatin plus irradiation followed by durvalumab for unresectable stage III non-small cell lung cancer patients with PS 2 or elderly (≧75 years): NEJ039A

(jRCTs031190070).

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Shizuoka Cancer Center[1], Saitama Medical University International Medical Center[2], Kasukabe medical center[3], Akita Kousei Medical Center[4], Omagari Kosei Medical Center[5], Hirosaki University Graduate School of Medicine[6], Toho University Omori Medical Center[7], Hiroshima Prefectural Hospital[8], Kanagawa Cancer center[9], Iwate Medical University[10], Japanese Red Cross Okayama Hospital[11], Asahi General Hospital[12], Hiroshima University Hospital[13]

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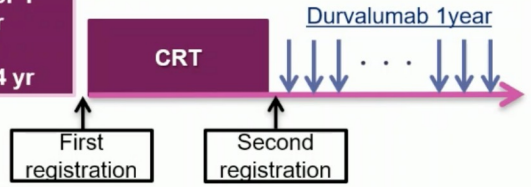
Statistical analysis and Consort diagrams

Unresectable Stage ⅢA/ⅢB/ⅢC (UICC 8th edition)

ECOG PS 0 or 1 from 75 yr or PS 2 up to 74 yr

Low dose CBDCA[1)]

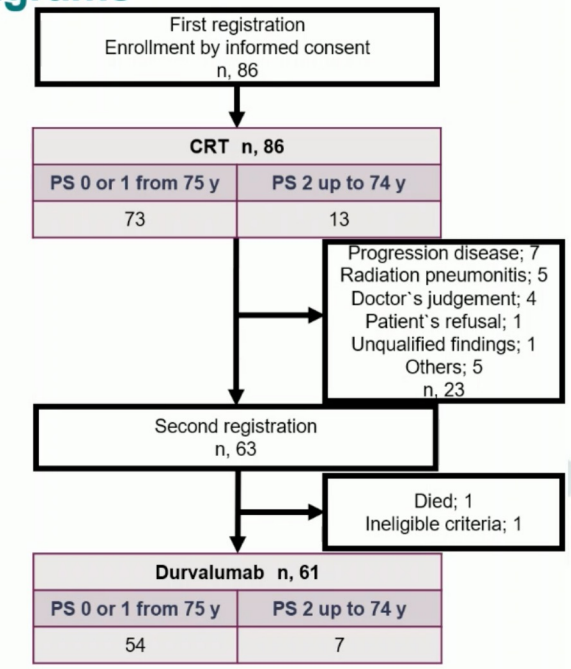
Daily, intravenous, carboplatin (30 mg/m^2 in a 30-min infusion) was administered 1h before radiotherapy for the first 20 fr



Primary endpoint	12-month PFS rate [2)]
Secondary endpoints	the feasibility, ORR, PFS, OS, and AE
Planned number of subjects	58 (second registration)

Assuming that a 12-month PFS rate of 35% in eligible patients would indicate potential usefulness, whereas a 12-month PFS rate of 20% would constitute the lower limit of interest, with $\alpha = 0.10$ and $\beta = 0.20$, the estimated accrual was 53 patients.

Data cutoff date: December 2022 PFS, progression free survival; OS overall survival; CRT, chemoradiotherapy



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Ryo Ko MD, PhD

1) Atagi S, et al. Lancet Oncol. 2012;13:671-678.
2) Kaira K, et al. BMC Cancer. 2020;20:961.

Different variables		Second enrollment n, 61 (%)
Age	Median (range) - year	78.0 (55-89)
Sex	Male	50 (82.0)
	Female	11 (18.0)
Smoking history	Former or current	53 (86.9)
	Never	8 (13.1)
Histologic type	Adenocarcinoma	22 (36.1)
	Squamous cell carcinoma	34 (55.7)
	Others	5 (8.2)
ECOG PS	0	28 (45.9)
	1	26 (42.6)
	2	7 (11.5)
Disease stage*	ⅢA	31 (50.8)
	ⅢB	27 (44.3)
	ⅢC	3 (4.9)
Driver oncogene**	EGFR Negative / Positive / Unknown	27 (44.3) / 7 (11.5) / 27 (44.3)
	ALK Negative / Positive / Unknown	29 (47.5) / 0 (0) / 32 (52.5)
PD-L1 status	<1	17 (27.9)
	1-49	17 (27.9)
	≥50	14 (23.0)
	Unknown	13 (21.3)
Response of CRT	PR	29
	SD	32

