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Dr./Dra.

02 EMPOWER-Lung 1: Eficacia
Dr./Dra.

03 Anti PD-(L)1s en 1L CPNM ¿qué aporta Libtayo®?
Dr./Dra.

04 Metaanálisis PD-L1. Monoterapia en 1L
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05 Eficacia en función de los niveles de PD-L1
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06 Pacientes con metástasis cerebrales: ¿cómo tratarlos?
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07 Eficacia en histología escamosa
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# Anti PD-(L)1s en 1L CPNM ¿qué aporta Libtayo®?

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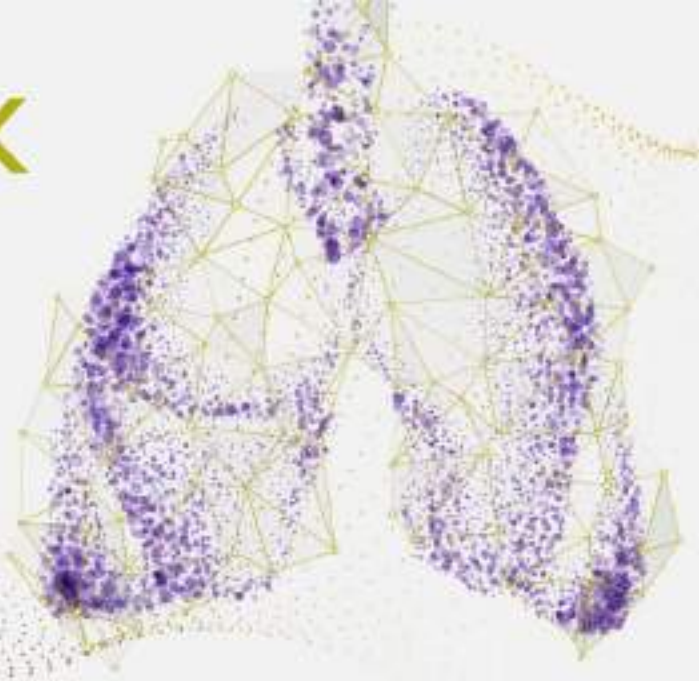


# Características de Cemiplimab, Pembrolizumab y Atezolizumab

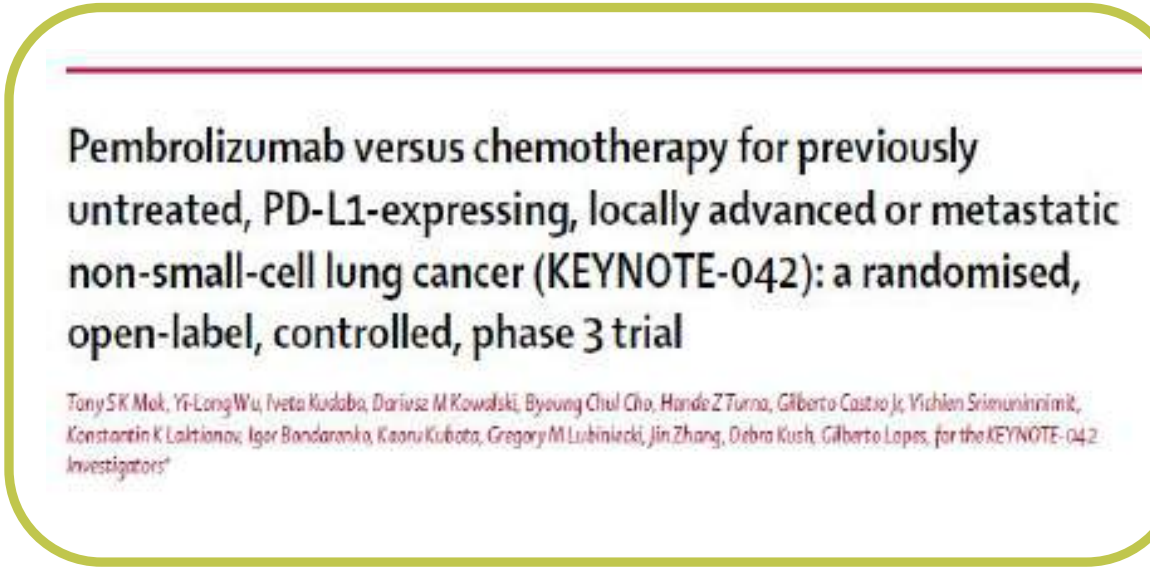
03

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 NOVEMBER 10, 2016 VOL. 375 NO. 19

Pembrolizumab versus Chemotherapy for PD-L1–Positive Non–Small-Cell Lung Cancer

Martin Reck, M.D., Ph.D., Delvys Rodríguez-Abreu, M.D., Andrew G. Robinson, M.D., Rina Hui, M.B., B.S., Ph.D., Tibor Csőszi, M.D., Andrea Fülöp, M.D., Maya Gottfried, M.D., Nir Peled, M.D., Ph.D., Ali Tafreshi, M.D., Sinead Cuffe, M.D., Mary O'Brien, M.D., Suman Rao, M.D., Katsuyuki Hotta, M.D., Ph.D., Melanie A. Leiby, Ph.D., Gregory M. Lubiniecki, M.D., Yue Shentu, Ph.D., Reshma Rangwala, M.D., Ph.D., and Julie R. Brahmer, M.D., for the KEYNOTE-024 Investigators*



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Tony S K Mok, Yi-Long Wu, Iveta Kudaba, Dariusz M Kowalski, Byoung Chul Cho, Hande Z Turna, Gilberto Castro Jr, Yuchen Srimuninnimit, Konstantin K Laktionov, Igor Bondarenko, Kaoru Kubota, Gregory M Lubiniecki, Jin Zhang, Debra Kush, Gilberto Lopes, for the KEYNOTE-042 Investigators*

ORIGINAL ARTICLE

Atezolizumab for First-Line Treatment of PD-L1–Selected Patients with NSCLC

Roy S. Herbst, M.D., Ph.D., Giuseppe Giaccone, M.D., Ph.D., Filippo de Marinis, M.D., Niels Reinmuth, M.D., Alain Vergnenegre, M.D., Carlos H. Barrios, M.D., Masahiro Morise, M.D., Enriqueta Felip, M.D., Zoran Andric, M.D., Sarayut Geater, M.D., Mustafa Özgüroğlu, M.D., Wei Zou, Ph.D., Alan Sandler, M.D., Ida Enquist, Ph.D., Kimberly Komatsubara, M.D., Yu Deng, Ph.D., Hiroshi Kuriki, M.Sc., Xiaohui Wen, M.D., Mark McCleland, Ph.D., Simonetta Mocci, M.D., Ph.D., Jacek Jassem, M.D., Ph.D., and David R. Spigel, M.D.

Cemiplimab monotherapy for first-line treatment of advanced non-small-cell lung cancer with PD-L1 of at least 50%: a multicentre, open-label, global, phase 3, randomised, controlled trial

Ahmet Sezer, Saadettin Kilickap, Mahmut Gumus, Igor Bondarenko, Mustafa Ozguroglu, Miranda Gogishvili, Haci M Turk, Irfan Cicin, Dmitry Bentsion, Oleg Gladkov, Philip Clingan, Virote Sriuranpong, Naiyer Rizvi, Bo Gao, Siyu Li, Sue Lee, Kristina McGuire, Chieh-I Chen, Tamta Makharadze, Semra Paydas, Marina Nechaeva, Frank Seebach, David M Weinreich, George D Yancopoulos, Giuseppe Gullo, Israel Lowy, Petra Rietschel

*Cemiplimab está aprobado para indicaciones de CPNM localmente avanzado y CPNM metastásico. El Sistema Nacional de Salud (SNS) en España solamente financia la indicación en CPNM que expresan PD-L1 ≥50% y en estadio metastásico*

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# Pembrolizumab versus Chemotherapy for PD-L1–Positive Non–Small-Cell Lung Cancer

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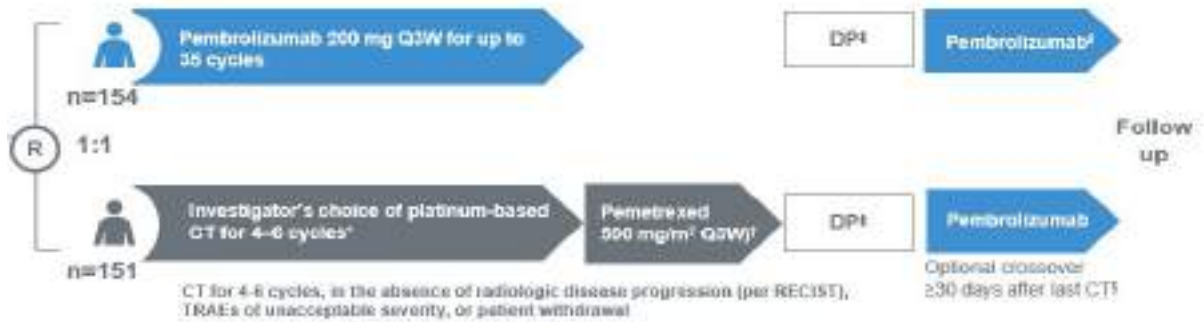
## KEYNOTE-024

**Phase III Trial of Pembrolizumab vs Platinum-Based CT (PD-L1 TPS ≥50%)**




**Primary endpoints:**
PFS per RECIST v1.1 (BICR)

**Key secondary endpoints:**
OS, ORR, safety
Exploratory endpoints:
DoR

**Referencia**: **1**. Reck M*, et al*. N Engl J Med. 2016;375:1823–1833

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# KEYNOTE-024

| Characteristic | Pembrolizumab Group (N = 154) | Chemotherapy Group (N = 151) |
|---|---|---|
| Age — yr | | |
| Median | 64.5 | 66.0 |
| Range | 33–90 | 38–85 |
| Male sex — no. (%) | 92 (59.7) | 95 (62.9) |
| Region of enrollment — no. (%) | | |
| East Asia | 21 (13.6) | 19 (12.6) |
| Non–East Asia | 133 (86.4) | 132 (87.4) |
| ECOG performance-status score — no. (%)† | | |
| 0 | 54 (35.1) | 53 (35.1) |
| 1 | 99 (64.3) | 98 (64.9) |
| Smoking status — no. (%) | | |
| Current | 34 (22.1) | 31 (20.5) |
| Former | 115 (74.7) | 101 (66.9) |
| Never | 5 (3.2) | 19 (12.6) |
| Histology — no. (%) | | |
| Squamous | 29 (18.8) | 27 (17.9) |
| Nonsquamous | 125 (81.2) | 124 (82.1) |
| Brain metastases — no. (%) | 18 (11.7) | 10 (6.6) |
| Previous systemic neoadjuvant therapy — no. (%) | 3 (1.9) | 1 (0.7) |
| Previous systemic adjuvant therapy — no. (%) | 6 (3.9) | 3 (2.0) |

