MSD

TAKE A CLOSER LOOK AT BILL

Could KEYTRUDA in combination with plat-pem transform treatment expectations for patients like Bill?*

KEYTRUDA, in combination with pemetrexed and platinum chemotherapy, is indicated for the first-line treatment of metastatic non-squamous NSCLC in adults whose tumours have no EGFR or ALK positive mutations.[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]

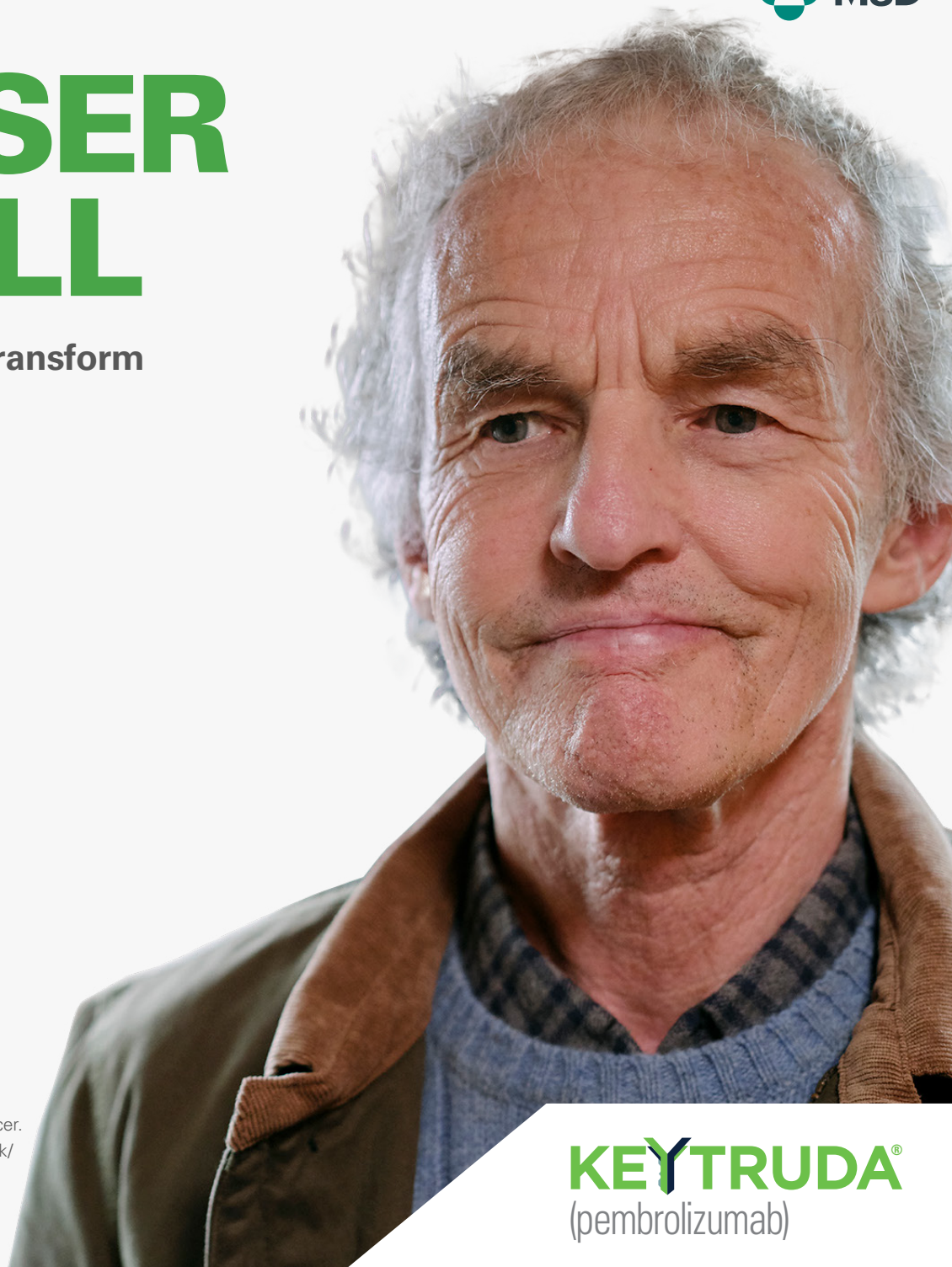
Prescribing information for Great Britain.

