KEYTRUDA®
(pembrolizumab)

KEYTRUDA SC™
(pembrolizumab)
subcutaneous injection
395 mg/2.4 mL
790 mg/4.8 mL

For UK healthcare professionals only.

KEYTRUDA SC™ NON-INFERIOR PK TO KEYTRUDA IV[1]

For **adults**[1]

ADMINISTERED SUBCUTANEOUSLY over 1 or 2 MINUTES*[1]

*Based on recommended dose. This does not account for all aspects of treatment. Actual clinic time may vary.

KEYTRUDA SC is licensed for use in adult patients across most KEYTRUDA IV indications, whether alone or in combination with other therapies[1,2]

Please refer to the individual product SmPC for the full list of indications.

KEYTRUDA IV and KEYTRUDA SC, in combination with pemetrexed and platinum chemotherapy, are each 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.[1,2]

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 MSD (Tel: 020 8154 8000). By clicking the above link, you will leave the MSD website and be taken to the MHRA website.

Prescribing Information for KEYTRUDA IV and KEYTRUDA SC can be accessed via the 'PI' buttons at the bottom of this page and throughout this document.

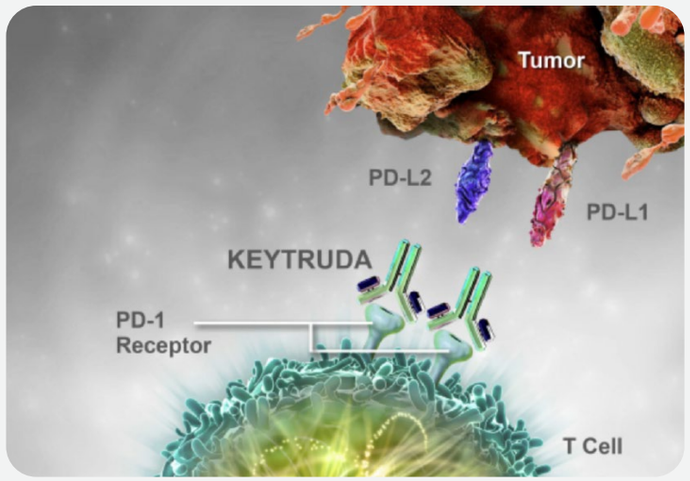
Please consult the KEYTRUDA IV and KEYTRUDA SC Summary of Product Characteristics and the Risk Management Materials for further information before making any prescribing decisions.

ALK, anaplastic lymphoma kinase; *EGFR*, epidermal growth factor receptor; IV, intravenous; PK, pharmacokinetic; SC, subcutaneous.

Pembrolizumab with recombinant berahyaluronidase alfa[1]

- Pembrolizumab is a selective, humanised, monoclonal antibody designed to block the interaction between PD-1 and both PD-L1 and PD-L2[1]
- Berahyaluronidase alfa is a variant of human hyaluronidase, an enzyme that temporarily and locally breaks down hyaluronan, a polysaccharide found in the extracellular matrix of the subcutaneous tissue. This results in enhanced drug dispersion and permeation, facilitating delivery of pembrolizumab[1,3,4]

Pembrolizumab MoA[1,5]

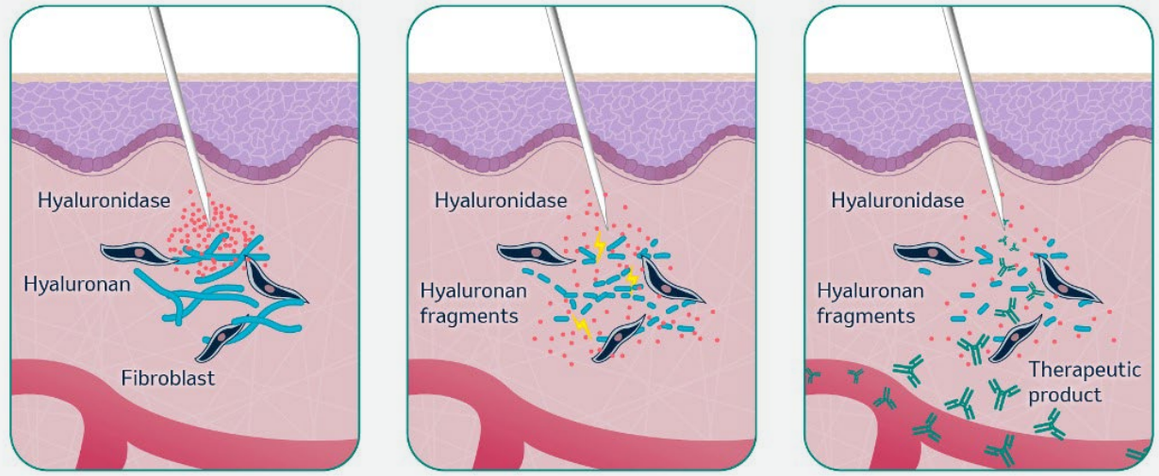


By inhibiting PD-1 receptor binding, pembrolizumab reactivates tumour-specific cytotoxic T lymphocytes in the tumour microenvironment, resulting in anti-tumour immunity

Adapted from Pardoll DM, *et al.* 2012.

with

Hyaluronidase MoA[1,3,4]



Hyaluronan creates a resistance to bulk fluid flow

Hyaluronidase depolymerises hyaluronan

SC bulk fluid flow and increased dispersion of co-administered drug

Adapted from Connor RJ, *et al.* 2020.

MoA, mechanism of action; PD-1, programmed cell death protein 1; PD-L1, programmed death-ligand 1; PD-L2, programmed death-ligand 2; SC, subcutaneous.

MK-3475A-D77 was a randomised, multicentre, open-label, active-controlled, Phase III non-inferiority study comparing KEYTRUDA SC and KEYTRUDA IV, each in combination with chemotherapy[1,6,7]

Studied in 1L mNSCLC across histologies and PD-L1 TPS expression status

Key patient inclusion criteria

- Patients with previously untreated mNSCLC with no *EGFR*, *ALK*, or *ROS1* genomic tumour aberrations

Key patient exclusion criteria

- Patients were excluded if they had autoimmune disease that required systemic therapy within 2 years of treatment, had a medical condition that required immunosuppression, or had received more than 30 Gy of thoracic radiation within the prior 26 weeks

Randomisation*

2:1

(N=377)

SC
(n=251)

Non-squamous:
KEYTRUDA SC 790 mg and berahyaluronidase alfa SC Q6W + pemetrexed + cisplatin or carboplatin, followed by pemetrexed maintenance†

Squamous:
KEYTRUDA SC 790 mg and berahyaluronidase alfa SC Q6W + carboplatin + paclitaxel or paclitaxel protein-bound‡

IV
(n=126)

Non-squamous:
KEYTRUDA 400 mg IV Q6W + pemetrexed + cisplatin or carboplatin, followed by pemetrexed maintenance†

Squamous:
KEYTRUDA 400 mg IV Q6W + carboplatin + paclitaxel or paclitaxel protein-bound‡

Treatment continued until disease progression, unacceptable toxicity or for a maximum of 18 cycles (approximately 24 months)§1

Adapted from Felip E, *et al*. 2025.