**Referencia**: **1**. Reck M, *et al*. N Engl J Med. 2016;375:1823–1833

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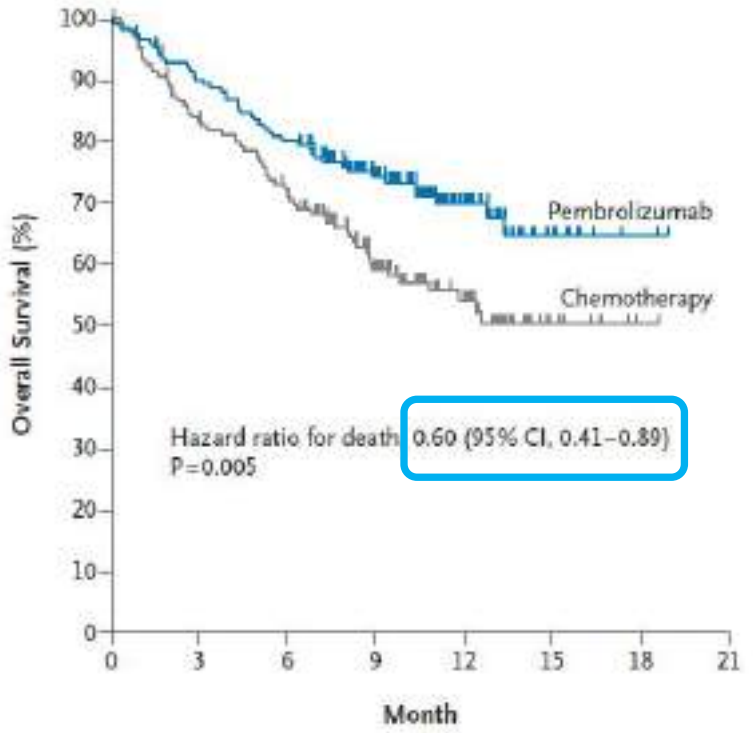


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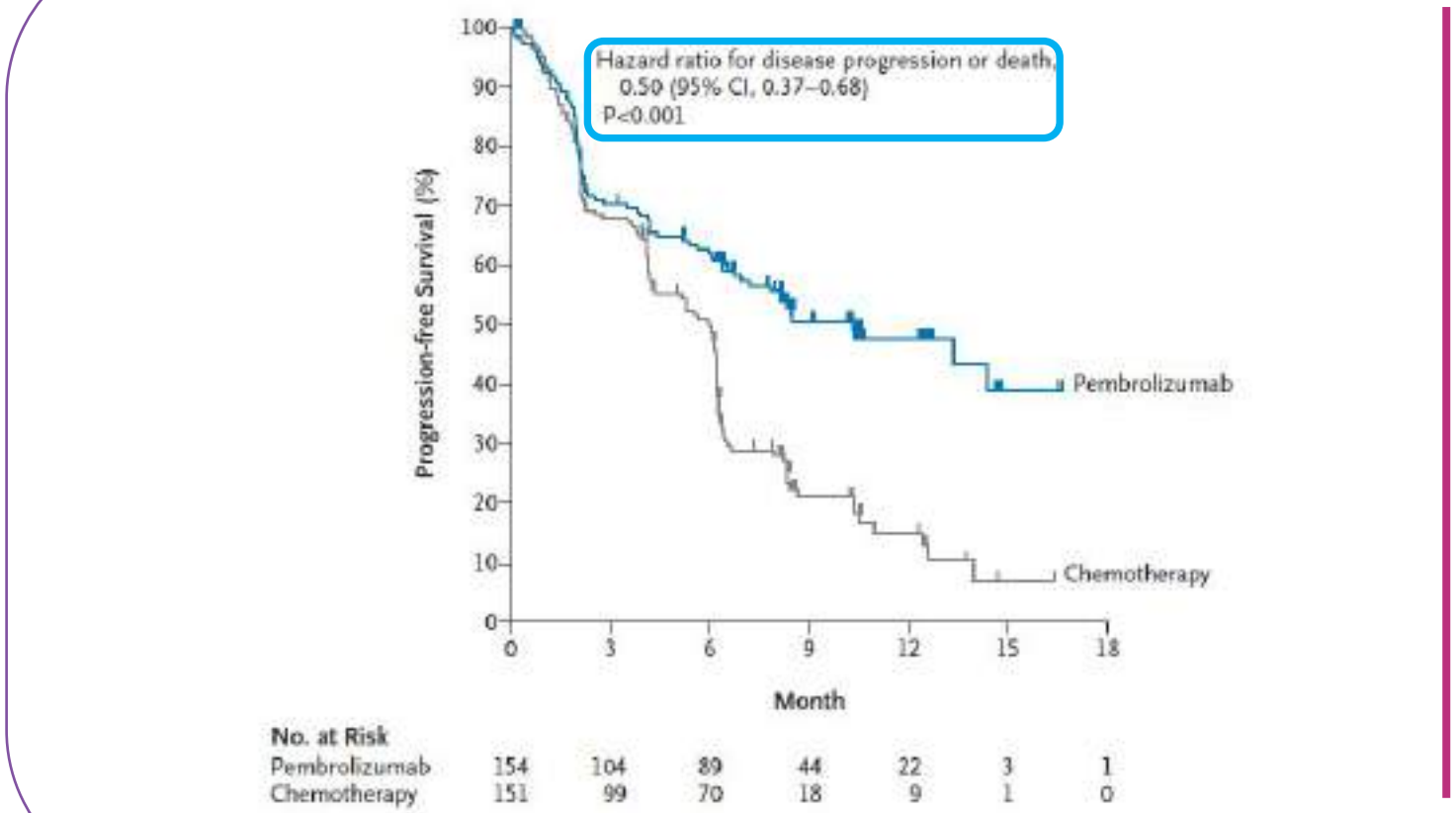


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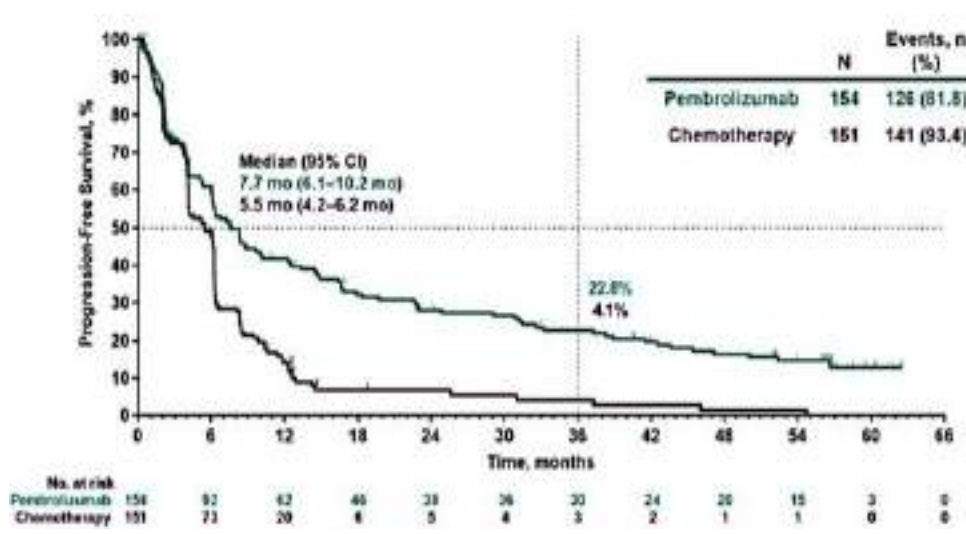
# KEYNOTE-024 [1]

## SG seguimiento a 5 años


| | N | Events, n (%) | HR (95% CI) |
|---|---|---|---|
| Pembrolizumab | 154 | 103 (66.9) | 0.62 (0.48–0.81) |
| Chemotherapy[b] | 151 | 123 (81.5) | |

## SLP seguimiento a 5 años




| | N | Events, n (%) | HR (95% CI) |
|---|---|---|---|
| Pembrolizumab | 154 | 126 (81.8) | 0.50 (0.39–0.65) |
| Chemotherapy | 151 | 141 (93.4) | |

**Referencia: 1**. Reck M, *et al*. Journal of Clinical Oncology 2021 39:21, 2339-2349

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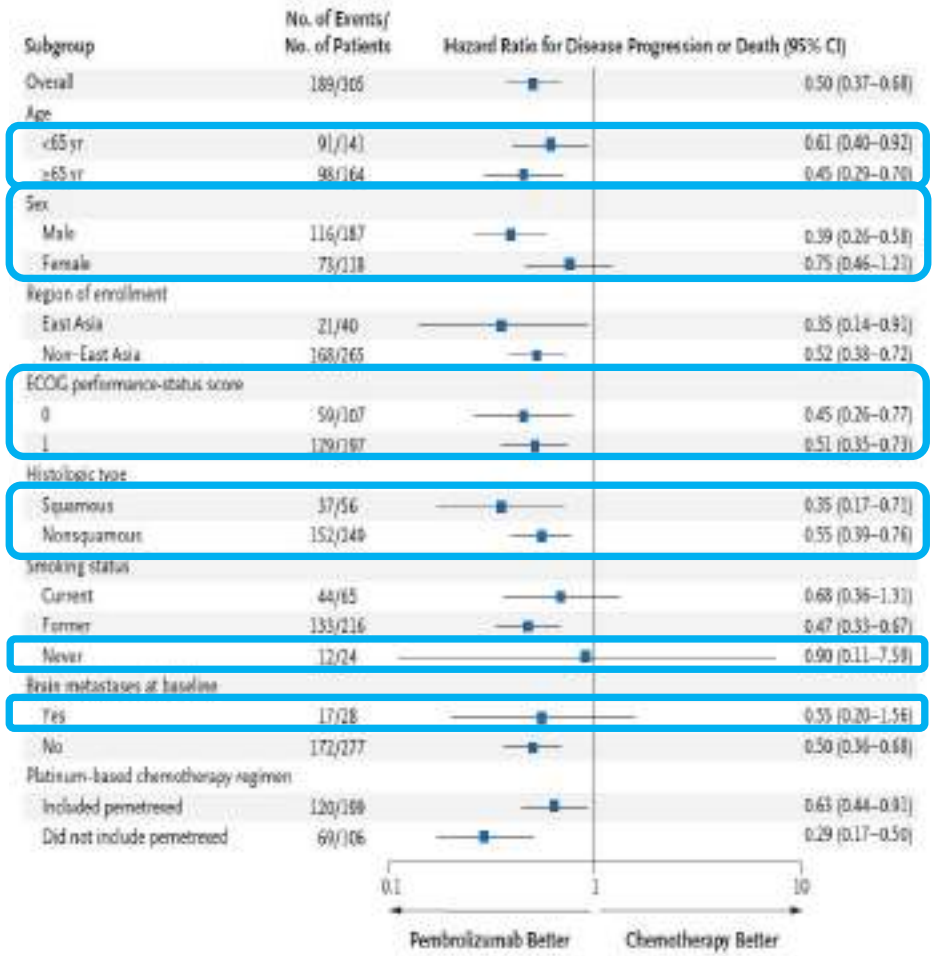