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 www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to MSD, UK (Tel: 0208 154 8000).



KEYTRUDA® (pembrolizumab)

Patient is fictional and for illustrative purposes only.

*First-line patients with non-squamous metastatic NSCLC (excluding EGFR/ALK positive mutations).[2]

ALK: anaplastic lymphoma kinase; **EGFR:** epidermal growth factor receptor; **NSCLC:** non-small cell lung cancer.

References: 1. KEYTRUDA Summary of Product Characteristics. Available from: https://www.medicines.org.uk/emc/product/2498/smpc. **2.** Gandhi L, *et al. N Engl J Med* 2018; 378: 2078–2092.

Date of Preparation: September 2021. GB-PDO-01780.

MEET BILL

Bill is not a quitter (except when it came to smoking). He's able to self care and can still walk around – something he and Scruffy both hope won't change too soon.

- 67-year-old male
- Stage IV NSCLC, adenocarcinoma
- Negative for EGFR and ALK mutations
- PD-L1 non-expressor
- No liver or brain metastases at diagnosis
- Former smoker with a 10 pack-year history

How do you approach first-line treatment in non-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.

PATIENTS LIKE BILL CAN UNDERGO RAPID CLINICAL DETERIORATION DURING DISEASE PROGRESSION[1,2]

Less than half of patients with advanced NSCLC ever receive second-line therapy[1]

With KEYTRUDA + plat-pem, you can provide improved survival vs. plat-pem alone to more patients like Bill[3–5]

Helping you make more tomorrows possible[3–5]

NSCLC: non-small cell lung cancer.

References: **1.** Davies J, *et al. PLoS One* 2017; 12(4): e0175679. **2.** Lazzari C, *et al. Front Med (Lausanne)* 2017; 4: 4. **3.** Gandhi L, *et al. N Engl J Med* 2018; 378: 2078–2092. **4.** KEYTRUDA Summary of Product Characteristics. Available from: https://www.medicines.org.uk/emc/product/2498/smpc. **5.** Gray J, *et al.* Presented virtually at World Conference on Lung Cancer (WCLC) 2020; January 28–31, 2021; virtual.

MORE TOMORROWS MADE POSSIBLE FOR THESE mNSCLC PATIENTS*

First-line patients with non-squamous metastatic NSCLC (excluding EGFR/ALK positive mutations)[1]

KEYTRUDA + plat-pem proved its efficacy in the original analysis of KEYNOTE-189 (ITT population)*[1]

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

OS[1]

KEYTRUDA + plat-pem halved the risk of death vs. placebo + plat-pem

HR = 0.49
(95% CI 0.38–0.64) p<0.001

mOS NR with KEYTRUDA + plat-pem vs. **11.3 months** (95% CI 8.7–15.1) with placebo + plat-pem

PFS[1]

The risk of disease progression or death was nearly halved with KEYTRUDA + plat-pem vs. placebo + plat-pem

HR = 0.52
(95% CI 0.43–0.64) p<0.001

mPFS 8.8 months (95% CI 7.6–9.2) with KEYTRUDA + plat-pem vs. **4.9 months** (95% CI 4.7–5.5) with placebo + plat-pem

ORR[1]

Overall response was improved with KEYTRUDA + plat-pem vs. placebo + plat-pem

ORR 47.6% (95% CI 42.6–52.5) with KEYTRUDA + plat-pem vs. **18.9%** (95% CI 13.8–25.0) with placebo + plat-pem p<0.001

*Based on the results of the ITT population in the original analysis of KEYNOTE-189, a randomised, controlled phase 3 trial (n=616); primary endpoints: OS and PFS; median follow-up 10.5 months.[1] The baseline demographic and disease characteristics were generally well balanced between treatment groups.[1]

ALK: anaplastic lymphoma kinase; **CI:** confidence interval; **EGFR:** epidermal growth factor receptor; **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; **PFS:** progression-free survival.

Reference: 1. Gandhi L, *et al. N Engl J Med* 2018; 378: 2078–2092.