Co-primary endpoints (non-inferiority of KEYTRUDA SC vs KEYTRUDA IV) based on:

- Cycle 1 $AUC_{0–6wk}$
- Steady state (cycle 3) C_{trough}

Secondary endpoints (based on descriptive analysis):

- ORR¶
- PFS¶
- OS
- Safety
- Immunogenicity

*Randomisation was stratified by ECOG PS (0 vs 1), histology (squamous vs non-squamous), PD-L1 TPS (<50% vs ≥50%) and geographic region (East Asia vs North America/Western Europe/Australia/New Zealand vs Rest of the World).[1]
†Pemetrexed 500 mg/m^2 and a platinum chemotherapy (cisplatin 75 mg/m^2 or carboplatin AUC 5 mg/mL/min) intravenously every 3 weeks for 4 cycles, followed by pemetrexed 500 mg/m^2 intravenously every 3 weeks.[1] ‡Carboplatin AUC 6 mg/mL/min and a taxane (paclitaxel 200 mg/m^2 on Day 1 of each 21-day cycle or nab-paclitaxel 100 mg/m^2 on Days 1, 8, and 15 of each 21-day cycle) intravenously every 3 weeks for 4 cycles.[1] §Treatment with KEYTRUDA SC or KEYTRUDA IV could be reinitiated for subsequent disease progression and administered for up to an additional 9 cycles (approximately 1 year).[1] ¶As assessed by BICR using RECIST v1.1.[1]

1L, first-line; *ALK*, anaplastic lymphoma kinase; AUC, area under the curve; BICR, blinded independent central review; C_{trough}, trough concentration; ECOG PS, Eastern Cooperative Oncology Group performance status; *EGFR*, epidermal growth factor receptor; Gy, gray; IV, intravenous; mNSCLC, metastatic non-small cell lung carcinoma; nab-paclitaxel, paclitaxel protein-bound; ORR, objective response rate; OS, overall survival; PD-L1, programmed death-ligand 1; PFS, progression-free survival; Q6W, every 6 weeks; RECIST, Response Evaluation Criteria In Solid Tumours; *ROS1*, ROS proto-oncogene 1, receptor tyrosine kinase; SC, subcutaneous; TPS, tumour proportion score.

Baseline patient characteristics were balanced overall between treatment groups[6]

Baseline patient characteristics	KEYTRUDA SC + chemotherapy (n=251)	KEYTRUDA IV + chemotherapy (n=126)
Median age, years (range)	65.0 (39–87)	66.0 (37–83)
<65	119 (47.4)	57 (45.2)
≥65	132 (52.6)	69 (54.8)
Sex, n (%)		
Male	182 (72.5)	86 (68.3)
Female	69 (27.5)	40 (31.7)
Race, n (%)		
American Indian or Alaska Native	2 (0.8)	4 (3.2)
Asian	74 (29.5)	36 (28.6)
Black or African American	5 (2.0)	5 (4.0)
Multiple	12 (4.8)	3 (2.4)
White	158 (62.9)	78 (61.9)
ECOG PS, n (%)		
0	89 (35.5)	42 (33.3)
1	162 (64.5)	84 (66.7)
Histology, n (%)		
Squamous	84 (33.5)	43 (34.1)
Non-squamous	167 (66.5)	83 (65.9)

Baseline patient characteristics (continued)	KEYTRUDA SC + chemotherapy (n=251)	KEYTRUDA IV + chemotherapy (n=126)
PD-L1 expression, n (%)		
TPS <50%	181 (72.1)	91 (72.2)
TPS <1%	101 (40.2)	57 (45.2)
TPS 1–49%	80 (31.9)	34 (27.0)
TPS ≥50%	48 (19.1)	25 (19.8)
TPS unknown	22 (8.8)	10 (7.9)
Overall stage, n (%)		
IVA	141 (56.2)	64 (50.8)
IVB	110 (43.8)	62 (49.2)
Smoking status, n (%)		
Never	38 (15.1)	23 (18.3)
Former	142 (56.6)	62 (49.2)
Current	71 (28.3)	41 (32.5)
Other, n (%)		
Stable brain metastases at baseline	19 (7.6)	14 (11.1)

Adapted from Felip E, *et al*. 2025.

ECOG PS, Eastern Cooperative Oncology Group performance status; IV, intravenous; PD-L1, programmed death-ligand 1; SC, subcutaneous; TPS, tumour proportion score.

Pembrolizumab overall drug exposure for KEYTRUDA SC was non-inferior to that of KEYTRUDA IV[6]

The non-inferiority margin was prespecified as 0.8[6]

Co-primary endpoints (non-inferiority of KEYTRUDA SC vs KEYTRUDA IV) based on:[6]

Pharmacokinetic measures	KEYTRUDA SC + chemotherapy (n=245)*	KEYTRUDA IV + chemotherapy (n=126)	Geometric mean ratio†
Cycle 1 AUC_{0-6wk} µg•day/mL‡	1633.24 (95% CI: 1555.23–1715.15)	1437.58 (95% CI: 1373.68–1504.46)	1.14 (96% CI: 1.06–1.22); p<0.0001§
	Geometric %CV 40.4	Geometric %CV 26.2	

	KEYTRUDA SC + chemotherapy (n=202)	KEYTRUDA IV + chemotherapy (n=101)	Geometric mean ratio†
Steady state (cycle 3) C_{trough} µg/mL¶	39.23 (95% CI: 37.04–41.55)	23.49 (95% CI: 21.61–25.54)	1.67 (94% CI: 1.52–1.84); p<0.0001‖
	Geometric %CV 43.3	Geometric %CV 44.2	–