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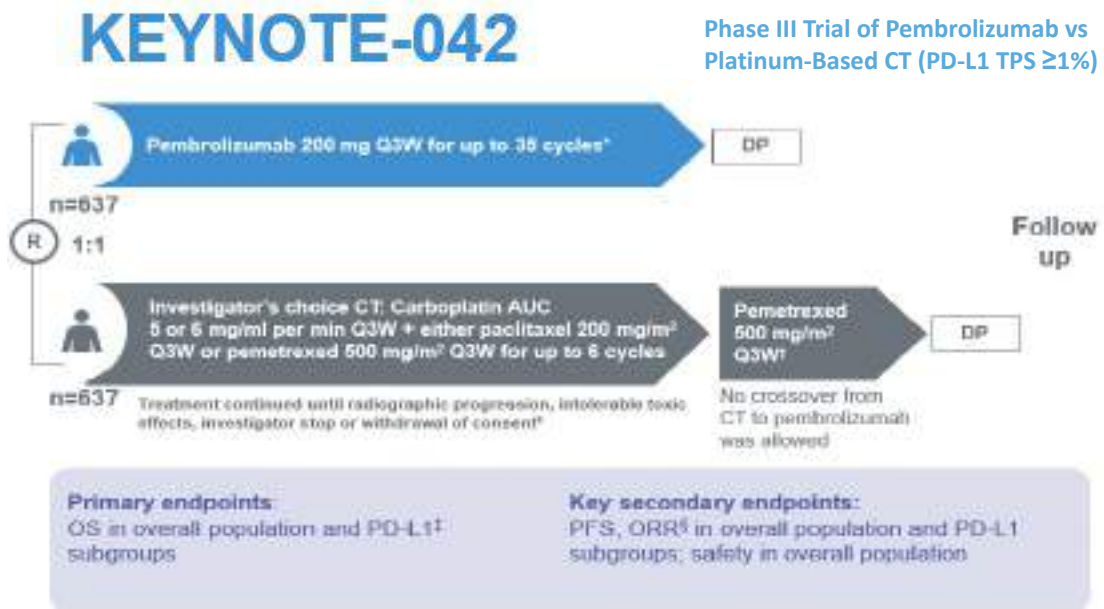
03

# Pembrolizumab versus chemotherapy for previously untreated, PD-L1-expressing, locally advanced or metastatic non-small-cell lung cancer (KEYNOTE-042): a randomised, open-label, controlled, phase 3 trial

Tony S K Mok, Yi-Long Wu, Iveta Kudaba, Dariusz M Kowalski, Byoung Chul Cho, Hande Z Turna, Gilberto Castro Jr, Yichien Srimuninnimit, Konstantin K Laktionov, Igor Bondarenko, Kaoru Kubota, Gregory M Lubiniecki, Jin Zhang, Debra Kush, Gilberto Lopes, for the KEYNOTE-042 Investigators*




**Referencia**: **1.** Mok TSK, *et al.* Lancet. 2019;393:1819–1830.

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# KEYNOTE-042[1]

| | Pembrolizumab group (n=637) | | |
|---|---|---|---|
| | Tumour proportion score ≥50% (n=299) | Tumour proportion score ≥20% (n=413) | Tumour proportion score ≥1% (n=637) |
| Age (years) | 63·0 (56·0–68·0) | 63·0 (56·0–69·0) | 63·0 (57·0–69·0) |
| <65 | 167 (56%) | 228 (55%) | 359 (56%) |
| Men | 205 (69%) | 283 (69%) | 450 (71%) |
| Women | 94 (31%) | 130 (31%) | 187 (29%) |
| Region of enrolment | | | |
| East Asia | 92 (31%) | 128 (31%) | 185 (29%) |
| Europe | 71 (24%) | 96 (23%) | 149 (23%) |
| Latin America | 53 (18%) | 78 (19%) | 136 (21%) |
| Other | 83 (28%) | 111 (27%) | 167 (26%) |
| ECOG performance status score | | | |
| 0 | 96 (32%) | 122 (30%) | 198 (31%) |
| 1 | 203 (68%) | 291 (70%) | 439 (69%) |
| Smoking status | | | |
| Current | 57 (19%) | 75 (18%) | 125 (20%) |
| Former | 178 (60%) | 243 (59%) | 370 (58%) |
| Never | 64 (21%) | 95 (23%) | 142 (22%) |
| Tumour histological features | | | |
| Squamous | 107 (36%) | 148 (36%) | 243 (38%) |
| Non-squamous | 192 (64%) | 265 (64%) | 394 (62%) |
| Disease status | | | |
| Locally advanced | 27 (9%) | 42 (10%) | 76 (12%) |
| Metastatic | 272 (91%) | 371 (90%) | 561 (88%) |
| Brain metastases | 19 (6%) | 23 (6%) | 35 (5%) |

**Referencia**: **1.** Mok TSK, *et al.* Lancet. 2019;393:1819–1830.

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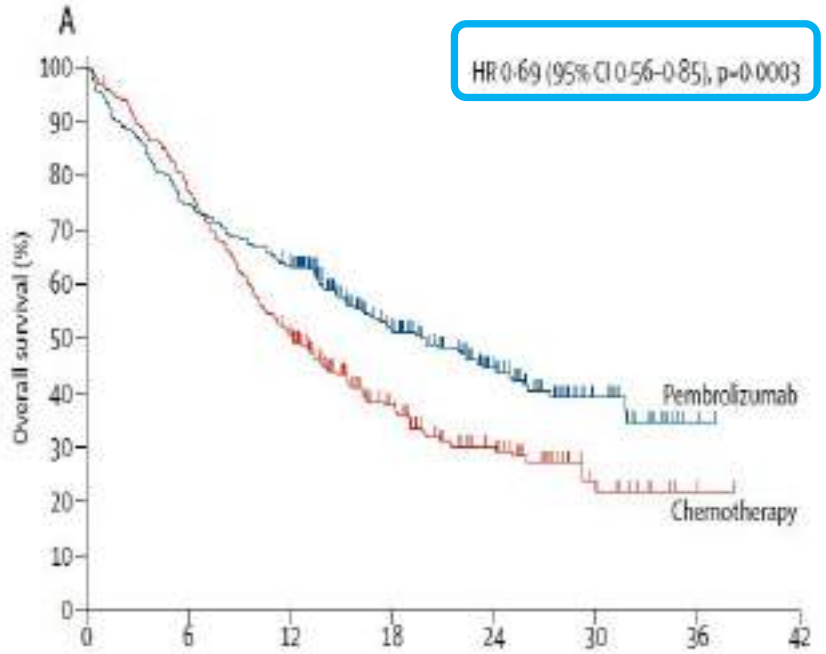


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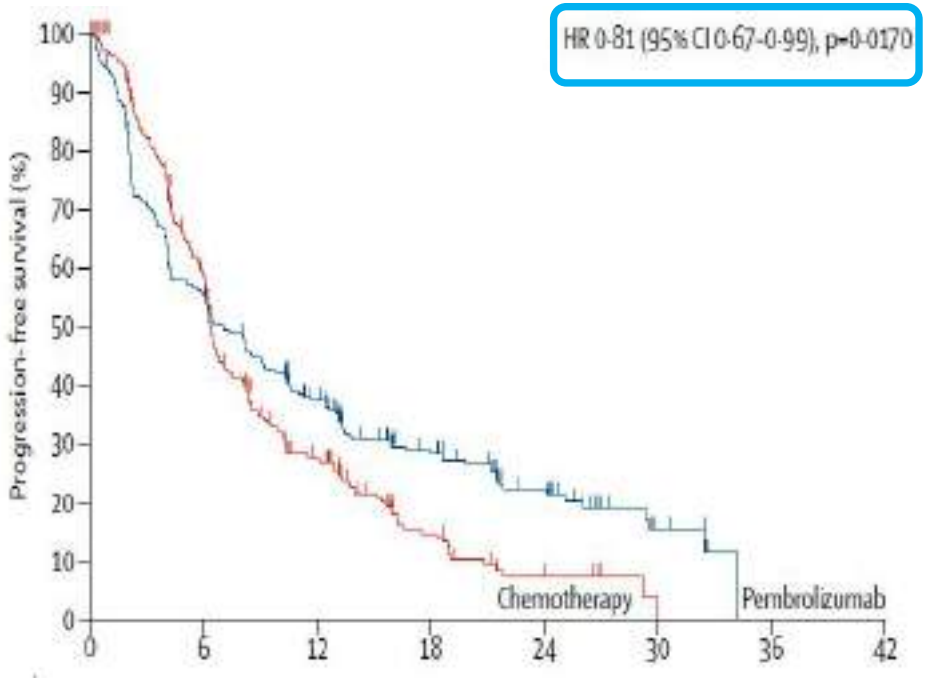


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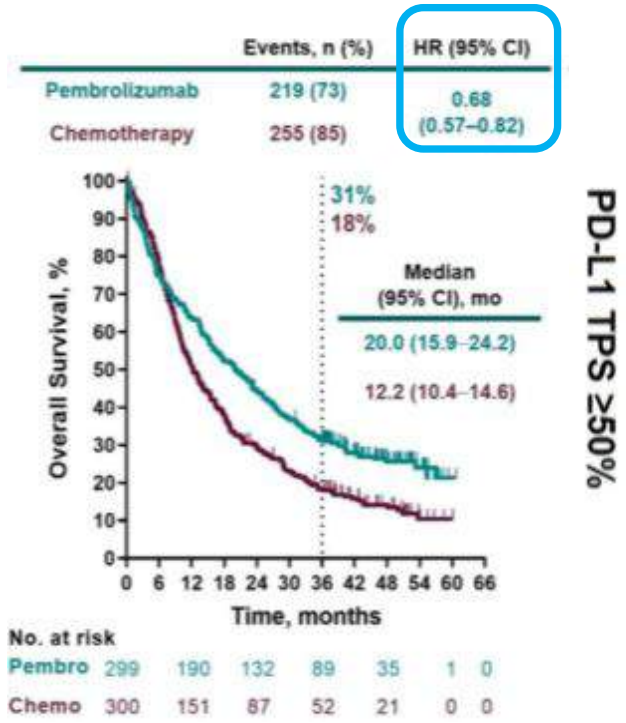
# KEYNOTE-042 [1,2]

## SG seguimiento a 3 años




## SLP seguimiento a 3 años

| | TPS ≥50% | |
|---|---|---|
| | Pembro (N = 299) | Chemo (N = 300) |
| PFS,[a,b,c] median (95% CI), mo | 6.5 (5.9–8.6) | 6.5 (6.2–7.6) |
| HR (95% CI) | 0.85 (0.72–1.02) | |
| PFS,[a] 3-y rate (95% CI), % | 14.5 (10.5–19.0) | 5.3 (3.0–8.7) |
| **PFS2,[a,b] median (95% CI), mo** | **15.0 (11.6–19.2)** | **10.1 (8.9–11.2)** |
| **HR (95% CI)** | **0.62 (0.52–0.74)** | |

**Referencia**: **1.** Mok TSK, *et al.* Lancet. 2019;393:1819–1830. **2.** Cho, B. et al. (2021) Journal of thoracic oncology. 2021; 16 (3), S225–S226.

