MSD

TAKE A CLOSER LOOK AT BOB

Could KEYTRUDA in combination with carb-pac transform treatment expectations for patients like Bob?*

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.[1]

The recommended dose of KEYTRUDA as part of combination therapy is 200 mg every 3 weeks administered as an intravenous infusion over 30 minutes.[1]

Prescribing information for Great Britain.

Prescribing information for Northern Ireland.

If using a downloaded version of this material, please ensure that you are accessing the most recent version of the prescribing information.

Refer to the Summary of Product Characteristics and Risk Minimisation materials available on the EMC website before prescribing.

Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Merck Sharp & Dohme (UK) Limited (Tel: 0208 154 8000).

Patient is fictional and for illustrative purposes only.

*First-line patients with squamous metastatic NSCLC regardless of tumour PD-L1 expression status.[1,2]

NSCLC: non-small cell lung cancer; **PD-L1:** programmed death-ligand 1.

References: 1. KEYTRUDA Summary of Product Characteristics. Available from: https://www.medicines.org.uk/emc/search?q=Keytruda.
2. Paz-Ares L, *et al. N Engl J Med* 2018; 379: 2040–2051.

Date of Preparation: August 2021. GB-PDO-00935.

KEYTRUDA®
(pembrolizumab)

MEET BOB

Bob's lived a wild life and it shows – but he still loves his record collection and even rides his motorbike when he's able. He can still self-care and move about (although some days are harder than others).

- 62-year-old male from Dawlish
- Stage IV NSCLC, squamous
- Negative for EGFR and ALK mutations; PD-L1 TPS<1%
- No liver or brain metastases at diagnosis
- Current smoker with a 25 pack-year history

How do you approach first-line treatment in squamous mNSCLC?

ALK: anaplastic lymphoma kinase; **EGFR:** epidermal growth factor receptor; **mNSCLC:** metastatic non-small cell lung cancer; **NSCLC:** non-small cell lung cancer; **PD-L1:** programmed death-ligand 1; **TPS:** tumour proportion score.

TREATMENT OPTIONS REMAIN LIMITED FOR FIRST-LINE THERAPY OF SQUAMOUS METASTATIC NSCLC[1]

Median survival for squamous metastatic NSCLC is approximately 30% shorter than for patients with other NSCLC subtypes[1]

With KEYTRUDA plus carb-pac/nabpac, you can provide improved survival at first-line vs. carb-pac/nabpac alone to more patients like Bob[2–4]

Helping you make more tomorrows possible[2–4]

NSCLC: non-small cell lung cancer.

References: **1.** Socinski MA, *et al. J Thorac Oncol* 2018; 132(2): 165–183. **2.** Paz-Ares L, *et al. N Engl J Med* 2018; 379: 2040–2051. **3.** Robinson A, *et al.* Presented at European Lung Cancer Virtual Congress (ELCC) 2021; March 25–27, 2021; virtual. **4.** KEYTRUDA Summary of Product Characteristics. Available from: https://www.medicines.org.uk/emc/search?q=Keytruda.

MORE TOMORROWS MADE POSSIBLE FOR THESE mNSCLC PATIENTS

First-line patients with squamous metastatic NSCLC, regardless of tumour PD-L1 expression status[1]

KEYTRUDA + carb-pac/nabpac proved its efficacy in the second interim analysis of KEYNOTE-407 (ITT population)*[1]

Both primary endpoints were met at the time of the second interim analysis*[1]

OS[1]

KEYTRUDA + carb-pac/nabpac reduced the risk of death by 36% vs. placebo + carb-pac/nabpac

HR = 0.64
(95% CI 0.49–0.85) p<0.001

mOS 15.9 months (95% CI 13.2–NR) with KEYTRUDA + carb-pac/nabpac vs. **11.3 months** (95% CI 9.5–14.8) with placebo + carb-pac/nabpac

PFS[1]

The risk of disease progression or death was reduced by 44% with KEYTRUDA + carb-pac/nabpac vs. placebo + carb-pac/nabpac

HR = 0.56
(95% CI 0.45–0.70) p<0.001

mPFS 6.4 months (95% CI 6.2–8.3) with KEYTRUDA + carb-pac/nabpac vs. **4.8 months** (95% CI 4.3–5.7) with placebo + carb-pac/nabpac

ORR[1]

Overall response was improved with KEYTRUDA + carb-pac/nabpac vs. placebo + carb-pac/nabpac