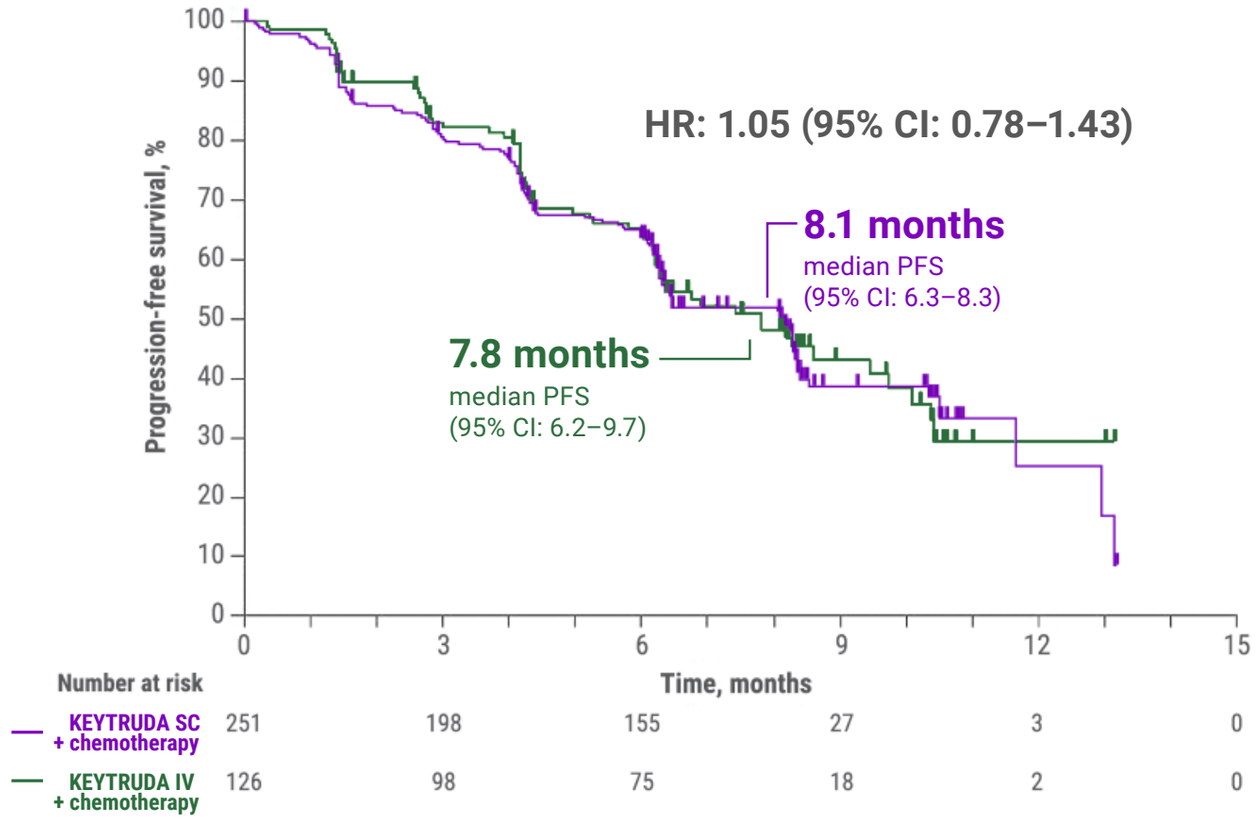
Adapted from Felip E, *et al*. 2025.

*Six participants in the KEYTRUDA SC arm were excluded from the pharmacokinetics modelling analysis due to clinically meaningful protocol deviation (n=4) and absence of cycle 1 samples for pharmacokinetics analysis (n=2).[6] †KEYTRUDA SC + chemotherapy vs KEYTRUDA IV + chemotherapy.[6] ‡AUC (area under the curve) = the total amount of the drug reaching the systemic circulation. §The one-sided p value non-inferiority boundary is 0.02 for the analysis of cycle 1 AUC_{0-6wk}.[6] ¶C_{trough} (trough concentration) = lowest concentration of drug in the blood. ‖The one-sided p value non-inferiority boundary is 0.03 for the analysis of cycle 3 (steady state) C_{trough}.[6]
AUC, area under curve; CI, confidence interval; C_{trough}, trough concentration; CV, coefficient of variation; IV, intravenous; SC, subcutaneous.

Efficacy endpoints were comparable between KEYTRUDA SC and KEYTRUDA IV[6,7]

Efficacy was a descriptive analysis and was not powered to demonstrate statistical significance.[6]

PFS (median follow up 9.6 months)*[6]



Adapted from Felip E, *et al*. 2025.

ORR[6,7]

Secondary endpoints	KEYTRUDA SC + chemotherapy (n=251)	KEYTRUDA IV + chemotherapy (n=126)
ORR*†	45.4% (95% CI: 39.1–51.8)	42.1% (95% CI: 33.3–51.2)
Complete response	3.2%	1.6%
Partial response	42.2%	40.5%
Difference in ORR‡	3.5% (95% CI: -7.0–13.7)	

OS event rate (was not mature)[6]

OS (not yet mature)	61 deaths; 24.3%	37 deaths; 29.4%
Hazard ratio	0.81 (95% CI: 0.53–1.22)	

Data cutoff: 12 July 2024.

*As assessed by BICR using RECIST v1.1. The tail end of the Kaplan-Meier curve should be interpreted with caution due to factors such as the number of censored events and a lower number of patients at this time.[6] †Based on patients with a best overall response as confirmed complete or partial response.[6] ‡KEYTRUDA SC arm minus KEYTRUDA IV arm; based on stratified Miettinen and Nurminen method.[6]

BICR, blinded independent central review; CI, confidence interval; HR, hazard ratio; IV, intravenous; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; RECIST; Response Evaluation Criteria in Solid Tumours; SC, subcutaneous.

The immunogenicity profile of KEYTRUDA SC was consistent with the known immunogenicity profile of KEYTRUDA IV[6]

Immunogenicity[6]

Observed incidence of ADAs, n (%)*	KEYTRUDA SC + chemotherapy (n=211)	KEYTRUDA IV + chemotherapy (n=114)
Developed anti-pembrolizumab antibodies	3 (1.4)	1 (0.9)
Developed neutralising antibodies against pembrolizumab	1 (0.5)	0 (0)

For participants who were ADA positive, the pembrolizumab exposure was comparable to that for participants who were ADA negative and treated by the same route of administration[6]

Observed incidence of ADAs, n (%)*†	KEYTRUDA SC + chemotherapy (n=194)	KEYTRUDA IV + chemotherapy
Developed anti-berahyaluronidase alfa antibodies	3 (1.5)	NA

Adapted from Felip E, *et al*. 2025.

The median duration of treatment with KEYTRUDA SC was 6.9 months (range: 1 day – 1 year).[6] The immunogenicity profile of subcutaneous pembrolizumab was consistent with the known immunogenicity profile of intravenous pembrolizumab.[6]

*Because of the low occurrence of anti-pembrolizumab or anti-berahyaluronidase antibodies, the effect of these antibodies on the pharmacokinetics, safety and effectiveness of KEYTRUDA SC is unknown.[6] †No analysis of neutralising antibodies was performed for berahyaluronidase alfa ADA-positive samples.[6]

ADA, anti-drug antibody; IV, intravenous; NA, not applicable; SC, subcutaneous.