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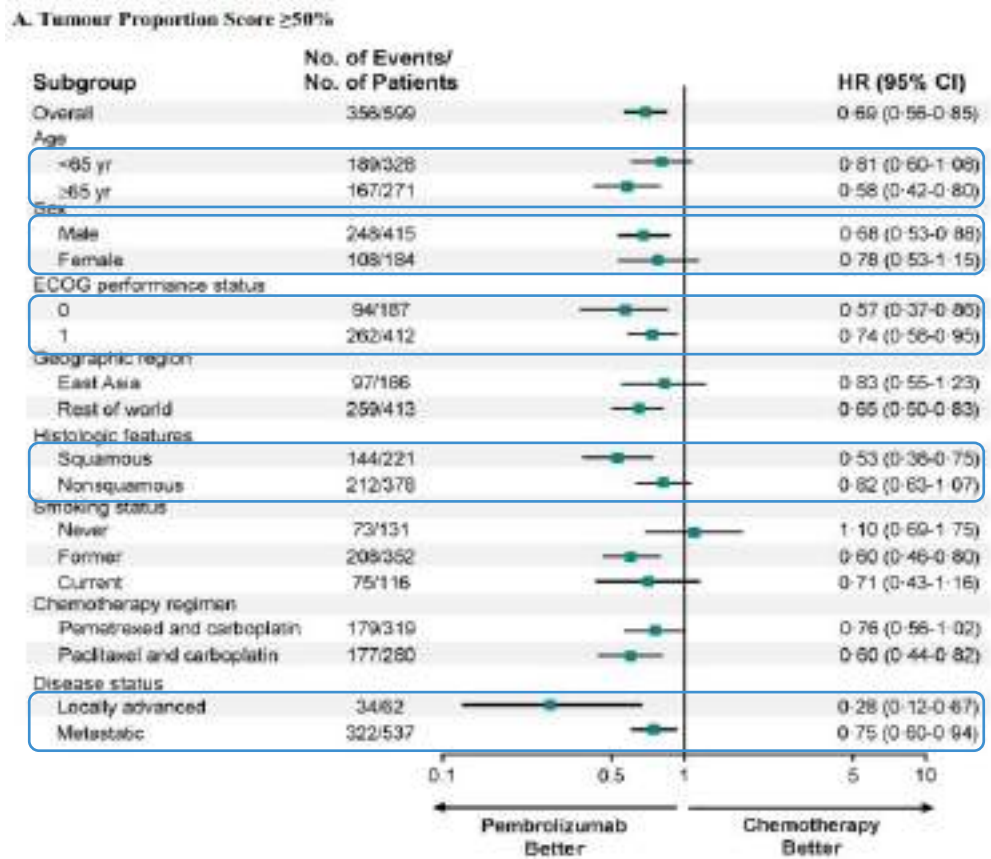


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ORIGINAL ARTICLE

# Atezolizumab for First-Line Treatment of PD-L1–Selected Patients with NSCLC

Roy S. Herbst, M.D., Ph.D., Giuseppe Giaccone, M.D., Ph.D., Filippo de Marinis, M.D., Niels Reinmuth, M.D., Alain Vergnenegre, M.D., Carlos H. Barrios, M.D., Masahiro Morise, M.D., Enriqueta Felip, M.D., Zoran Andric, M.D., Sarayut Geater, M.D., Mustafa Özgüroğlu, M.D., Wei Zou, Ph.D., Alan Sandler, M.D., Ida Enquist, Ph.D., Kimberly Komatsubara, M.D., Yu Deng, Ph.D., Hiroshi Kuriki, M.Sc., Xiaohui Wen, M.D., Mark McCleland, Ph.D., Simonetta Mocci, M.D., Ph.D., Jacek Jassem, M.D., Ph.D., and David R. Spigel, M.D.

## IMpower110

**Phase III Trial of Atezolizumab Compared with a Platinum Agent (Cisplatin or Carboplatin) + (Pemetrexed or Gemcitabine) (PD-L1 TPS ≥1%)**


**Referencia**: **1.** Herbst RS, *et al.* N Engl J Med. 2020;383:1328–1339.

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# IMpower110[1]

| Characteristic | Any PD-L1 Expression | | High or Intermediate PD-L1 Expression | | High PD-L1 Expression | |
|---|---|---|---|---|---|---|
| | Atezolizumab (N = 277) | Chemotherapy (N = 277) | Atezolizumab (N = 166) | Chemotherapy (N = 162) | Atezolizumab (N = 107) | Chemotherapy (N = 98) |
| Median age (range) — yr | 64 (30–81) | 65 (30–87) | 63 (33–81) | 65 (33–87) | 63 (33–79) | 66 (33–87) |
| Male sex — no. (%) | 196 (70.8) | 193 (69.7) | 122 (73.5) | 107 (66.0) | 79 (73.8) | 64 (65.3) |
| Race — no. (%)† | | | | | | |
| White | 227 (81.9) | 240 (86.6) | 133 (80.1) | 139 (85.8) | 87 (81.3) | 82 (83.7) |
| Asian | 45 (16.2) | 30 (10.8) | 31 (18.7) | 20 (12.3) | 20 (18.7) | 15 (15.3) |
| Black | 2 (0.7) | 2 (0.7) | 1 (0.6) | 0 | 0 | 0 |
| Unknown | 2 (0.7) | 5 (1.8) | 1 (0.6) | 3 (1.9) | 0 | 1 (1.0) |
| ECOG performance-status score — no. (%)‡ | | | | | | |
| 0 | 97 (35.0) | 102 (36.8) | 60 (36.1) | 62 (38.3) | 35 (32.7) | 38 (38.8) |
| 1 | 180 (65.0) | 175 (63.2) | 106 (63.9) | 100 (61.7) | 72 (67.3) | 60 (61.2) |
| History of tobacco use — no. (%) | | | | | | |
| Never | 37 (13.4) | 35 (12.6) | 21 (12.7) | 17 (10.5) | 9 (8.4) | 15 (15.3) |
| Current | 74 (26.7) | 81 (29.2) | 38 (22.9) | 52 (32.1) | 20 (18.7) | 29 (29.6) |
| Previous | 166 (59.9) | 161 (58.1) | 107 (64.5) | 93 (57.4) | 78 (72.9) | 54 (55.1) |
| Histologic type at diagnosis — no. (%) | | | | | | |
| Nonsquamous | 192 (69.3) | 193 (69.7) | 122 (73.5) | 116 (71.6) | 80 (74.8) | 75 (76.5) |
| Squamous | 85 (30.7) | 84 (30.3) | 44 (26.5) | 46 (28.4) | 27 (25.2) | 23 (23.5) |

**Referencia**: **1.** Herbst RS, *et al.* N Engl J Med. 2020;383:1328–1339.

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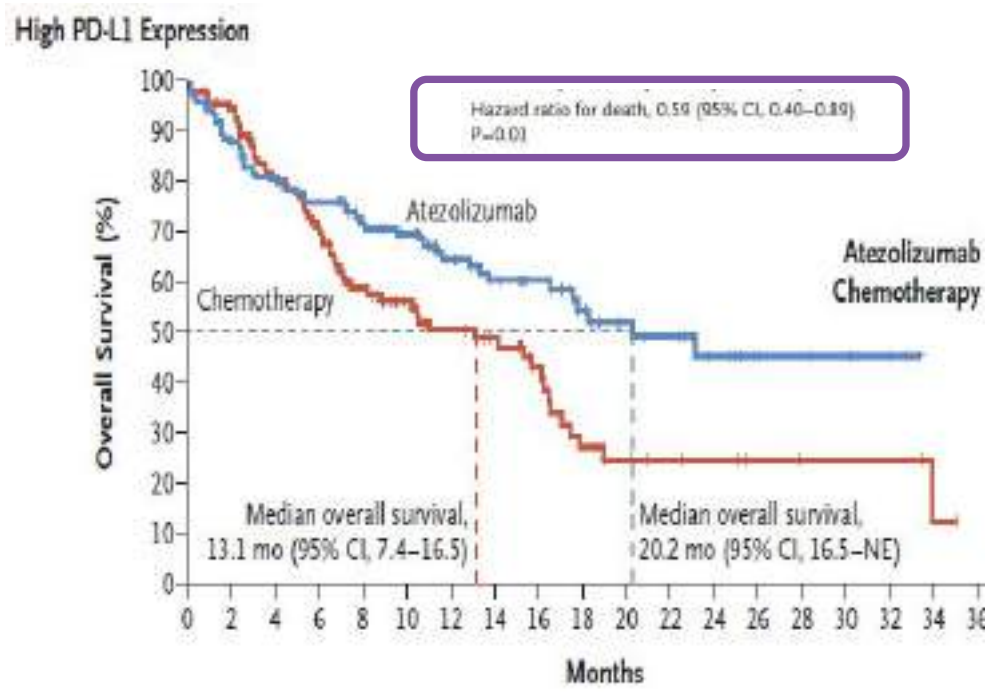


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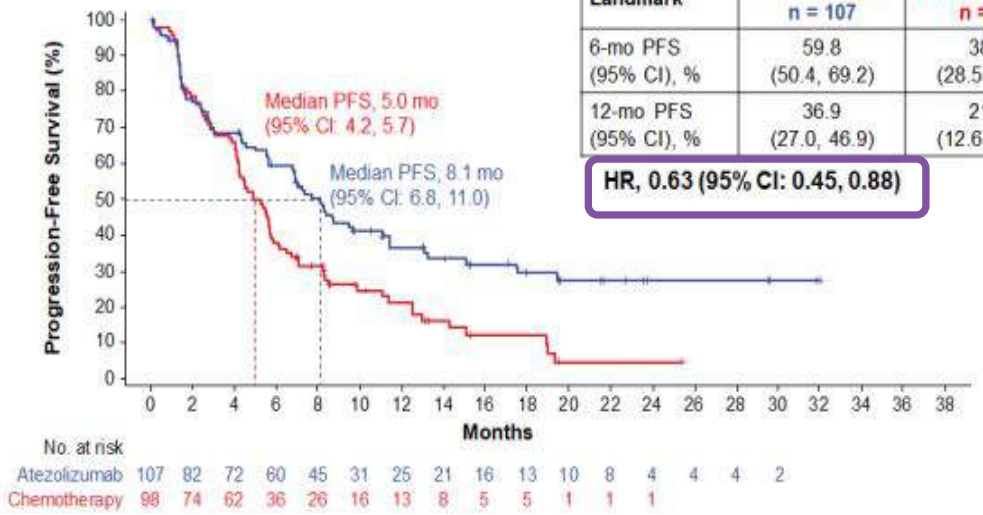
# IMpower110[1]

**A) TC3 or IC3 WT**




| Landmark | Arm A (atezo) n = 107 | Arm B (chemo) n = 98 |
|---|---|---|
| 6-mo PFS (95% CI), % | 59.8 (50.4, 69.2) | 38.3 (28.5, 48.1) |
| 12-mo PFS (95% CI), % | 36.9 (27.0, 46.9) | 21.6 (12.6, 30.6) |

**HR, 0.63 (95% CI: 0.45, 0.88)**

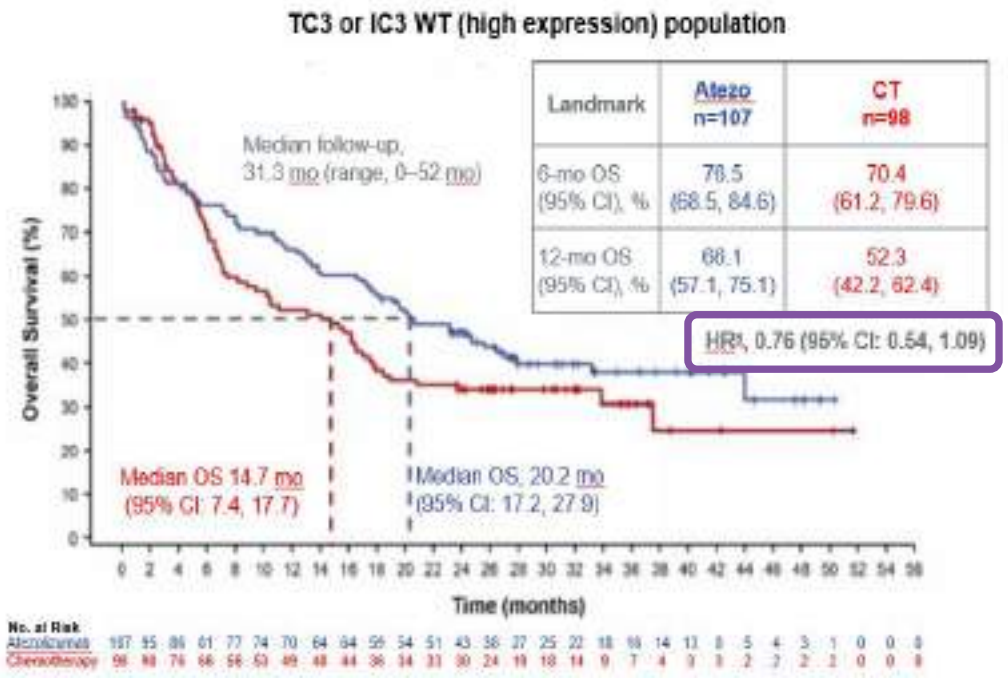
**Referencia**: **1.** Herbst RS, *et al.* N Engl J Med. 2020;383:1328–1339.