WITH BENEFITS MAINTAINED IN AN EXPLORATORY 4-YEAR FOLLOW-UP ANALYSIS*

KEYTRUDA + plat-pem doubled OS and ORR vs. placebo + plat-pem in the 4-year follow-up analysis of KEYNOTE-189 (ITT population; p not tested)*[1]

OS[1]

KEYTRUDA + plat-pem maintained OS benefit vs. placebo + plat-pem

HR = 0.60
(95% CI 0.50–0.72)

mOS 22.0 months (95% CI 19.5–24.5) with KEYTRUDA + plat-pem vs. **10.6 months** (95% CI 8.7–13.6) with placebo + plat-pem

PFS[1]

KEYTRUDA + plat-pem maintained PFS benefit vs. placebo + plat-pem

HR = 0.50
(95% CI 0.41–0.59)

mPFS 9.0 months (95% CI 8.1–10.4) with KEYTRUDA + plat-pem vs. **4.9 months** (95% CI 4.7–5.5) with placebo + plat-pem

ORR[1]

Overall response more than doubled with KEYTRUDA + plat-pem vs. placebo + plat-pem

ORR 48.3%
with KEYTRUDA + plat-pem vs. **19.9%** with placebo + plat-pem

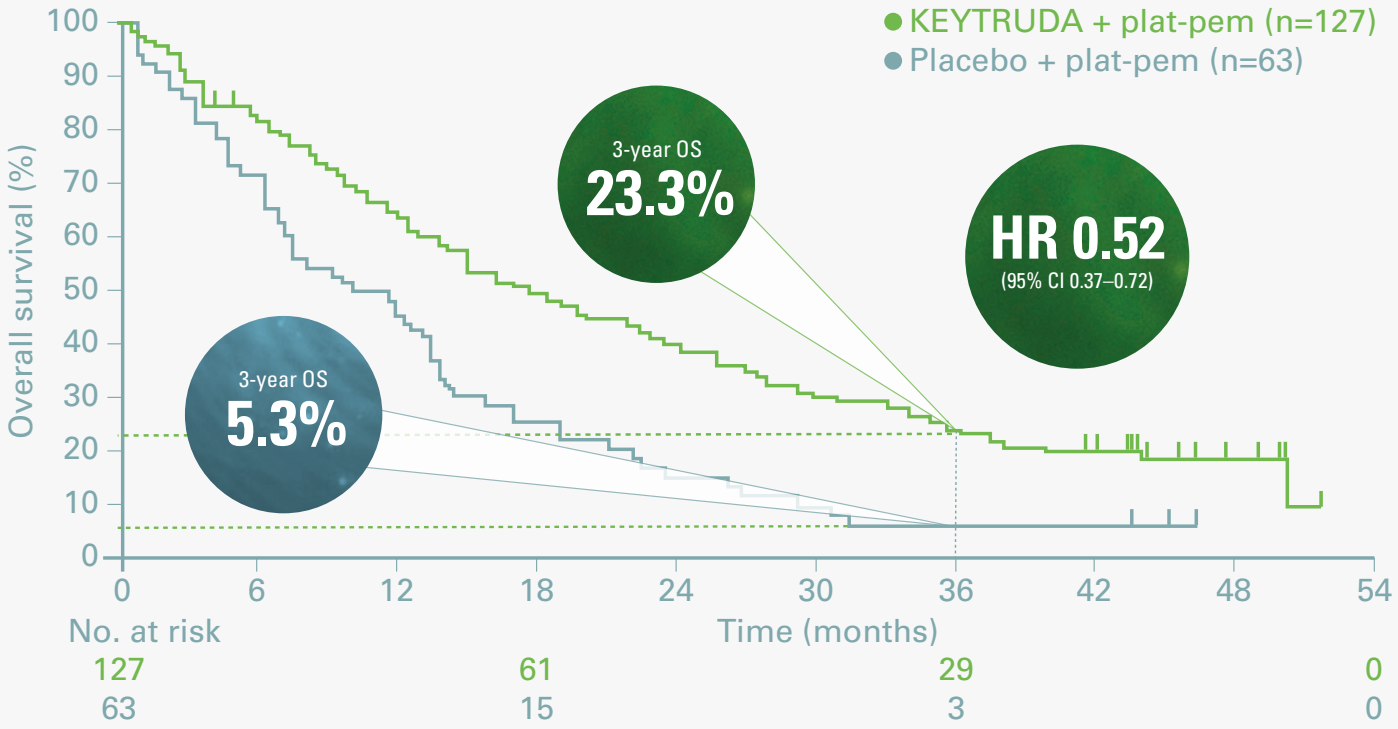
*First-line patients with non-squamous metastatic NSCLC (excluding EGFR/ALK positive mutations).[1] Based on results from the ITT population of a 4-year follow-up analysis of KEYNOTE-189, a randomised, controlled phase 3 trial (n=616); primary endpoints: OS and PFS; median follow-up 46.3 months.[1,2] 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; **ORR:** objective response rate; **OS:** overall survival; **PFS:** progression-free survival.