The safety profile of KEYTRUDA SC was consistent with the known safety profile of KEYTRUDA IV, with an addition of injection site reactions[6]

Safety summary[6]

Participants, n (%)*	KEYTRUDA SC + chemotherapy (n=251)	KEYTRUDA IV + chemotherapy (n=126)
First-line treatment: median time on treatment (range)	6.87 months (1 day – 13.2 months)	6.21 months (1 day – 15.9 months)
AEs, ≥1	249 (99.2)	123 (97.6)
TRAEs†	226 (90.0)	121 (96.0)
Grade 3–5	118 (47.0)	60 (47.6)
Serious	53 (21.1)	25 (19.8)
Discontinuation of any treatment due to a TRAE†	44 (17.5)	19 (15.1)
Discontinued KEYTRUDA SC or KEYTRUDA IV	21 (8.4)	11 (8.7)
Discontinued chemotherapy	38 (15.1)	15 (11.9)
Deaths due to TRAEs†	9 (3.6)‡	3 (2.4)§

- Similar proportions of patients in the two treatment arms experienced one or more serious AEs. The most frequent serious AEs included pneumonia, febrile neutropenia, thrombocytopenia, neutropenia, anaemia and pulmonary embolism[6]
- In total, 38 patients in the study had an AE that resulted in death, including 26 (10.4%) patients in the KEYTRUDA SC arm and 12 (9.5%) patients in the KEYTRUDA IV arm†[6]

All injection site reactions were Grade 1[6]

- For patients receiving KEYTRUDA SC, injection-site reactions occurred in 2.4% (6/251) of patients¶[6]
- The median time to onset of the first injection-site AEs from the most recent dose administration was 2.0 days (range: 1–2 days)[6]
- The median duration of the first event of injection-site AE was 5.5 days (range: 2–20 days)[6]
- No participant discontinued treatment in the KEYTRUDA SC arm due to injection-site AEs[6]

Adapted from Felip E, *et al*. 2025.

Data cutoff: 12 July 2024. Median study follow-up: 9.6 months (range: 6.24–16.39 months). The median time on study treatment was 6.87 months (range: 1 day – 13.2 months) in the KEYTRUDA SC arm and 6.21 months (range: 1 day – 15.9 months) in the KEYTRUDA IV arm.[6]
*Participants are counted a single time for each applicable row and column. Non-serious AEs up to 30 days after the last dose and serious AEs up to 90 days after the last dose are included.[6] †Determined by the investigator to be related to treatment.[6] ‡Includes febrile neutropenia (n=3), neutropenic colitis (n=1), neutropenic sepsis (n=1), parotitis (n=1), pneumonia (n=1), septic shock (n=1) and pneumonitis (n=1).[6] §Includes septic shock (n=2) and multiple organ dysfunction syndrome (n=1).[6] ¶The reported injection-site reactions included terms of injection-site reaction (0.8%), injection-site erythema (0.4%), injection-site haemorrhage (0.4%), injection-site induration (0.4%) and injection-site pain (0.4%).[6]
AE, adverse event; IV, intravenous; SC, subcutaneous; TRAE, treatment-related adverse event.

The incidence, type and severity of imAEs were generally consistent between treatment groups[7]

imAEs occurring in >0% of patients in either treatment group[7]

Participants, n (%)*	KEYTRUDA SC + chemotherapy (n=251)		KEYTRUDA IV + chemotherapy (n=126)	
One or more imAEs*	78 (31.1)		33 (26.2)	
Type of events†, by category	**Any grade**	**Grade 3–5**	**Any grade**	**Grade 3–5**
Hypothyroidism	35 (13.9)	0 (0)	15 (11.9)	0 (0)
Hyperthyroidism	20 (8.0)	0 (0)	6 (4.8)	0 (0)
Pneumonitis	13 (5.2)	6 (2.4)	1 (0.8)	0 (0)
Infusion reactions	8 (3.2)	0 (0)	3 (2.4)	0 (0)
Gastritis	7 (2.8)	2 (0.8)	1 (0.8)	0 (0)
Adrenal insufficiency	5 (2.0)	1 (0.4)	3 (2.4)	3 (2.4)
Severe skin reactions	4 (1.6)	4 (1.6)	3 (2.4)	2 (1.6)
Colitis	3 (1.2)	2 (0.8)	3 (2.4)	1 (0.8)
Thyroiditis	1 (0.4)	0 (0)	1 (0.8)	0 (0)
Hepatitis	1 (0.4)	0 (0)	0 (0)	0 (0)
Myositis	1 (0.4)	0 (0)	0 (0)	0 (0)
Type 1 diabetes mellitus	1 (0.4)	1 (0.4)	0 (0)	0 (0)
Nephritis	0 (0)	0 (0)	2 (1.6)	0 (0)
Hypophysitis	0 (0)	0 (0)	1 (0.8)	1 (0.8)

Recommended dose modifications are the same for KEYTRUDA SC and KEYTRUDA IV.[1]

No dose reductions are recommended for KEYTRUDA SC. Withhold or discontinue KEYTRUDA SC to manage adverse reactions. Please refer to the individual product's SmPC for full details about dosing modification, treatment monitoring and AE management.

Adapted from Felip E, *et al*. 2025.

Data cutoff: 12 July 2024. Median study follow-up: 9.6 months (range: 6.24–16.39 months). The median time on study treatment was 6.87 months (range: 1 day – 13.2 months) in the KEYTRUDA SC arm and 6.21 months (range: 1 day – 15.9 months) in the KEYTRUDA IV arm.[6]
*imAEs and infusion reactions are based on a list of preferred terms specified by the sponsor intended to capture the known risks of KEYTRUDA and are considered regardless of attribution to trial treatment by the investigator.[7] †Patients are counted a single time for each applicable row and column.[7]
AE, adverse event; imAE, immune-mediated adverse event; IV, intravenous; SC, subcutaneous; SmPC, Summary of Product Characteristics.