*Cemiplimab está aprobado para indicaciones de CPNM localmente avanzado y CPNM metastásico. El Sistema Nacional de Salud (SNS) en España solamente financia la indicación en CPNM que expresan PD-L1 ≥50% y en estadio metastásico*

03

# IMpower110[3]

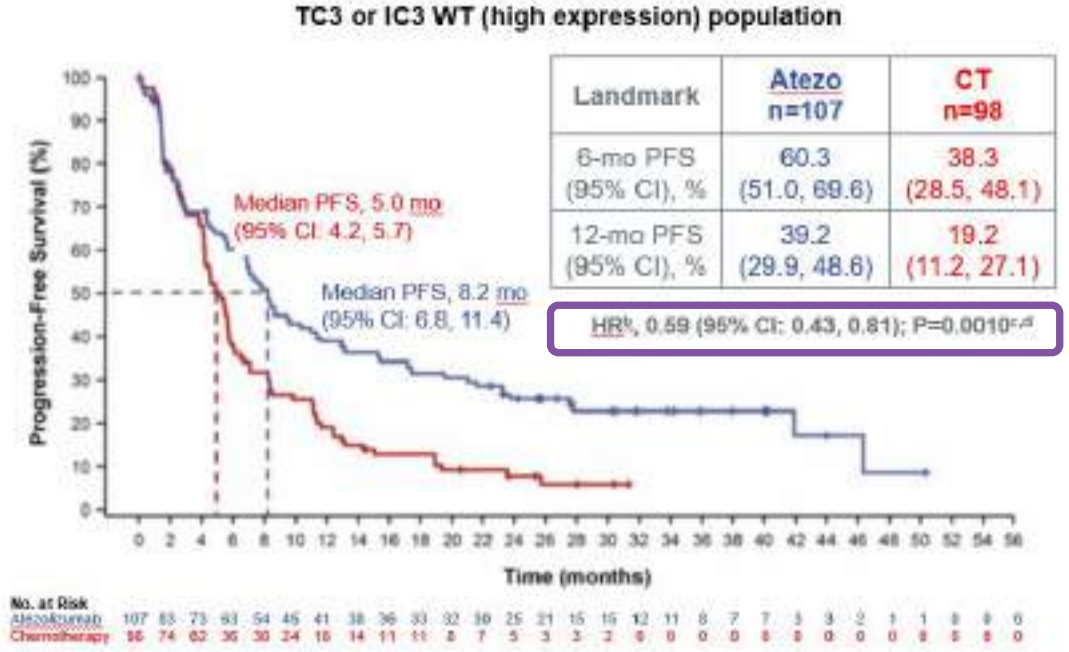
## SG análisis exploratorio




| Landmark | Atezo n=107 | CT n=98 |
|---|---|---|
| 6-mo OS (95% CI), % | 76.5 (68.5, 84.6) | 70.4 (61.2, 79.6) |
| 12-mo OS (95% CI), % | 66.1 (57.1, 75.1) | 52.3 (42.2, 62.4) |

HR[a], 0.76 (95% CI: 0.54, 1.09)

## SLP análisis exploratorio




| Landmark | Atezo n=107 | CT n=98 |
|---|---|---|
| 6-mo PFS (95% CI), % | 60.3 (51.0, 69.6) | 38.3 (28.5, 48.1) |
| 12-mo PFS (95% CI), % | 39.2 (29.9, 48.6) | 19.2 (11.2, 27.1) |

HR[b], 0.59 (95% CI: 0.43, 0.81); P=0.0010[c,d]

**Referencia**: **1**. Herbst RS, *et al*. N Engl J Med. 2020;383:1328–1339. **2.** https://clinicaltrials.gov/ct2/show/NCT02409342. 3. Herbst RS, *et al.* IASLC-WCLC Virtual Congress 2020.

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03

# IMpower110[1]

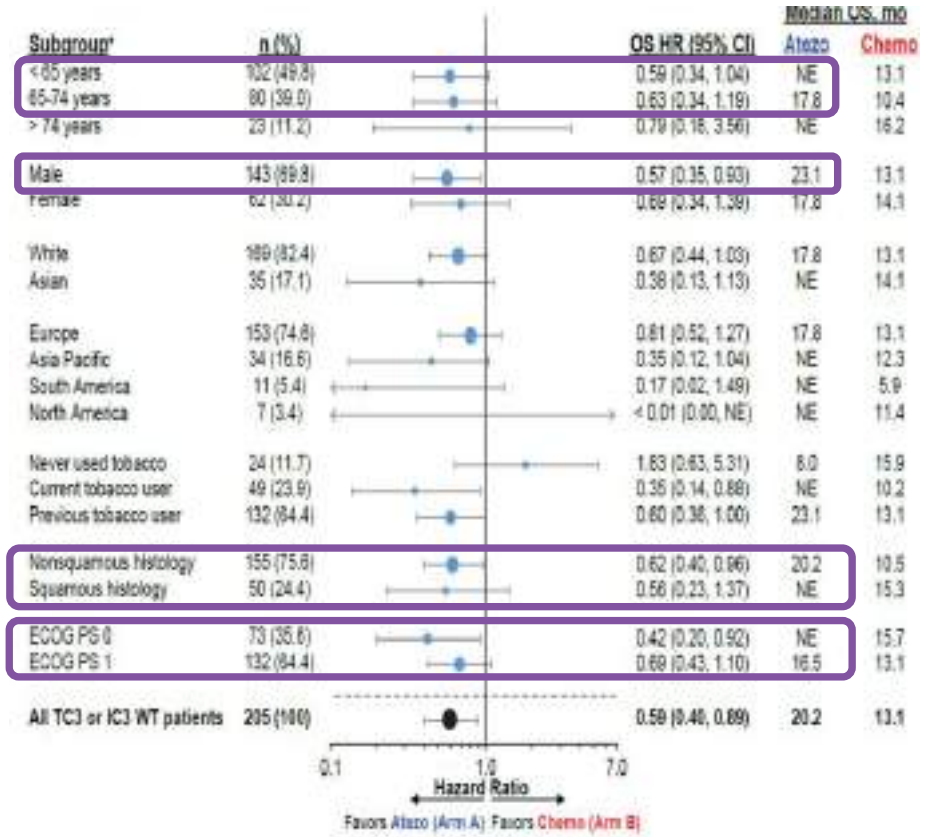



**Figure S4. OS in Key Subgroups of the TC3 or IC3 WT population.**

**Referencia**: **1.** Herbst RS, *et al.* N Engl J Med. 2020;383:1328–1339.

*Cemiplimab está aprobado para indicaciones de CPNM localmente avanzado y CPNM metastásico. El Sistema Nacional de Salud (SNS) en España solamente financia la indicación en CPNM que expresan PD-L1 ≥50% y en estadio metastásico*

03

## Cemiplimab monotherapy for first-line treatment of advanced non-small-cell lung cancer with PD-L1 of at least 50%: a multicentre, open-label, global, phase 3, randomised, controlled trial

Ahmet Sezer, Saadettin Kilickap, Mahmut Gumus, Igor Bondarenko, Mustafa Ozguroglu, Miranda Gogishvili, Hasi M Turk, Irfan Cicin, Dmitry Bentsion, Oleg Gladkov, Philip Clingan, Virote Sriuranpong, Naiyer Rizvi, Bo Gao, Siyu Li, SueLee, Kristina McGuire, Chieh-I Chen, Tamta Makharadze, Semra Paydas, Marina Nacheva, Frank Seebach, David M Weinreich, George D Yancopoulos, Giuseppe Gullo, Israel Lowy, Petra Rietschel

## EMPOWER-Lung 1

**Phase III Trial of Cemiplimab vs Platinum-Based CT (PD-L1 TPS ≥50%)**


**Referencia**: **1.** Sezer A, *et al.* Lancet. 2021;397:592–604

*Cemiplimab está aprobado para indicaciones de CPNM localmente avanzado y CPNM metastásico. El Sistema Nacional de Salud (SNS) en España solamente financia la indicación en CPNM que expresan PD-L1 ≥50% y en estadio metastásico*