ORR 57.9% (95% CI 51.9–63.8) with KEYTRUDA + carb-pac/nabpac vs. **38.4%** (95% CI 32.7–44.4) with placebo + carb-pac/nabpac

*Based on the results of the ITT population in the second interim analysis of KEYNOTE-407, a randomised, controlled phase 3 trial (n=559); primary endpoints: OS and PFS; median follow-up 7.8 months.[1] The baseline demographic and disease characteristics were generally well balanced between treatment groups.[1]

CI: confidence interval; **HR:** hazard ratio; **ITT:** intention-to-treat; **mNSCLC:** metastatic non-small cell lung cancer; **mOS:** median overall survival; **mPFS:** median progression-free survival; **NR:** not reached; **NSCLC:** non-small cell lung cancer; **ORR:** objective response rate; **OS:** overall survival; **PD-L1:** programmed death-ligand 1; **PFS:** progression-free survival.

Reference: 1. Paz-Ares L, *et al. N Engl J Med* 2018; 379: 2040–2051.

WITH BENEFITS MAINTAINED IN AN EXPLORATORY 3-YEAR FOLLOW-UP ANALYSIS*

KEYTRUDA + carb-pac/nabpac maintained its efficacy in the 3-year follow-up analysis of KEYNOTE-407 (ITT population; p not tested)*[1]

OS[1]

KEYTRUDA + carb-pac/nabpac maintained OS benefit with a 29% reduced risk of death vs. placebo + carb-pac/nabpac

HR = 0.71
(95% CI 0.59–0.86)

mOS 17.2 months (95% CI 14.4–19.7) with KEYTRUDA + carb-pac/nabpac vs. **11.6 months** (95% CI 10.1–13.7) with placebo + carb-pac/nabpac

PFS[1]

KEYTRUDA + carb-pac/nabpac maintained PFS benefit with a 41% reduced risk of progression or death vs. placebo + carb-pac/nabpac

HR = 0.59
(95% CI 0.49–0.71)

mPFS 8.0 months (95% CI 6.3–8.5) with KEYTRUDA + carb-pac/nabpac vs. **5.1 months** (95% CI 4.3–6.0) with placebo + carb-pac/nabpac

ORR[1]

KEYTRUDA + carb-pac/nabpac maintained ORR benefit vs. placebo + carb-pac/nabpac

ORR 62.6% (95% CI 56.6–68.3) with KEYTRUDA + carb-pac/nabpac vs. **38.8%** (95% CI 33.1–44.8) with placebo + carb-pac/nabpac

117 patients crossed over onto KEYTRUDA + carb-pac/nabpac. The effective crossover rate was 51.1% (143/280)[1]