KEYTRUDA SC demonstrated non-inferior PK results and faster administration vs KEYTRUDA IV[1,2,6]

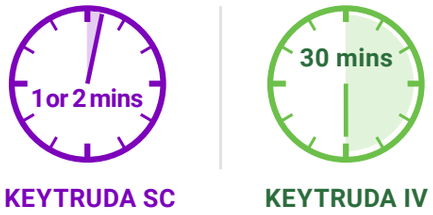
Comparable results to KEYTRUDA IV[6]

- **Non-inferior pembrolizumab exposure** with KEYTRUDA SC and KEYTRUDA IV as measured by Cycle 1 AUC_{0-6wks} and Cycle 3 C_{trough}, p<0.0001
- **PFS, ORR and OS** were descriptive and **were comparable to KEYTRUDA IV**
- **The safety profile of KEYTRUDA SC was generally consistent** with the known AEs of KEYTRUDA IV plus chemotherapy
  - With an addition of injection site reactions, which occurred in 2.4% of patients

Faster administration than KEYTRUDA IV[1,2]

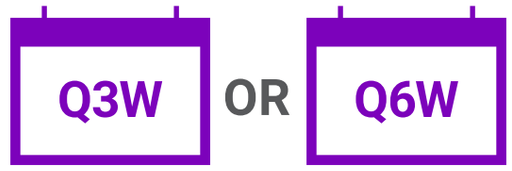
KEYTRUDA SC provides faster administration than a 30-minute infusion of KEYTRUDA IV

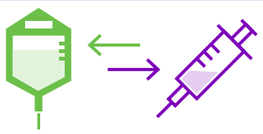
- **Q3W:** Administered over **1 minute** KEYTRUDA SC 395 mg/2.4 mL injection volume
- **Q6W:** Administered over **2 minutes** KEYTRUDA SC 790 mg/4.8 mL injection volume



Flexible treatment administration[1]

- Two dosing options – **Q3W** and **Q6W**
- Vials contain **ready-to-use solution** for injection – no dilution required
- **Does not require a port**, offering the opportunity for administration outside the infusion suite
- Two injection site options: **abdomen** or **thigh**





Patients can switch from KEYTRUDA IV to KEYTRUDA SC, or from KEYTRUDA SC to KEYTRUDA IV, at their next scheduled dose[1]

AE, adverse event; AUC, area under the curve; C_{trough}, trough concentration; GMR, geometric mean ratio; IV, intravenous; NICE, National Institute for Health and Care Excellence; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; Q3W, every 3 weeks; Q6W, every 6 weeks; SC, subcutaneous.

KEYTRUDA SC provides two dosing options and is a ready-to-use solution which doesn't require dilution[1]

KEYTRUDA SC™

Dose: Q3W

Administered subcutaneously over
1 minute*

Low injection volume: 2.4 mL

395 mg pembrolizumab

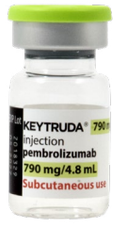
OR

Dose: Q6W

Administered subcutaneously over
2 minutes*

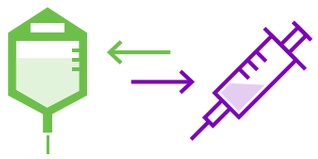
Low injection volume: 4.8 mL

790 mg pembrolizumab



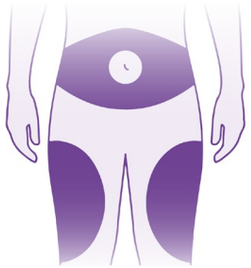
Vials shown to scale, not actual size.

Option to switch



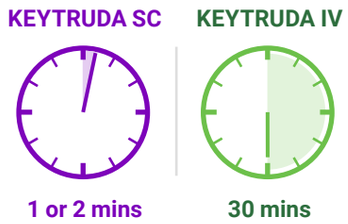
Patients have the option to switch from KEYTRUDA IV to KEYTRUDA SC — or KEYTRUDA SC to KEYTRUDA IV — at their next scheduled dose

Two injection site options



Thigh or abdomen, avoiding the 5 cm area around the navel

Faster administration vs KEYTRUDA IV



KEYTRUDA SC can be administered over 1 or 2 minutes, providing faster administration than a 30-minute infusion of KEYTRUDA IV*

*Does not account for all aspects of treatment. Actual clinic time may vary.
IV, intravenous; Q3W, every 3 weeks; Q6W, every 6 weeks; SC, subcutaneous.

The KEYTRUDA SC syringe can be prepared for injection in four steps[1]

1 Check the vial

Check the vial label to ensure the correct formulation is prepared and administered to the patient as prescribed.

Visually inspect the vial for particulate matter and discolouration. The solution is clear to slightly opalescent, colourless to slightly yellow.

Discard the vial if visible particles or discolouration are observed.

2 Bring the vial to room temperature

Allow the refrigerated vial to come to room temperature for at least 30 minutes.

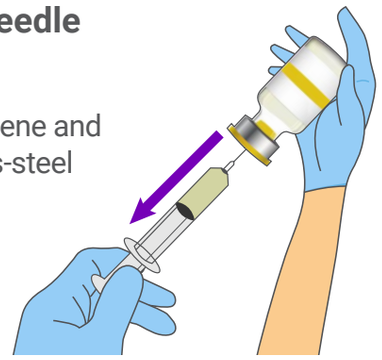
- Prior to preparation for administration, if needed, the **unpunctured vial may be stored at room temperature for up to 24 hours**

Do not dilute, do not shake the vial.

3 Withdraw the required volume

Withdraw either 2.4 mL (395 mg) or 4.8 mL (790 mg) using a sterile syringe and a **transfer needle (18–21G recommended).**

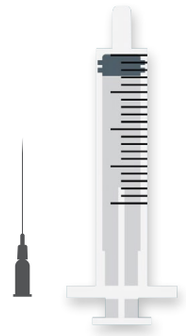
- KEYTRUDA SC is compatible with polypropylene and polycarbonate syringe material and stainless-steel transfer and injection needles



KEYTRUDA SC vial is for single use only. Discard the empty vial or any unused portion left in the vial.*

4 Change to injection needle before use

To avoid needle clogging, change the needle to a 25–30G, 13 mm hypodermic injection needle immediately prior to subcutaneous injection.



Do not attach the hypodermic needle until immediately prior to administration to avoid clogging.

*Any unused medicinal product or waste material should be disposed of in accordance with local requirements.
SC, subcutaneous.

How to store KEYTRUDA SC vials and prepared syringes[1]

Storage of the vials

- Store in a refrigerator at 2°C–8°C
- Store in the original carton to protect from light
- Do not freeze
- Do not shake
- If removed from refrigeration, vials can remain at room temperature (≤25°C) for up to 24 hours before preparation for administration

Storage of prepared syringes*

The product does not contain preservative and **should be used immediately after withdrawing from the vial.** If not used immediately, store the syringe containing KEYTRUDA SC solution for injection with the **transfer needle and cap in place for:**†

If refrigerated, the filled syringe must be allowed to come to room temperature for at least 30 minutes prior to use.

The filled syringe must not be frozen.