03

# EMPOWER-Lung 1[1]

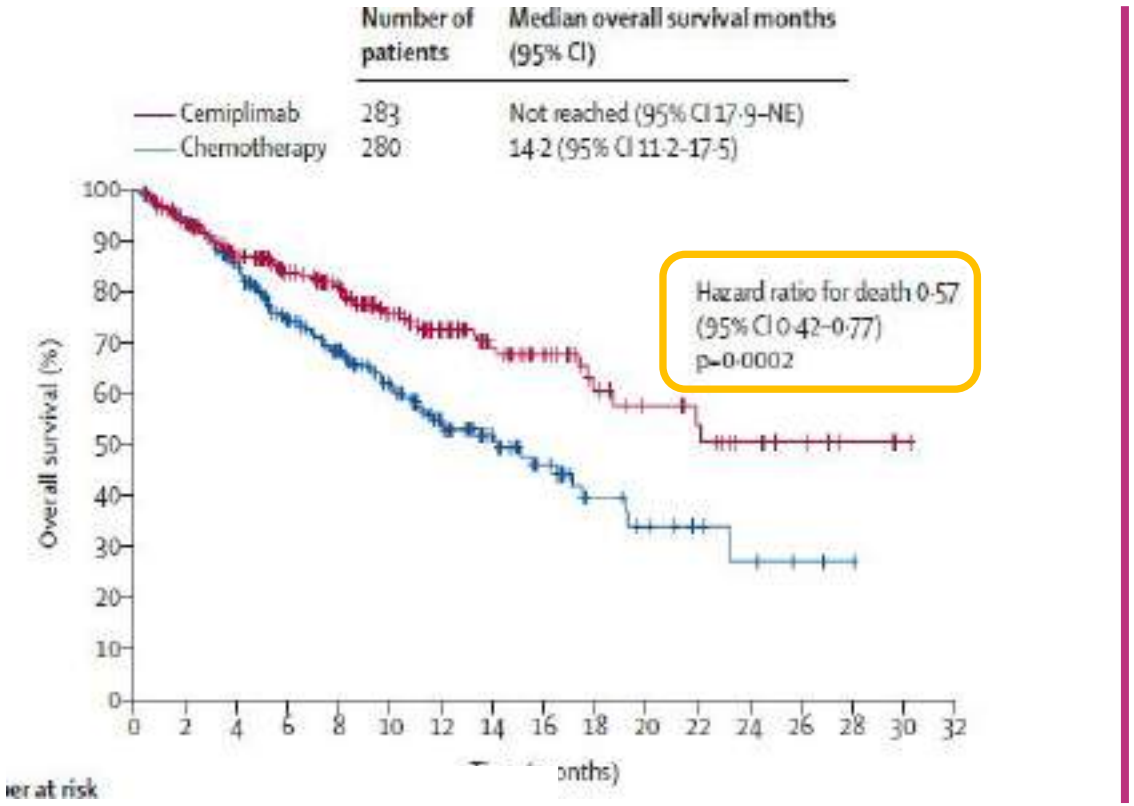
| | Intention-to-treat population | | PD-L1 ≥50% population | |
|---|---|---|---|---|
| | Cemiplimab group (n=356) | Chemotherapy group (n=354) | Cemiplimab group (n=283) | Chemotherapy group (n=280) |
| Age | | | | |
| Median (IQR) | 63 (58-69) | 64 (57-69) | 63 (58-69) | 64 (58-70) |
| ≥65 | 156 (44%) | 164 (46%) | 126 (45%) | 133 (48%) |
| Sex | | | | |
| Female | 44 (12%) | 60 (17%) | 35 (12%) | 49 (18%) |
| Male | 312 (88%) | 294 (83%) | 248 (88%) | 231 (83%) |
| Region of enrolment | | | | |
| Europe | 275 (77%) | 278 (79%) | 215 (76%) | 216 (77%) |
| Asia | 39 (11%) | 38 (11%) | 31 (11%) | 29 (10%) |
| Rest of the world | 42 (12%) | 38 (11%) | 37 (13%) | 35 (13%) |
| Eastern Cooperative Oncology Group performance status score | | | | |
| 0 | 96 (27%) | 96 (27%) | 77 (27%) | 75 (27%) |
| 1 | 260 (73%) | 258 (73%) | 206 (73%) | 205 (73%) |
| Smoking status | | | | |
| Current smoker | 133 (37%) | 120 (34%) | 105 (37%) | 92 (33%) |
| Past smoker | 223 (63%) | 234 (66%) | 178 (63%) | 188 (67%) |
| Histology | | | | |
| Squamous | 159 (45%) | 152 (43%) | 122 (43%) | 121 (43%) |
| Non-squamous | 197 (55%) | 202 (57%) | 161 (57%) | 159 (57%) |
| Brain metastases | 44 (12%) | 39 (11%) | 34 (12%) | 34 (12%) |
| Cancer stage at screening | | | | |
| Locally advanced | 63 (18%) | 52 (15%) | 45 (16%) | 42 (15%) |
| Metastatic | 293 (82%) | 302 (85%) | 238 (84%) | 238 (85%) |
| Previous systemic neoadjuvant therapy | 4 (1%) | 7 (2%) | 3 (1%) | 4 (1%) |
| Previous systemic adjuvant therapy | 9 (3%) | 15 (4%) | 5 (2%) | 12 (4%) |

**Referencia**: **1.** Sezer A, *et al.* Lancet. 2021;397:592–604

*Cemiplimab está aprobado para indicaciones de CPNM localmente avanzado y CPNM metastásico. El Sistema Nacional de Salud (SNS) en España solamente financia la indicación en CPNM que expresan PD-L1 ≥50% y en estadio metastásico*

03

# EMPOWER-Lung 1[1]




**Referencia**: **1.** Sezer A, *et al.* Lancet. 2021;397:592–604

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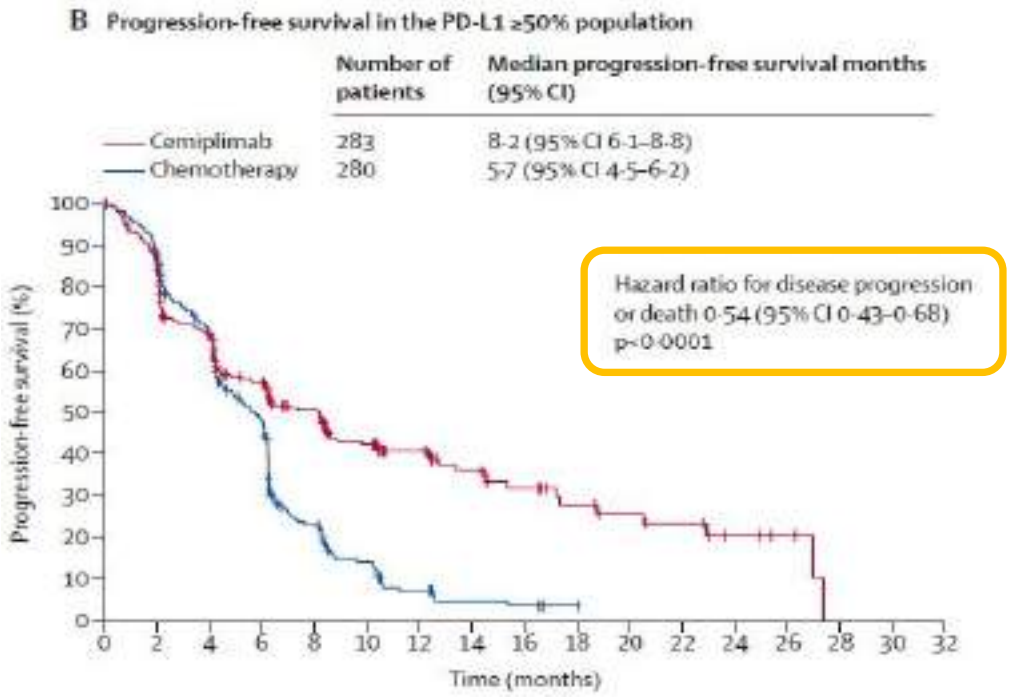
03

# EMPOWER-Lung 1[1]




**Referencia**: **1.** Sezer A, *et al.* Lancet. 2021;397:592–604

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# EMPOWER-Lung 1[1]

**C Overall survival by subgroups in the PD-L1 ≥50% population**

| | Events/number of patients | | Hazard ratio for overall survival (95% CI) | $p_{interaction}$ value |
|---|---|---|---|---|
| | Cemiplimab | Chemotherapy | | |
| **Age (years)** | | | | 0·31 |
| <65 | 41/157 | 50/147 | 0·66 (0·44–1·00) | |
| ≥65 | 29/126 | 55/133 | 0·48 (0·30–0·76) | |
| **Sex** | | | | 0·05 |
| Male | 58/248 | 92/231 | 0·50 (0·36–0·69) | |
| Female | 12/35 | 13/49 | 1·11 (0·49–2·52) | |
| **Region of enrolment** | | | | 0·94 |
| Europe | 55/215 | 84/216 | 0·54 (0·39–0·77) | |
| Asia | 5/31 | 7/29 | 0·76 (0·24–2·41) | |
| Rest of the world | 10/37 | 14/35 | 0·59 (0·26–1·33) | |
| **Eastern Cooperative Oncology Group performance status score** | | | | 0·32 |
| 0 | 18/77 | 23/75 | 0·77 (0·41–1·44) | |
| 1 | 52/206 | 82/205 | 0·54 (0·38–0·76) | |
| **Histology** | | | | 0·53 |
| Squamous | 30/122 | 48/121 | 0·48 (0·30–0·77) | |
| Non-squamous | 40/161 | 57/159 | 0·64 (0·43–0·96) | |
| **Brain metastases at baseline** | | | | 0·23 |
| Yes | 4/34 | 12/34 | 0·17 (0·04–0·76) | |
| No | 66/249 | 93/246 | 0·60 (0·44–0·83) | |
| **Cancer stage at screening** | | | | 0·55 |
| Locally advanced | 9/45 | 15/42 | 0·48 (0·20–1·14) | |
| Metastatic | 61/238 | 90/238 | 0·59 (0·43–0·82) | |
| **Overall** | **70/283** | **105/280** | **0·57 (0·42–0·77)** | |


**Referencia**: **1.** Sezer A, *et al.* Lancet. 2021;397:592–604

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# 03 INDICACIONES APROBADAS POR LA EMA PARA CEMIPLIMAB[1-4]

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## THERAPEUTIC INDICATION

Cutaneous Squamous Cell Carcinoma

- LIBTAYO as monotherapy is indicated for the treatment of adult patients with metastatic or locally advanced cutaneous squamous cell carcinoma (mCSCC or laCSCC) who are not candidates for curative surgery or curative radiation.

Basal Cell Carcinoma

- LIBTAYO as monotherapy is indicated for the treatment of adult patients with locally advanced or metastatic basal cell carcinoma (laBCC or mBCC) who have progressed on or are intolerant to a hedgehog pathway inhibitor (HHI).

Non-Small Cell Lung Cancer

- LIBTAYO as monotherapy is indicated for the first-line treatment of adult patients with non-small cell lung cancer (NSCLC) expressing PD-L1 (in 50% tumour cells), with no EGFR, ALK or ROS1 aberrations, who have:
  - locally advanced NSCLC who are not candidates for definitive chemoradiation, or
  - metastatic NSCLC

## EMMA PENDING APPROVALS

Non-Small Cell Lung Cancer

- Cemiplimab in combination with carboplatin and either paclitaxel or nab-paclitaxel is being tested in EMPOWER LUNG03

Cervical Cancer

- Cemiplimab as monotherapy in R/M cervical cancer that has progressed after 1L platinum-based treatment is being tested in EMPOWER-Cervical 1

**Referencias: 1.** Ficha técnica Libtayo® (Cemiplimab). **2.** NCCN clinical practice guidelines, NSCLC, v6.2020; **2.** Migden MR, *et al*. N Engl J Med..2018;379:341–351; **3.** Migden MR, *et al.* Lancet Oncol.2020;21:294–305; **4.** Papadopoulos KP, *et al.* Clin Cancer Res. 2020;26:1025–1033.

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# INDICACIONES APROBADAS POR LA EMA PARA PEMBROLIZUMAB[1]

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## Melanoma

Keytruda as monotherapy is indicated for the treatment of advanced (unresectable or metastatic) melanoma in adults.
Keytruda as monotherapy is indicated for the adjuvant treatment of adults with Stage III melanoma and lymph node involvement who have undergone complete resection (see section 5.1).

## Non-small cell lung carcinoma (NSCLC)

Keytruda as monotherapy is indicated for the first-line treatment of metastatic non-small cell lung carcinoma in adults whose tumours express PD-L1 with a ≥ 50% tumour proportion score (TPS) with no EGFR or ALK positive tumour mutations.

Keytruda, in combination with pemetrexed and platinum chemotherapy, is indicated for the first-line treatment of metastatic non-squamous non-small cell lung carcinoma in adults whose tumours have no EGFR or ALK positive mutations.

Keytruda, in combination with carboplatin and either paclitaxel or nab-paclitaxel, is indicated for the first-line treatment of metastatic squamous non-small cell lung carcinoma in adults.
Keytruda as monotherapy is indicated for the treatment of locally advanced or metastatic non-small cell lung carcinoma in adults whose tumours express PD-L1 with a ≥ 1% TPS and who have received at least one prior chemotherapy regimen. Patients with EGFR or ALK positive tumour mutations should also have received targeted therapy before receiving KEYTRUDA.

## Classical Hodgkin lymphoma (cHL)

Keytruda as monotherapy is indicated for the treatment of adult and paediatric patients aged 3 years and older with relapsed or refractory classical Hodgkin lymphoma who have failed autologous stem cell transplant (ASCT) or following at least two prior therapies when ASCT is not a treatment option.