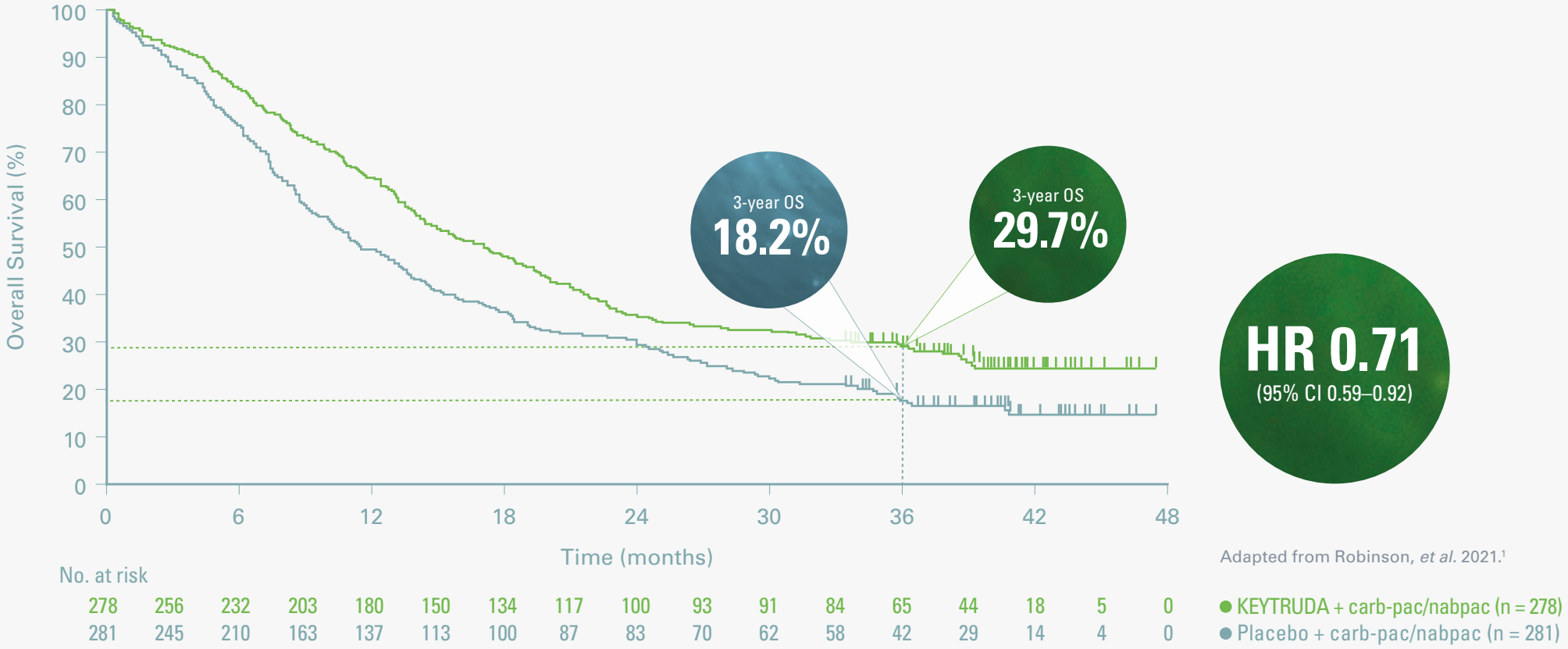
*First-line patients with squamous metastatic NSCLC, regardless of tumour PD-L1 expression status.[1] Based on the results of the ITT population in the 3-year follow-up analysis of KEYNOTE-407, a randomised, controlled phase 3 trial (n=559); primary endpoints: OS and PFS; median follow-up 40.1 months.[1] The baseline demographic and disease characteristics were generally well balanced between treatment groups.[2] No statistical conclusions can be made. P-value not tested.[1]

CI: confidence interval; **HR:** hazard ratio; **ITT:** intention-to-treat; **mOS:** median overall survival; **mPFS:** median progression-free survival; **NSCLC:** non-small cell lung cancer; **ORR:** objective response rate; **OS:** overall survival; **PD-L1:** programmed death-ligand 1; **PFS:** progression-free survival.

References: 1. Robinson A, *et al.* Presented at European Lung Cancer Virtual Congress (ELCC) 2021; March 25–27, 2021; virtual. **2.** Paz-Ares L, *et al. N Engl J Med* 2018; 379: 2040–2051.

WITH BENEFITS MAINTAINED IN AN EXPLORATORY 3-YEAR FOLLOW-UP ANALYSIS*

OS in the 3-year follow-up analysis of KEYNOTE-407 (ITT population; p not tested)*[1]



Adapted from Robinson, *et al.* 2021.[1]

In patients who completed **35 cycles of KEYTUDA** + carb-pac/nabpac (n = 55) **ORR was 92.7%**[1]

*Median follow-up 40.1 months.[1] No statistical conclusions can be made. P-value not tested.[1]

CI: confidence interval; **HR:** hazard ratio; **ITT:** intention-to-treat; **ORR:** objective response rate; **OS:** overall survival.

Reference: 1. Robinson A, *et al.* Presented at European Lung Cancer Virtual Congress (ELCC) 2021; March 25–27, 2021; virtual.

HELP BOB, AND PATIENTS LIKE HIM, WITH KEYTRUDA + CARB-PAC/NABPAC

OS and PFS in the PD-L1 non-expressor subgroup in the 3-year follow-up analysis of KEYNOTE-407 (exploratory analysis; p not tested)*[1]

OS[1]

At 3 years OS in the KEYTRUDA + carb-pac/nabpac group was 22.1% vs. 16.4% in the placebo + carb-pac/nabpac group

HR = 0.78
(95% CI 0.57–1.07)

mOS 15.0 months (95% CI 13.2–19.4) with KEYTRUDA + carb-pac/nabpac vs. **11.0 months** (95% CI 8.7–13.8) with placebo + carb-pac/nabpac

PFS[1]

At 3 years PFS in the KEYTRUDA + carb-pac/nabpac group was 10.3% vs. 9.1% in the placebo + carb-pac/nabpac group

HR = 0.68
(95% CI 0.50–0.93)

mPFS 6.3 months (95% CI 6.1–8.5) with KEYTRUDA + carb-pac/nabpac vs. **5.9 months** (95% CI 4.4–6.2) with placebo + carb-pac/nabpac