Up to 8 hours

At room temperature
(≤25°C)

OR

Up to 24 hours

In the refrigerator at **2°C–8°C**
The 24-hour period may include up to 8 hours at room temperature

Discard if storage time exceeds these limits.
Do not store any unused portion of the solution for injection for reuse. Any unused medicine or waste material should be disposed of in accordance with local requirements.

*In-use storage times and conditions prior to use are the responsibility of the user. †Do not attach the hypodermic needle until immediately prior to administration to avoid clogging.
SC, subcutaneous.

KEYTRUDA SC is administered over 1 or 2 minutes, with two subcutaneous injection-site options – abdomen or thigh[1]

Should be administered by an HCP and must be administered by subcutaneous injection only

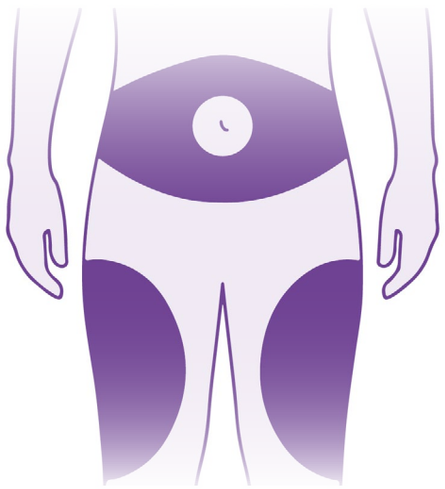
Q3W

Inject over
1 minute*
one dose
(395 mg/2.4 mL)

OR

Q6W

Inject over
2 minutes*
one dose
(790 mg/4.8 mL)



Administration techniques

- Inject into the subcutaneous tissue of the thigh or abdomen, avoiding 5 cm around the navel
- Do not inject into skin that is damaged, sore, bruised, scarred, scaly, or has red patches
- Rotate injection sites for subsequent injections (ensure the injection site is at least 2.5 cm from the previous injection site)
- During treatment with KEYTRUDA SC do not administer other medications for subcutaneous use at the same site

For certain patients, treatment with **KEYTRUDA SC** could offer opportunity for administration outside the infusion suite[8]

*Does not account for all aspects of treatment. Actual clinic time may vary.
HCP, healthcare professional; Q3W, every 3 weeks; Q6W, every 6 weeks; SC, subcutaneous.

KEYTRUDA SC is a distinct product from KEYTRUDA IV: each pack has a different colour and is associated with a unique GTIN code to ensure accurate identification and ordering[1,2]

Vial identifications

KEYTRUDA SC™

Q3W

Yellow cap

395 mg pembrolizumab/2.4 mL (165 mg/mL), single-dose vials

- **GTIN: 00366582512479**
- **Carton x1 vial**
  50 mm x 50 mm x 90 mm

Q6W

Light green cap

790 mg pembrolizumab/4.8 mL (165 mg/mL), single-dose vials

- **GTIN: 00366582512486**
- **Carton x1 vial**
  50 mm x 50 mm x 90 mm

KEYTRUDA IV

Navy blue cap

100 mg pembrolizumab/4 mL (25 mg/mL), single-dose vials

- **GTIN: 00191778025422**
- **Carton x2 vials**
  60 mm x 57 mm x 90 mm

Vials and cartons shown to scale, not actual size.

EAN, European Article Number; GTIN, ordering code; IV, intravenous; PL, marketing authorisation; Q3W, every 3 weeks; Q6W, every 6 weeks; SC, subcutaneous.

KEYTRUDA SC is administered over 1 or 2 minutes, and may lead to important time and resource efficiencies[1,2,8]

93%

reduction in drug administration time with KEYTRUDA SC (over 1 or 2 mins) vs KEYTRUDA IV (30 mins)[1,2]

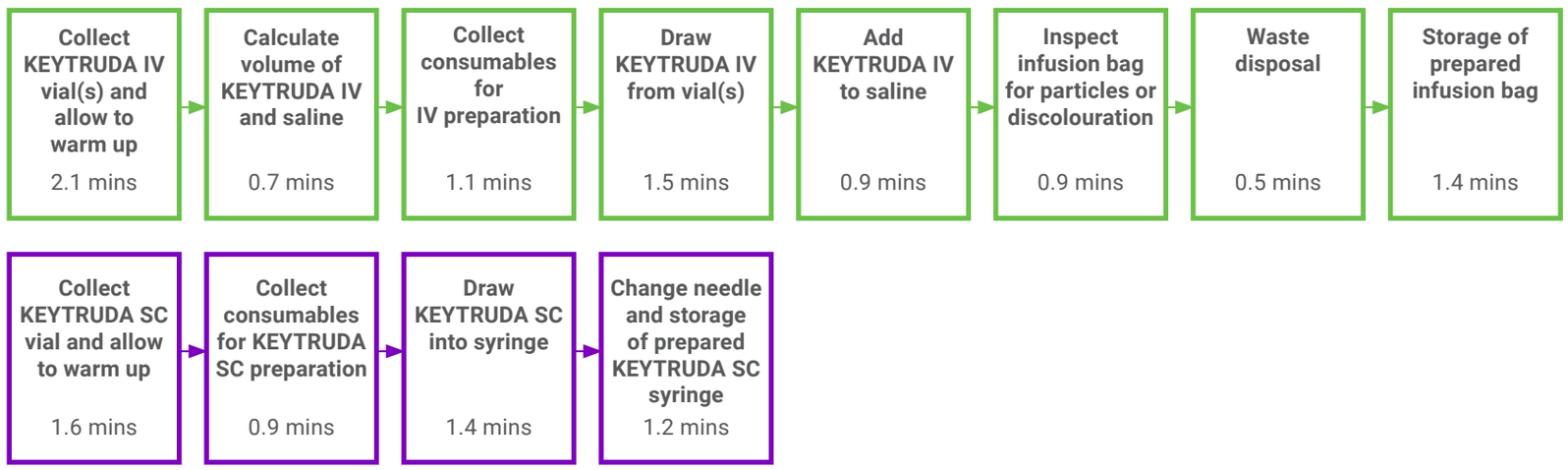
- A prospective observational T&M study across 17 sites participating in MK-3475A-D77 across eight countries in Europe (n=4), South America (n=3) and Asia (n=1). In total, 212 observations were analysed (KEYTRUDA SC, n=153; KEYTRUDA IV, n=59). Process tasks were selected and observed to quantify and compare active HCP time (associated with preparation and administration processes), patient time (in the chair/bed, treatment room and healthcare facility) and consumables usage[8]

Preparation time* | Administration process* | Patient chair time*

Active HCP time per visit for treatment preparation of KEYTRUDA SC vs IV[8]

44.3%

reduction in active HCP time for the preparation process with KEYTRUDA SC vs IV (5.1 mins vs 9.1 mins, respectively)†



This is a representative example from a T&M study, and may not be representative of individual processes at local level.