## UROTHELIAL CARCINOMA

Keytruda as monotherapy is indicated for the treatment of locally advanced or metastatic urothelial carcinoma in adults who have received prior platinum-containing chemotherapy (see section 5.1).
Keytruda as monotherapy is indicated for the treatment of locally advanced or metastatic urothelial carcinoma in adults who are not eligible for cisplatin-containing chemotherapy and whose tumours express PD-L1 with a combined positive score (CPS) ≥ 10 (see section 5.1).

## Head and neck squamous cell carcinoma (HNSCC)

Keytruda, as monotherapy or in combination with platinum and 5-fluorouracil (5-FU) chemotherapy, is indicated for the first-line treatment of metastatic or unresectable recurrent head and neck squamous cell carcinoma in adults whose tumours express PD-L1 with a CPS ≥ 1 (see section 5.1).

Keytruda as monotherapy is indicated for the treatment of recurrent or metastatic head and neck squamous cell carcinoma in adults whose tumours express PD-L1 with a ≥ 50% TPS and progressing on or after platinum-containing chemotherapy (see section 5.1).

## Renal cell carcinoma (RCC)

Keytruda, in combination with axitinib, is indicated for the first-line treatment of advanced renal cell carcinoma in adults (see section 5.1).

KEYTRUDA, in combination with lenvatinib, is indicated for the first-line treatment of advanced renal cell carcinoma in adults (see section 5.1).

KEYTRUDA as monotherapy is indicated for the adjuvant treatment of adults with renal cell carcinoma at increased risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions (for selection criteria, please see section 5.1).

## Colorectal cancer (CRC)

Keytruda as monotherapy is indicated for the first-line treatment of metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer in adults.

## Oesophageal carcinoma

Keytruda, in combination with platinum and fluoropyrimidine based chemotherapy, is indicated for the first-line treatment of patients with locally advanced unresectable or metastatic carcinoma of the oesophagus or HER-2 negative gastroesophageal junction adenocarcinoma in adults whose tumours express PD-L1 with a CPS ≥ 10 (see section 5.1).

## Triple-negative breast cancer (TNBC)

Keytruda, in combination with chemotherapy, is indicated for the treatment of locally recurrent unresectable or metastatic triple-negative breast cancer in adults whose tumours express PD-L1 with a CPS ≥ 10 and who have not received prior chemotherapy for metastatic disease (see section 5.1).

## Endometrial carcinoma (EC)

KEYTRUDA, in combination with lenvatinib, is indicated for the treatment of advanced or recurrent endometrial carcinoma in adults who have disease progression on or following prior treatment with a platinum-containing therapy in any setting and who are not candidates for curative surgery or radiation.

**Referencias**: **1.** EMA - European Medicines Agency. Keytruda® (pembrolizumab). Ficha Técnica [en línea] [consulta: 18 feb. 2022]. Disponible en: https://www.ema.europa.eu/en/documents/product-information/keytruda-epar-product-information_en.pdf

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03

# INDICACIONES APROBADAS POR LA EMA PARA ATEZOLIZUMAB[1]

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## Urothelial carcinoma

Tecentriq® as monotherapy is indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma (UC):

after prior platinum containing chemotherapy, or - who are considered cisplatin ineligible, and whose tumours have a PD-L1 expression ≥ 5% (see section 5.1)

## Non-small cell lung cancer

Tecentriq® , in combination with bevacizumab, paclitaxel and carboplatin, is indicated for the first-line treatment of adult patients with metastatic non-squamous non small cell lung cancer (NSCLC). In patients with EGFR mutant or ALK-positive NSCLC, Tecentriq® , in combination with bevacizumab, paclitaxel and carboplatin, is indicated only after failure of appropriate targeted therapies (see section 5.1).

Tecentriq® , in combination with nab paclitaxel and carboplatin, is indicated for the first line treatment of adult patients with metastatic non-squamous NSCLC who do not have EGFR mutant or ALK positive NSCLC (see section 5.1).

Tecentriq® as monotherapy is indicated for the first-line treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumours have a PD-L1 expression ≥ 50% tumour cells (TC) or ≥ 10% tumour-infiltrating immune cells (IC) and who do not have EGFR mutant or ALK-positive NSCLC (see section 5.1).

Tecentriq® as monotherapy is indicated for the treatment of adult patients with locally advanced or metastatic NSCLC after prior chemotherapy. Patients with EGFR mutant or ALK positive NSCLC should also have received targeted therapies before receiving Tecentriq® (see section 5.1).

## Small cell lung cancer

Tecentriq® , in combination with carboplatin and etoposide, is indicated for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC) (see section 5.1).

## Hepatocellular carcinoma

Tecentriq® , in combination with bevacizumab, is indicated for the treatment of adult patients with advanced or unresectable hepatocellular carcinoma (HCC) who have not received prior systemic therapy (see section 5.1).

## Urothelial carcinoma

Tecentriq® as monotherapy is indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma (UC):

- after prior platinum containing chemotherapy, or who are considered cisplatin ineligible, and whose tumours have a PD-L1 expression ≥ 5% (see section 5.1).

## Non-small cell lung cancer

Tecentriq® as monotherapy is indicated for the first-line treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumours have a PD-L1 expression ≥ 50% tumour cells (TC) or ≥ 10% tumour-infiltrating immune cells (IC) and who do not have EGFR mutant or ALK-positive NSCLC (see section 5.1).

Tecentriq® as monotherapy is indicated for the treatment of adult patients with locally advanced or metastatic NSCLC after prior chemotherapy. Patients with EGFR mutant or ALK positive NSCLC should also have received targeted therapies before receiving Tecentriq® (see section 5.1).

## Triple-negative breast cancer

Tecentriq® in combination with nab-paclitaxel is indicated for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) whose tumours have PD-L1 expression ≥ 1% and who have not received prior chemotherapy for metastatic disease.

**Referencias**: **1.** EMA - European Medicines Agency. **Tecentriq®** (atezolizumab). Ficha Técnica [en línea] [consulta: 28 abril. 2022]. Disponible en: https://cima.aemps.es/cima/pdfs/es/ft/1171220001/FT_1171220001.pdf

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# 03 CEMIPLIMAB

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| | Cemiplimab | | | | | | |
|---|---|---|---|---|---|---|---|
| Pivotal Study Name(s) | EMPOWER-Lung 1[1] | | | | | | |
| Patient Population | • 1L metastatic or locally advanced NSCLC<br>• PD-L1 ≥50% per FDA-approved test<br>• No sensitizing *EGFR*, *ALK*, or *ROS1* aberrations | Stratification factors | Histology (nonsquamous vs squamous); Region (Europe, Asia or ROW) | Histology:<br>Nonsquamous<br>Squamous | Cemiplimab vs Chemo<br>57% vs 57%<br>43% vs 43% | Overall Survival<br>OS; Hazard ratio (95% CI) | Primary endpoint<br>HR=0.57 (0.42-0.77)<br>(primary) |
| Dosing | 350 mg Q3W until progression or 108 weeks | Treatment beyond progression option? | 32% who progressed on cemiplimab received extended cemiplimab treatment with the addition of chemo | Cancer at screening:<br>Metastatic<br>Locally advanced | Cemiplimab vs Chemo<br>84% vs 85%<br>16% vs 15% | Overall Survival<br>Median OS; months<br>(95% CI) | Primary endpoint<br>NR (17.9-NE) vs 14.2 (11.2-17.5)<br>(primary) |
| Patient Number | ITT: N=710 pts<br>TPS ≥50%: n=563 pts | | | Patients with brain metastases | Cemiplimab vs Chemo<br>12% vs 12% | Progression-Free Survival<br>Median PFS; months<br>(95% CI) | Primary endpoint<br>8.2 (6.1-8.8) vs 5.7 (4.5-6.2), HR=0.54 (0.43-0.68)<br>(primary) |
| PD-L1 Expression Groups | TPS ≥50% | Option to crossover? | 74% who progressed on chemo received cemiplimab as a crossover treatment | EGOP PS<br>0<br>1 | Cemiplimab vs Chemo<br>27% vs 27%<br>73% vs 73% | Overall Response Rate<br>ORR (95% CI) | Secondary endpoint<br>39% (34-45) vs 20% (16-26) (primary) |
| Comparator Arm | Platinum-doublet chemo Q3W<br>(4-6 cycles) | | | Smoking Status | Never-smokers ineligible | Duration of Response Median<br>DOR; months (range) | Secondary endpoint<br>16.7 (12.5 to 22.8) vs 6.0 (4.3 to 6.5)<br>(primary) |
| | | | | | | Median Duration of Follow-Up | 10.8 months (IQR, 7.6 to 15.8) vs 10.9 months (IQR, 7.8 to 15.6)<br>(primary) |

**Referencia**: **1.** . Sezer A, *et al.* Lancet. 2021;397:592–604

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# 03 PEMBROLIZUMAB

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| | Pembrolizumab | | | | | | |
|---|---|---|---|---|---|---|---|
| Pivotal Study Name(s) | KEYNOTE-024[1-5] | | | | | | |
| Patient Population | • 1L Stage IV NSCLC<br>• PD-L1 ≥50% per FDA-approved test<br>• No sensitizing EGFR or ALK aberrations | Stratification factors | ECOG PS (0 vs 1); Histology (nonsquamous vs squamous); Region (East Asian vs non–East Asian) | Histology:<br>Nonsquamous<br>Squamous | Pembrolizumab vs Chemo<br>81.2% vs 82.1%<br>18.8% vs 17.9% | Overall Survival OS; Hazard ratio (95% CI) | Secondary endpoint<br>HR=0.60 (primary)<br>HR=0.63 (extended)<br>HR=0.62 (5 y follow up) |
| Dosing | 200 mg Q3W until progression, unacceptable toxicity, or up to 24 months | Treatment beyond progression option? | No option. Pembrolizumab discontinued upon disease progression | Cancer at screening:<br>Metastatic<br>Locally advanced | Metastatic only | Overall Survival<br>Median OS; months (95% CI) | Secondary endpoint<br>NR vs NR (primary)<br>30 vs 14.2 (extended)<br>26.3 vs 13.4 (5 y follow up |
| Patient Number | N=305 pts | | | Patients with brain metastases | Pembrolizumab vs Chemo<br>11.7% vs 6.6% | Progression-Free Survival<br>Median PFS; months (95% CI) | Primary endpoint<br>10.3 vs 6.0 (primary)<br>HR=0.5<br>7.7 vs 5.5 (5 y follow up)<br>HR=0.5 |
| PD-L1 Expression Groups | TPS ≥50% | Option to crossover? | 64.2% who progressed on chemo received pembrolizumab as a crossover treatment (ITT population) | EGOP PS<br>0<br>1 | Pembrolizumab vs Chemo<br>35.1% vs 35.1%<br>64.3% vs 64.9% | Overall Response Rate<br>ORR (95% CI) | Secondary endpoint<br>45% vs 28% (primary)<br>46.1% vs 31.1% (5 y follow up |
| Comparator Arm | Platinum-based chemo Q3W<br>(4-6 cycles) | | | Smoking Status | Pembrolizumab vs Chemo<br>Current: 22.1% vs 20.5%<br>Former: 74.7% vs 66.9%<br>Never: 3.2% vs 12.6% | Duration of Response<br>Median DOR; months (range) | Secondary endpoint<br>NR vs 6.3 (primary)<br>29.1 vs 6.3 (5 y follow up) |
| | | | | | | Median Duration of Follow-Up | 11.2 months (primary)<br>25.2 months (extended)<br>59.9 months (5 y follow up) |