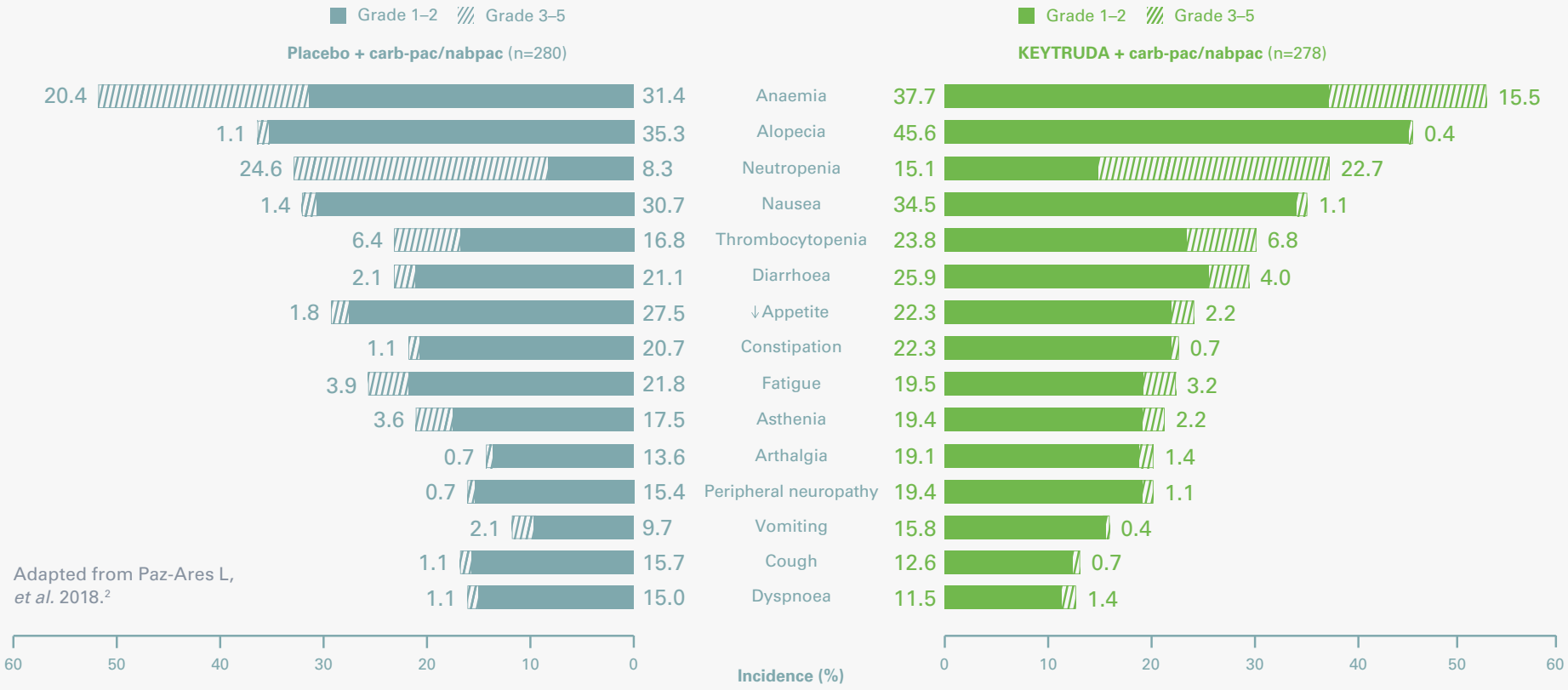
*Median follow-up 40.1 months.[1] No statistical conclusions can be made. P-value not tested.[1] The PD-L1 non-expressor subgroup had a PD-L1 TPS of <1%.[1]

CI: confidence interval; **HR:** hazard ratio; **ITT:** intention-to-treat; **mOS:** median overall survival; **mPFS:** median progression-free survival; **NSCLC:** non-small cell lung cancer; **ORR:** objective response rate; **OS:** overall survival; **PD-L1:** programmed death-ligand 1; **PFS:** progression-free survival; **TPS:** tumour proportion score.

Reference: 1. Robinson A, *et al.* Presented at European Lung Cancer Virtual Congress (ELCC) 2021; March 25–27, 2021; virtual.