References: 1. Gray J, *et al.* Presented virtually at World Conference on Lung Cancer (WCLC) 2020; January 28–31, 2021; virtual.
2. Gandhi L, *et al. N Engl J Med* 2018; 378: 2078–2092.

HELP BILL, AND PATIENTS LIKE HIM, WITH KEYTRUDA + PLAT-PEM

Overall survival in the PD-L1 non-expressor subgroup in the 4-year follow-up analysis of KEYNOTE-189 (exploratory analysis; p not tested)*[1]



In the PD-L1 non-expressor subgroup of the 4-year follow-up analysis of KEYNOTE-189 (exploratory analysis; p not tested):*[1]

- **ORR was 33.1%** with KEYTRUDA + plat-pem vs. **14.3%** with placebo + plat-pem
- **mPFS was 6.2 months** (95% CI 4.9–8.3) with KEYTRUDA + plat-pem vs. **5.1 months** (95% CI 4.5–6.8) with placebo + plat-pem; HR 0.68 (95% CI 0.49–0.93)

Adapted from Gray J, *et al.* 2021.[1]

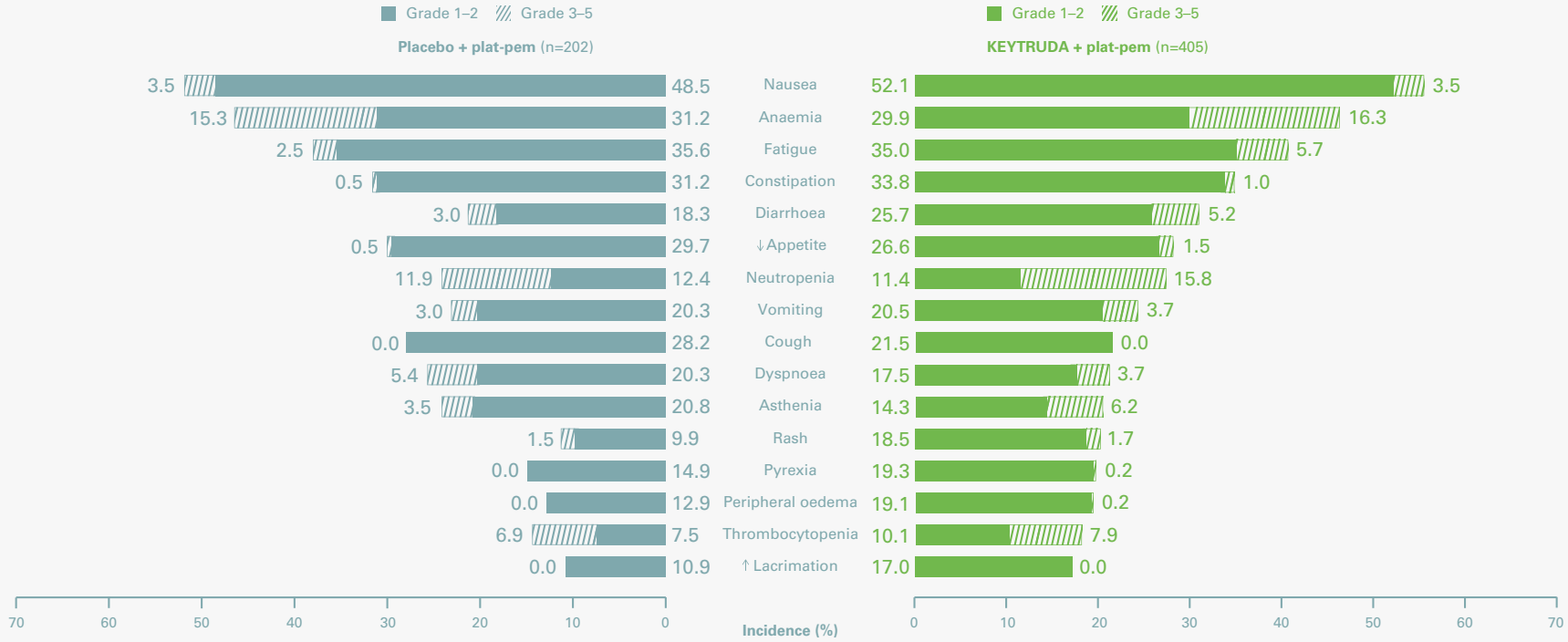
*Median follow-up 46.3 months.[1] PD-L1 non-expressor subgroup had a PD-L1 TPS of <1%.[1]