*Measured in minutes (weighted mean). †Numbers have been rounded to nearest decimal place, so totals may not sum exactly to the overall values.

HCP, healthcare professional; IV, intravenous; SC, subcutaneous; T&M, time and motion.

KEYTRUDA SC is administered over 1 or 2 minutes, and may lead to important time and resource efficiencies[1,2,8]

93%

reduction in drug administration time with KEYTRUDA SC (over 1 or 2 mins) vs KEYTRUDA IV (30 mins)[1,2]

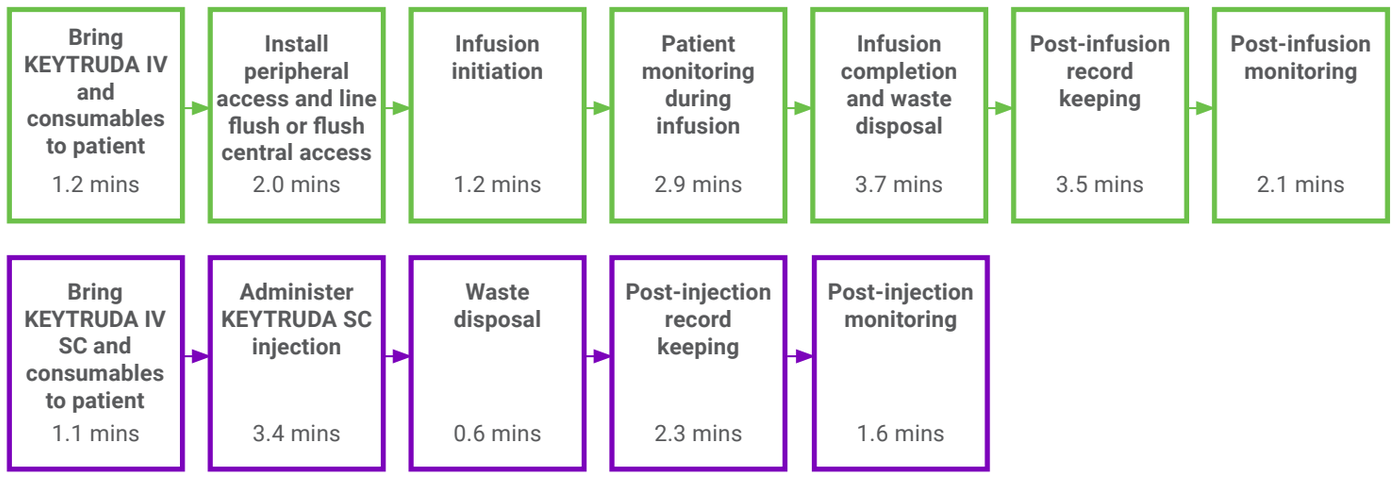
- A prospective observational T&M study across 17 sites participating in MK-3475A-D77 across eight countries in Europe (n=4), South America (n=3) and Asia (n=1). In total, 212 observations were analysed (KEYTRUDA SC, n=153; KEYTRUDA IV, n=59). Process tasks were selected and observed to quantify and compare active HCP time (associated with preparation and administration processes), patient time (in the chair/bed, treatment room and healthcare facility) and consumables usage[8]

Preparation time* | **Administration process*** | Patient chair time*

Active HCP time per visit for the treatment administration process of KEYTRUDA SC vs IV[8]

46.3%

reduction in active HCP time for the administration process with KEYTRUDA SC vs IV (8.9 mins vs 16.7 mins, respectively)†



This is a representative example from a T&M study, and may not be representative of individual processes at local level.

*Measured in minutes (weighted mean). †Numbers have been rounded to nearest decimal place, so totals may not sum exactly to the overall values.

HCP, healthcare professional; IV, intravenous; SC, subcutaneous; T&M, time and motion.

KEYTRUDA SC is administered over 1 or 2 minutes, and may lead to important time and resource efficiencies[1,2,8]

93%

reduction in drug administration time with KEYTRUDA SC (over 1 or 2 mins) vs KEYTRUDA IV (30 mins)[1,2]

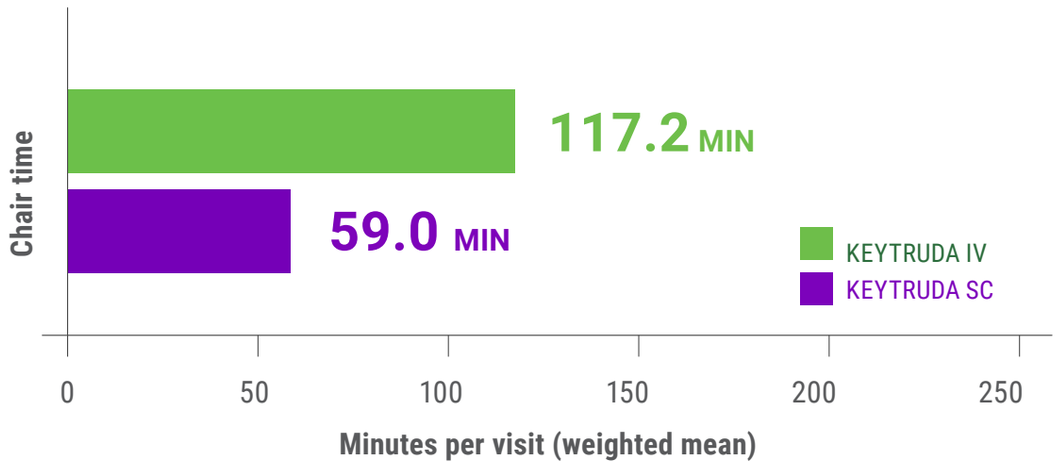
- A prospective observational T&M study across 17 sites participating in MK-3475A-D77 across eight countries in Europe (n=4), South America (n=3) and Asia (n=1). In total, 212 observations were analysed (KEYTRUDA SC, n=153; KEYTRUDA IV, n=59). Process tasks were selected and observed to quantify and compare active HCP time (associated with preparation and administration processes), patient time (in the chair/bed, treatment room and healthcare facility) and consumables usage[8]

Preparation time* | Administration process* | **Patient chair time***

Patient chair time[8]