KEYTRUDA + CARB-PAC/NABPAC OFFERS YOUR PATIENTS A GENERALLY MANAGEABLE TOLERABILITY PROFILE VS. CARB-PAC/NABPAC[1]

All-cause AEs occurring in ≥15% of patients in either treatment group (ITT population of the second interim analysis)*[2]



Adapted from Paz-Ares L, *et al.* 2018.[2]

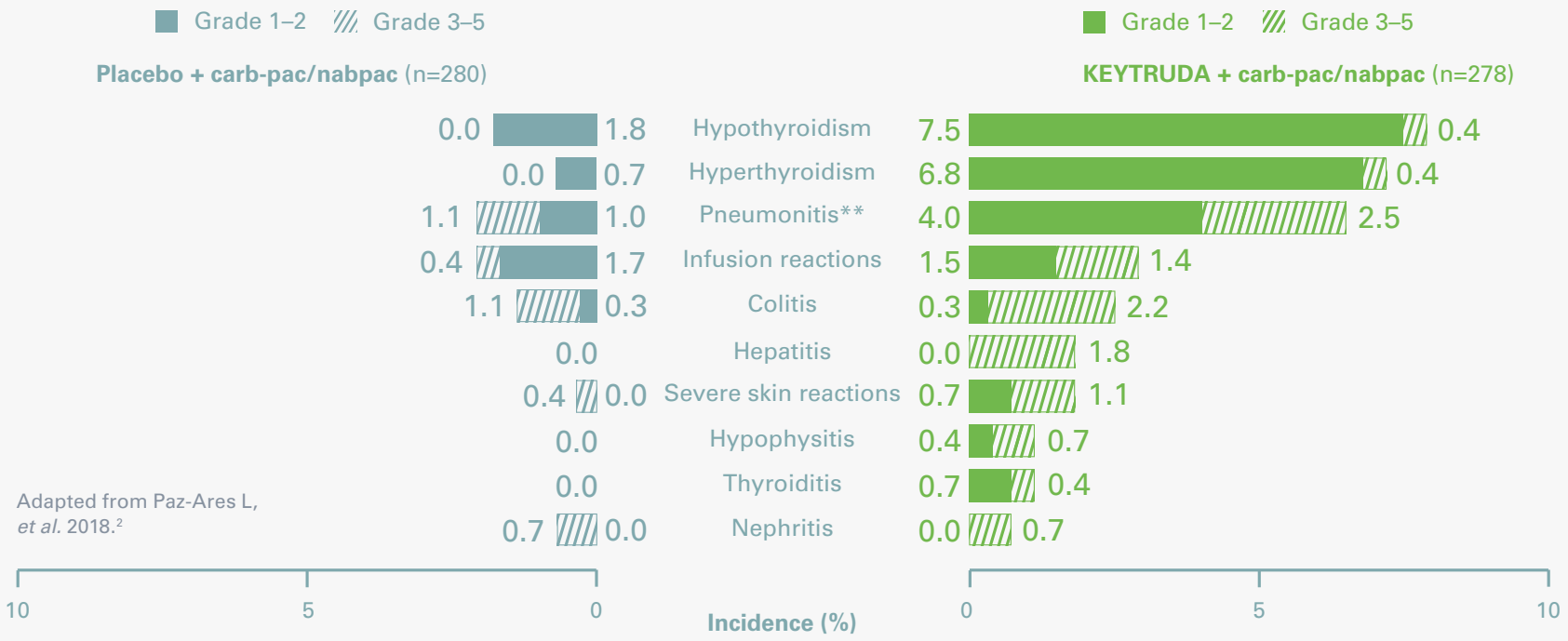
*Median follow-up 7.8 months.[2] Includes all patients who had undergone randomisation and received at least one dose of the assigned combined therapy; adverse events that occurred during crossover from the placebo-combination group to KEYTRUDA monotherapy were excluded.[2]

AE: adverse event; **ITT:** intention-to-treat.

References: 1. KEYTRUDA Summary of Product Characteristics. Available from: https://www.medicines.org.uk/emc/search?q=Keytruda. **2.** Paz-Ares L, *et al. N Engl J Med* 2018; 379: 2040–2051.

KEYTRUDA + CARB-PAC/NABPAC OFFERS YOUR PATIENTS A GENERALLY MANAGEABLE TOLERABILITY PROFILE VS. CARB-PAC/NABPAC[1]

Immune-related AEs occurring in KEYNOTE-407 (ITT population of the second interim analysis)*[2]



Adapted from Paz-Ares L, *et al.* 2018.[2]

Immune-related AEs with KEYTRUDA + carb-pac/nabpac were consistent with the adverse event profile of KEYTRUDA monotherapy[1–4]

*Median follow-up 7.8 months.[2] Includes all patients who had undergone randomisation and received at least one dose of the assigned combined therapy; adverse are considered regardless of attribution to a trial drug by the investigator.[2]

AE: adverse event; **ITT:** intention-to-treat.