CI: confidence interval; **HR:** hazard ratio; **mOS:** median overall survival; **mPFS:** median progression-free survival; **ORR:** objective response rate; **OS:** overall survival; **PD-L1:** programmed death-ligand 1; **TPS:** tumour proportion score.

Reference: 1. Gray J, *et al.* Presented virtually at World Conference on Lung Cancer (WCLC) 2020; January 28–31, 2021; virtual.

KEYTRUDA + PLAT-PEM OFFERS YOUR PATIENTS A GENERALLY MANAGEABLE TOLERABILITY PROFILE VS. PLAT-PEM[1,2]

All-cause AEs occurring in 15% of patients in either treatment group in KEYNOTE-189 (ITT population of the original analysis)*[1]



Adapted from Gandhi L, *et al.* 2018.[1]

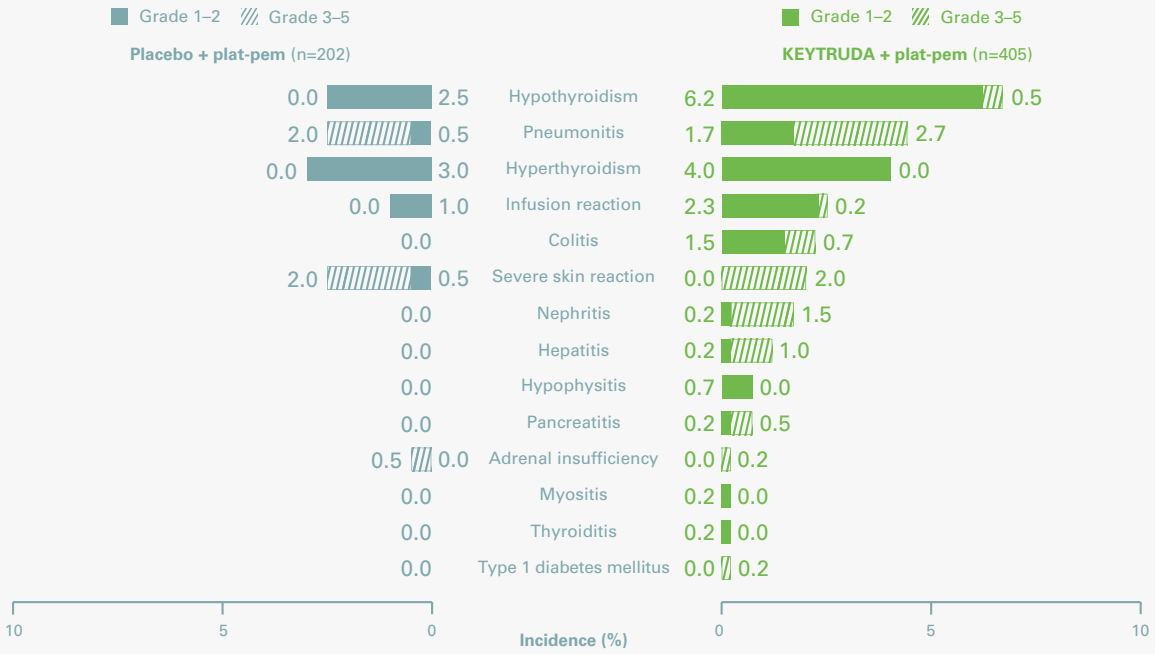
*In the as-treated population, regardless of attribution of treatment.[1] Median follow-up 10.5 months.[1]

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

References: 1. Gandhi L, *et al. N Engl J Med* 2018; 378: 2078–2092. **2.** KEYTRUDA Summary of Product Characteristics. Available from: https://www.medicines.org.uk/emc/product/2498/smpc.