**Referencia**: **1.** Reck M, *et al.* J Clin Oncol. 2019;37:537–546. **2.** Reck M, *et al.* N Engl J Med. 2016;375:1823–1833. **3.** Reck M, *et al.* J Thoracic Onc. 2019;14;S243. **4.** https://clinicaltrials.gov/ct2/show/NCT02142738. **5.** Reck M, et al. Journal of Clinical Oncology 2021 39:21, 2339-2349

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# 03 PEMBROLIZUMAB

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| | Pembrolizumab | | | | | | |
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| Pivotal Study Name(s) | KEYNOTE-042[1-3] | | | | | | |
| Patient Population | • 1L locally advanced or metastatic NSCLC<br>• PD-L1 positive (≥1%) per FDA-approved test<br>• No sensitizing EGFR or ALK aberrations | Stratification factors | Region (East Asia vs ROW); ECOG PS (0 vs 1); Histology (nonsquamous vs squamous); PD-L1 TPS (≥50% vs 1-49%) | Histology:<br>Nonsquamous<br>Squamous | Pembrolizumab vs Chemo (TPS ≥1%)<br>62% vs 60.9%<br>38.0% vs 39.1% | Overall Survival<br>OS; Hazard ratio (95% CI) | Primary endpoint<br>TPS ≥1%: HR=0.81 (0.71-0.93) (primary); HR=0.80 (0.71-0.90) (3 y follow up)<br>TPS ≥20%: HR=0.77 (0.64-0.92) (primary); HR=0.75 (0.64-0.88) (3 y follow up)<br>TPS ≥50%: HR=0.69 (0.56-0.85) (primary); HR=0.68 (0.57-0.82) (3 y follow up) |
| Dosing | 200 mg Q3W until progression, unacceptable toxicity, or up to 24 months | Treatment beyond progression option? | No option. Pembrolizumab discontinued upon disease progression | Cancer at screening:<br>Metastatic<br>Locally advanced | Pembrolizumab vs Chemo (TPS ≥1%)<br>88% vs 87%<br>12% vs 13% | Overall Survival<br>Median OS; months<br>(95% CI) | Primary endpoint<br>TPS ≥1%: 16.7 (13.9-19.7) vs 12.1 (11.3-13.3) (primary); 16.4 (14.0-19.6) vs 12.1 (11.3-13.3) (3 y follow up)<br>TPS ≥20%: 17.7 (15.3-22.1) vs 13.0 (11.6-15.3) (primary); 18.0 (15.5-21.5) vs 13.0 (11.6-15.3) (3 y follow up)<br>TPS ≥50%: 20.0 (15.4-24.9) vs 12.2 (10.4-14.2) (primary); 20.0 (15.9-24.2) vs 12.2 (10.4-14.6) (3 y follow up) |
| Patient Number | TPS ≥1%: N=1274 pts<br>TPS ≥20%: N=818 pts<br>TPS ≥50%: N=599 pts | | | Patients with brain metastases | Pembrolizumab vs Chemo (TPS ≥1%)<br>5% vs 5% | Progression-Free Survival<br>Median PFS; months<br>(95% CI) | Secondary endpoint<br>TPS ≥1%: 5.4 (4.3-6.2) vs 6.5 (6.3-7.0), HR=1.07 (0.94-1.21) (primary); 11.0 (8.6-13.7) vs 4.1 (2.6-6.2) (3 y follow up)<br>TPS ≥20%: 6.2 (5.1-7.8) vs 6.6 (6.2-7.3), HR=0.94 (0.80-1.11) (primary); 13.2 (10.0-16.9) vs 4.7 (2.7-7.5) (3 y follow up)<br>TPS ≥50%: 7.1 (5.9-9.0) vs 6.4 (6.1-6.9), HR=0.81 (0.67-0.99) (primary); 14.5 (10.5-19.0) vs 5.3 (3.0-8.7) (3 y follow up) |
| PD-L1 Expression Groups | TPS ≥1%<br>TPS ≥20%<br>TPS ≥50% | Option to crossover? | No crossover from chemo group to pembrolizumab was allowed as part of the study | EGOP PS<br>0<br>1 | Pembrolizumab vs Chemo (TPS ≥1%)<br>31% vs 30%<br>69% vs 70% | Overall Response Rate<br>ORR (95% CI) | Secondary endpoint<br>TPS ≥1%: 27% (24-31) vs 27% (23-30) (primary); 27.3% (23.9-31.0) vs 26.7% (23.3-30.3) (3 y follow up)<br>TPS ≥20%: 33% (29-38) vs 29% (25-34) (primary); 33.2% (28.6-37.9) vs 29.1% (24.8-33.8) (3 y follow up)<br>TPS ≥50%: 39% (34-45) vs 32% (27-38) (primary); 39.1% (33.6-44.9) vs 32.3% (27.1-37.9) (3 y follow up) |
| Comparator Arm | Platinum-based chemo Q3W<br>(4-6 cycles) | | | Smoking Status | Pembrolizumab vs Chemo (TPS ≥1%)<br>Current: 20% vs 23%<br>Former: 58% vs 55%<br>Never: 22% vs 22% | Duration of Response<br>Median DOR; months (range) | TPS ≥1%: 20.2 vs 8.3 (primary); 22.3 (2.1+ to 56.0+) vs 8.4 (1.8+ to 49.6+) (3 y follow up)<br>TPS ≥20%: 20.2 vs 8.3 (primary); 22.3 (2.1+ to 56.0+) vs 10.8 (1.8+ to 49.6+) (3 y follow up)<br>TPS ≥50%: 20.2 vs 10.8 (primary); 27.3 (2.1+ to 56.0+) vs 10.8 (1.8+ to 49.6+) (3 y follow up) |
| | | | | | | Median Duration of Follow-Up | 12.8 months (IQR, 6.0 to 20.0) (primary)<br>46.9 months (range, 35.8 to 62.1) (3 y follow up) |

**Referencia**: **1.** Mok TSK, *et al.* Lancet. 2019;393:1819–1830. 2. Cho, B. et al. (2021) Journal of thoracic oncology. 2021; 16 (3), S225–S226.

*Cemiplimab está aprobado para indicaciones de CPNM localmente avanzado y CPNM metastásico. El Sistema Nacional de Salud (SNS) en España solamente financia la indicación en CPNM que expresan PD-L1 ≥50% y en estadio metastásico*

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# 03 ATEZOLIZUMAB

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| | Atezolizumab | | | | | | |
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| Pivotal Study Name(s) | IMpower110[1,2] | | | | | | |
| Patient Population | • 1L Stage IV NSCLC<br>• PD-L1 ≥50% per FDA-approved test<br>• No sensitizing EGFR or ALK aberrations | Stratification factors | Sex; ECOG PS (0 vs 1); PD-L1 expression (≥1% on TC and any IC vs <1% on TC and ≥1% on IC); Histology (nonsquamous vs squamous) | Histology:<br>Nonsquamous<br>Squamous | Atezolizumab vs Chemo (WT)<br>69.3% vs 69.7%<br>30.7% vs 30.3% | Overall Survival OS; Hazard ratio (95% CI) | Primary endpoint<br>TPS ≥1%: HR=0.85 (0.69-1.04) (primary)<br>TPS ≥5%: HR=0.87 (0.66-1.14) (primary)<br>TPS ≥50%: HR=0.59 (0.40-0.89) (primary); HR=0.76 (0.54-1.09) (updated) |
| Dosing | 1200 mg Q3W until progression, unacceptable toxicity, loss of clinical benefit, or death | Treatment beyond progression option? | Continuation of atezolizumab after disease progression allowed in patients experiencing benefit, details not reported | Cancer at screening:<br>Metastatic<br>Locally advanced | Metastatic only | Overall Survival Median OS; months (95% CI) | Primary endpoint<br>TPS ≥1%: 18.9 (13.4-23.0) vs 14.7 (11.2-16.5) (primary)<br>TPS ≥5%: 19.9 (17.2-25.3) vs 16.1 (12.6-18.0) (primary)<br>TPS ≥50%: 20.2 (16.5, NE) vs 13.1 (7.4-16.5) (primary); 20.2 (17.2-27.9) vs 14.7 (7.4-17.7) (updated) |
| Patient Number | TC1/2/3 or IC1/2/3 WT (PD-L1 ≥1%): N=554 pts<br>TC2/3 or IC2/3 WT (PD-L1 ≥5%): N=328 pts<br>TC3 or IC3 WT (PD-L1 ≥50%): N=205 pts | | | Patients with brain metastases | Not reported | Progression-Free Survival Median PFS; months (95% CI) | Secondary endpoint<br>TPS ≥1%: 5.8 (5.5-7.3) vs 5.6 (4.7-5.7), HR=0.72 (0.60-0.86) (updated†)<br>TPS ≥5%: 7.3 (5.6-9.3) vs 5.5 (4.5-5.7), HR=0.64 (0.50-0.82) (updated†)<br>TPS ≥50%: 8.2 (6.8-11.4) vs 5.0 (4.2-5.7), HR=0.59 (0.43-0.81) (updated) |
| PD-L1 Expression Groups | TC1/2/3 (PD-L1≥1% on TC or IC)<br>TC2/3 (PD-L1 ≥5% on TC or IC)<br>TC3 (PD-L1≥50% on TC or ≥10% on IC) | Option to crossover? | Crossover at progression was not permitted by protocol | EGOP PS<br>0<br>1 | Atezolizumab vs Chemo (WT)<br>35.0% vs 36.8%<br>65.0% vs 63.2% | Overall Response Rate ORR (95% CI) | Secondary endpoint<br>TPS ≥1%: 31.4% vs 32.1% (updated)<br>TPS ≥5%: 33.7% vs 32.1% (updated)<br>TPS ≥50%: 40.2% vs 28.6% (updated) |
| Comparator Arm | Platinum-based chemo Q3W (4-6 cycles) | | | Smoking Status | Atezolizumab vs Chemo (WT)<br>Current: 26.7% vs 29.2%<br>Former: 59.9% vs 58.1%<br>Never: 13.4% vs 12.6% | Duration of Response Median DOR; months (range) | Secondary endpoint<br>TPS ≥1%: 26.3 (2.1 to 46.3+) vs 5.7 (2.4 to 31.2+) (updated†)<br>TPS ≥5%: 38.9 (2.8 to 46.3+) vs 5.8 (2.6 to 31.2+) (updated†)<br>TPS ≥50%: 38.9 (2.8 to 46.3+) vs 8.3 (2.6 to 30.0+) (updated†) |
| | | | | | | Median Duration of Follow-Up | TPS ≥1%: NA<br>TPS ≥5%: NA<br>TPS ≥50%: 15.7 months (range, 0 to 33) (primary); 31.3 months (range, 0 to 52) (updated) |

**Referencia**: **1.** https://clinicaltrials.gov/ct2/show/NCT02409342 **2.** Herbst RS, *et al.* N Engl J Med. 2020;383:1328–1339.

*Cemiplimab está aprobado para indicaciones de CPNM localmente avanzado y CPNM metastásico. El Sistema Nacional de Salud (SNS) en España solamente financia la indicación en CPNM que expresan PD-L1 ≥50% y en estadio metastásico*

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