References: 1. KEYTRUDA Summary of Product Characteristics. Available from: https://www.medicines.org.uk/emc/search?q=Keytruda. **2.** Paz-Ares L, *et al. N Engl J Med* 2018; 379: 2040–2051. **3.** Robinson A, *et al.* Presented at European Lung Cancer Virtual Congress (ELCC) 2021; March 25–27, 2021; virtual. **4.** Reck M, *et al. N Engl J Med* 2016; 375: 1823–1833.

KEYTRUDA + CARB-PAC/NABPAC OFFERS YOUR PATIENTS A GENERALLY MANAGEABLE TOLERABILITY PROFILE VS. CARB-PAC/NABPAC[1]

Adverse events occurring in the 3-year follow-up analysis of KEYNOTE-407 (ITT population)*[2]

Adverse events, n (%)	KEYTRUDA + carb-pac/nabpac (n=278)	Placebo + carb-pac/nabpac (n=280)	35 cycles (2 years) of KEYTRUDA + carb-pac/nabpac (n=55)
Any AE	274 (98.6)	275 (98.2)	55 (100)
Grade 3–5	208 (74.8)	196 (70.0)	35 (63.6)
Led to discontinuation			
Any treatment	80 (28.8)	37 (13.2)	3 (5.5)
All treatments	23 (8.3)	18 (6.4)	0
Leading to death	32 (11.5)	20 (7.1)	0
Treatment-related	12 (4.3)	5 (1.8)	0
Immune-mediated AEs and infusion reactions	99 (35.6)	26 (9.3)	21 (38.2)
Grade 3–5	36 (12.9)	9 (3.2)	1 (1.8)

A generally manageable tolerability profile that is comparable to carb-pac/nabpac.[1] The frequency of adverse events for combination was comparable to previous studies[2,3]

*Median follow-up 40.1 months.[2]

AE: adverse event; **ITT:** intention-to-treat.

References: 1. KEYTRUDA Summary of Product Characteristics. Available from: https://www.medicines.org.uk/emc/search?q=Keytruda. **2.** Robinson A, *et al.* Presented at European Lung Cancer Virtual Congress (ELCC) 2021; March 25–27, 2021; virtual. **3.** Paz-Ares L, *et al. N Engl J Med* 2018; 379: 2040–2051.

In the 3-year follow-up analysis of KEYNOTE-407 (p not tested):*

- The trend for OS benefit was maintained with more than a 5 month increase in mOS with KEYTRUDA + carb-pac/nabpac vs. carb-pac/nabpac alone (ITT population)[2]
- The trend for ORR benefit was maintained with improvement in ORR with KEYTRUDA + carb-pac/nabpac vs. carb-pac/nabpac alone (ITT population)[2]
- A generally manageable tolerability profile that is comparable to carb-pac/nabpac.[3] The frequency of adverse events for combination was comparable to previous studies[1,2]

Statistical significance was met for the primary endpoints in the second interim analysis (median follow-up 7.8 months).

*No statistical conclusions can be drawn from this analysis (median follow-up 40.1 months).

ITT: intention-to-treat; **mOS**: median overall survival; **ORR**: objective response rate; **OS**: overall survival; **PFS**: progression-free survival.

References: **1.** Paz-Ares L, *et al. N Engl J Med* 2018; 379: 2040–2051. **2.** Robinson A, *et al.* Presented at European Lung Cancer Virtual Congress (ELCC) 2021; March 25–27, 2021; virtual. **3.** KEYTRUDA Summary of Product Characteristics. Available from: https://www.medicines.org.uk/emc/search?q=Keytruda.

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WHO ELSE COULD BENEFIT FROM KEYTRUDA + CARB-PAC/NABPAC?

Take a closer look at your next untreated squamous metastatic NSCLC PD-L1 non-expressor patient

Connect with us

Sometimes it's better to talk things through, that's why we would appreciate the opportunity to speak with you more about these data. To arrange a meeting at your convenience, please email us at:

msdukoncology@msd.com

KEYTRUDA®
(pembrolizumab)

NSCLC: non-small cell lung cancer. **PD-L1:** programmed death-ligand 1.