KEYTRUDA + PLAT-PEM OFFERS YOUR PATIENTS A GENERALLY MANAGEABLE TOLERABILITY PROFILE VS. PLAT-PEM[1,2]

Immune-related AEs occurring in KEYNOTE-189 (ITT population of the original analysis)*[1]



Adapted from Gandhi L, *et al.* 2018.[1]

Immune-mediated AEs with KEYTRUDA + plat-pem were consistent with the adverse event profile of KEYTRUDA monotherapy.[1,3]

*In the as-treated population, regardless of attribution of treatment.[1] Median follow-up 10.5 months.[1]

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

References: 1. Gandhi L, *et al. N Engl J Med* 2018; 378: 2078–2092. **2.** KEYTRUDA Summary of Product Characteristics. Available from: https://www.medicines.org.uk/emc/product/2498/smpc. **3.** Reck M, *et al. N Engl J Med* 2016; 375: 1823–1833.

KEYTRUDA + PLAT-PEM OFFERS YOUR PATIENTS A GENERALLY MANAGEABLE TOLERABILITY PROFILE VS. PLAT-PEM[1–3]

Adverse events occurring in the 4-year follow-up analysis of KEYNOTE-189 (ITT population)

	KEYTRUDA + plat-pem (n=405)	Placebo + plat-pem (n=202)	35 cycles (2 years) of KEYTRUDA + pat-pem (n=56)
Treatment-related AEs, n (%)	376 (92.8)	183 (90.6)	55 (98.2)
Grade 3–5	211 (52.1)	85 (42.1)	26 (46.4)
Led to discontinuation	111 (27.4)	20 (9.9)	16 (28.6)
Led to death	8 (2.0)	2 (1.0)	0
Immune-mediated AEs and infusion reactions, (%)	112 (27.7)	27 (13.4)	22 (39.3)
Grade 3–5	51 (12.6)	9 (4.5)	6 (10.7)
Led to discontinuation	37 (9.1)	–	0
Led to death	2 (0.5)	0	0

Adapted from Gray J, *et al.* 2021.[2]

KEYTRUDA + plat-pem demonstrated a generally manageable tolerability profile. In the 4-year follow-up analysis, the frequency of adverse events for combination was comparable to previous studies. An increase in the frequency of immune-mediated AEs and infusion reactions was observed in patients who received 35 cycles of KEYTRUDA.[1–3]

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

References: 1. Gandhi L, *et al. N Engl J Med* 2018; 378: 2078–2092. **2.** Gray J, *et al.* Presented virtually at World Conference on Lung Cancer (WCLC) 2020; January 28–31, 2021; virtual. **3.** KEYTRUDA Summary of Product Characteristics. Available from: https://www.medicines.org.uk/emc/product/2498/smpc.

KEYTRUDA + plat-pem can help make more tomorrows for patients like Bill[1–3]

In the 4-year follow-up analysis of KEYNOTE-189 (p not tested):*

- The trend for OS benefit was maintained with a doubling of mOS with KEYTRUDA + plat-pem vs. plat-pem alone (ITT population)[3]
- The trend for ORR benefit was maintained with a doubling of ORR with KEYTRUDA + plat-pem vs. plat-pem alone (ITT population)[3]
- The safety profile was generally manageable, with the frequency of adverse events for combination being comparable to previous studies[1–3]
- An increase in the frequency of immune-mediated AEs and infusion reactions was observed in patients who received 35 cycles of KEYTRUDA[1–3]

Statistical significance was met for the primary endpoints in the original analysis (median follow-up 10.5 months).[1]

*No statistical conclusions can be drawn from this analysis (median follow-up 46.3 months.[3]

AE: adverse event; **ITT:** intention-to-treat; **mOS:** mean overall survival; **ORR:** objective response rate; **OS:** overall survival.

References: 1. Gandhi L, *et al. N Engl J Med* 2018; 378: 2078–2092. **2.** KEYTRUDA Summary of Product Characteristics. Available from: https://www.medicines.org.uk/emc/product/2498/smpc. **3.** Gray J, *et al.* Presented virtually at World Conference on Lung Cancer (WCLC) 2020; January 28–31, 2021; virtual.

MSD

WHO ELSE COULD BENEFIT FROM KEYTRUDA + PLAT-PEM?

Take a closer look at your next untreated non-squamous metastatic NSCLC (EGFR-/ALK-) 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)

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