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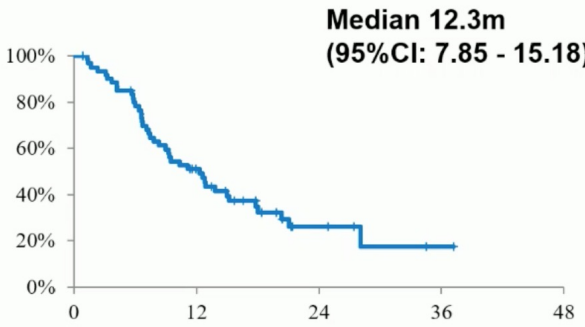
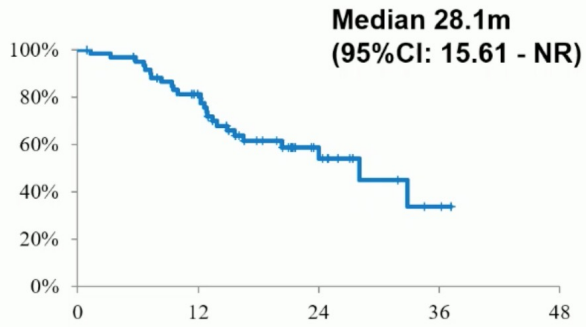
Results : Efficacy of durvalumab consolidation therapy (n, 61)

Primary endpoint：PFS rate of 12 months
51.0% (90%CI: 39.9 - 61.1)

PFS



OS



Adverse events*	All grade* n, (%)	Worst Grade				
		Grade 1 n, (%)	Grade 2 n, (%)	Grade 3 n, (%)	Grade 4 n, (%)	%Grade 3-4 n, (%)
Any event	60 (98.4)	4 (6.6)	26 (42.6)	26 (42.6)	1 (1.6)	44.2%
Hypoalbuminemia	56 (91.8)	43 (70.5)	11 (18.0)	2 (3.3)	0	3.3%
Pneumonitis or radiation pneumonitis	49 (80.3)	17 (27.9)	26 (42.6)	5 (8.2)	0	8.2%
Creatinine elevation	21 (34.4)	18 (29.5)	3 (4.9)	0	0	0
AST elevation	19 (31.1)	18 (29.5)	0	1 (1.6)	0	1.6%
Urine protein	16 (26.2)	13 (21.3)	3 (4.9)	0	-	0
γ-glutamyl transpeptidase elevation	15 (24.6)	11 (18.0)	4 (6.6)	0	0	0
Skin disorder	13 (21.3)	8 (13.1)	4 (6.6)	1 (1.6)	-	1.6%
ALT elevation	12 (19.7)	10 (16.4)	1 (1.6)	1 (1.6)	0	1.6%
Appetite loss	6 (9.8)	3 (4.9)	2 (3.3)	1 (1.6)	0	1.6%
Hypothyroidism	5 (8.2)	0	5 (8.2)	0	0	0
Constipation	5 (8.2)	3 (4.9)	2 (3.3)	0	0	0
Cough	5 (8.2)	5 (8.2)	0	0	-	0
Malaise	4 (6.6)	2 (3.3)	2 (3.3)	0	-	0
Diarrhea or colits	3 (4.9)	2 (3.3)	1 (1.6)	0	0	0
Pyrexia	3 (4.9)	2 (3.3)	1 (1.6)	0	0	0

Conclusions

- **At the end of CRT, around 30% patients could not start durvalumab consolidation due to disease progression, radiation pneumonitis, physician's judgment, and so on.**

- **The primary endpoint of 12 months PFS rate from durvalumab start was met, including durvalumab consolidation after daily carboplatin with radiotherapy was effective for LA-NSCLC vulnerable patients.**

  Statistical assumption of NEJ039A; We assumed that a 1 yr PFS of 35% in eligible patients would indicate potential clinical usefulness, whereas a 1 yr PFS of 20% would be the lower limit of clinical usefulness.

  PACIFIC study for pts with median age of 64; 1 yr PFS rate was 55.9% (95% CI, 51.0 to 60.4)
  NEJ039A for patients with median age 78; 1 yr PFS rate was 51.0% (90% CI, 39.9 to 61.1)

- **Pneumonitis or radiation pneumonitis at any grade were more prevalent than in the PACIFIC study, but Grade 3 or higher was reported less than 10%. Other adverse events were tolerable.**

Lung Cancer UPDATES
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Iniciativa científica de:
GECP
lung cancer research

CPCNP enfermedad localmente avanzada

Ivana Sullivan, MD, PhD

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