49.6%

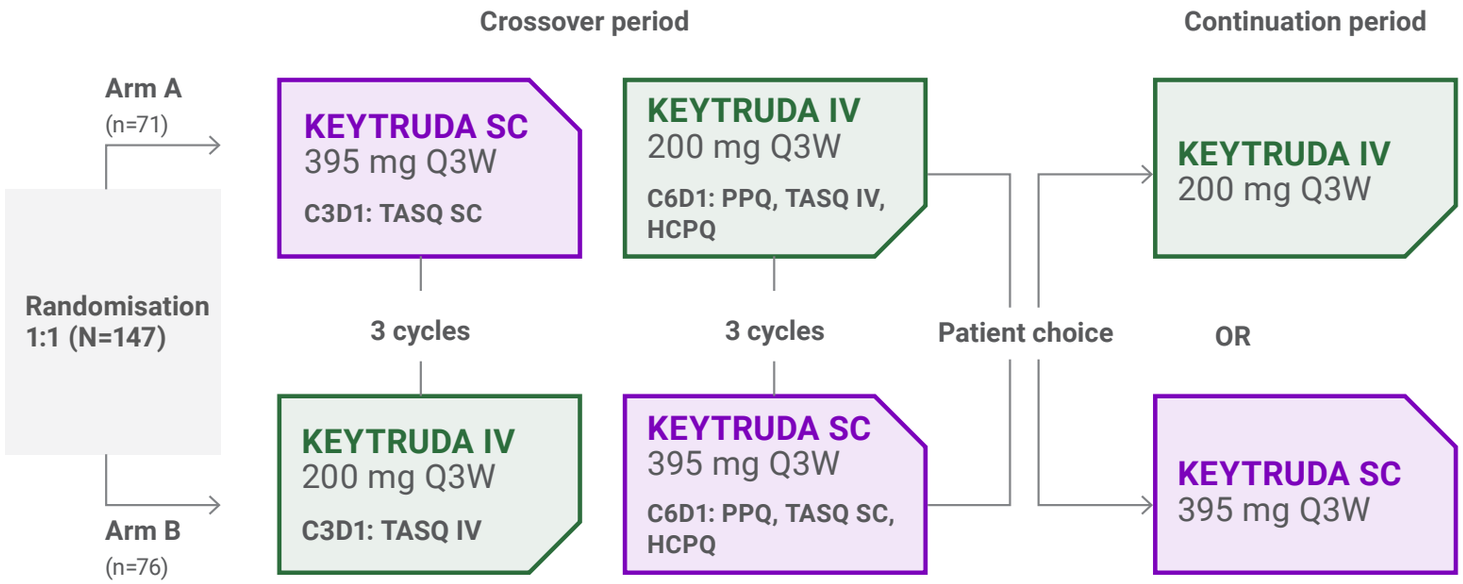
reduction in patient chair time with KEYTRUDA SC vs IV



Adapted from De Cock, *et al*. 2025.

This is a representative example from a T&M study, and may not be representative of individual processes at local level.
*Measured in minutes (weighted mean).
HCP, healthcare professional; IV, intravenous; SC, subcutaneous; T&M, time and motion.

MK3475-A-F11: A Phase II, crossover study of participant-reported preference for KEYTRUDA SC or KEYTRUDA IV[9]



Adapted from Casarini A, *et al*. 2025.

- Participants received up to a total of 17 cycles of treatment for melanoma or RCC, and up to a total of 35 cycles of treatment for NSCLC
- The analysis population for participant preference included all randomised participants who received 3 cycles of KEYTRUDA SC and 3 cycles of KEYTRUDA IV during the crossover period and completed the PPQ after the administration of study treatment on Day 1 of Cycle 6 (N=118)
- The safety analysis population included all randomised participants who received at least 1 dose of study treatment (N=147)

Participants

- Age ≥18 years
- Resected Stage IIB, IIC, or III melanoma OR
- Intermediate-high or high risk resected RCC OR
- Newly diagnosed, untreated Stage IV NSCLC with PD-L1 TPS ≥50%
- ECOG PS 0 or 1
- No pneumonitis or interstitial lung disease

Primary endpoint

Participant preference for KEYTRUDA SC or KEYTRUDA IV (PPQ question 1)

Secondary endpoints

- Reasons for preference (PPQ question 3)
- Participant satisfaction with route of administration (TASQ-SC/IV)
- Participant choice of administration for continuation period
- HCP preference for route of administration (HCPQ)
- Safety and tolerability

Randomisation stratified by ECOG PS and tumour type; KEYTRUDA SC is KEYTRUDA at 165 mg/mL with berahyaluronidase alfa at 2000 U/mL (injection volume ~2.4 mL).[9]

C3D1, cycle 3 Day 1; C6D1, cycle 6 Day 1; ECOG PS, Eastern Cooperative Oncology Group performance status; HCP, healthcare professional; HCPQ, HCP Preference Questionnaire; IV, intravenous; NSCLC, non-small cell lung cancer; PD-L1, programmed cell death-ligand 1; PPQ, patient preference questionnaire; Q3W, every 3 weeks; RCC, renal cell carcinoma; SC, subcutaneous; TASQ, Therapy Administration Satisfaction Questionnaire; TPS, tumour proportion score.

~2/3 of patients and HCPs prefer KEYTRUDA SC over KEYTRUDA IV[9]

Top reasons for **patient preference for SC administration:**[9]

- Requires less time in clinic (64%)
- Feels more comfortable during administration (62%)

'Lower level of injection site pain' (38%) and 'Feels less emotionally distressing' (21%) were other reasons for preference.

Top reasons for **HCP preference for SC administration:**[9]

- Ease of administration; more convenient to administer (95%)
- Length of administration time; time required to administer (95%)

'Patient's body type' (10%) was another reason for preference.

- **More patients chose to continue with KEYTRUDA SC than KEYTRUDA IV (68% vs 32%) after Cycle 6 in the treatment continuation period**[9]
- Safety findings were comparable within arms pre-and post-switch, indicating the safety of switching from one route of administration to the other[9]
- Injection-site AEs with pembrolizumab SC administration were similar regardless of the order in which treatment was given[9]

AE, adverse event; HCP, healthcare professional; IV, intravenous; SC, subcutaneous.

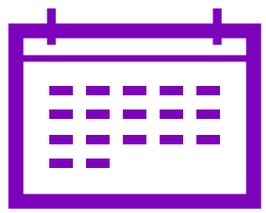
KEYTRUDA SC is licensed for use in adult patients across most KEYTRUDA IV indications, whether alone or in combination with other therapies[1,2]

KEYTRUDA SC offers:[1]

FAST SUBCUTANEOUS ADMINISTRATION

Over 1 minute for Q3W
Over 2 minutes for Q6W

vs 30 minutes for KEYTRUDA IV*



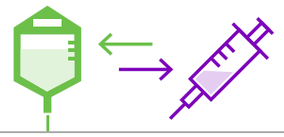
FLEXIBLE DOSING OPTIONS

Q3W and **Q6W**

Two sites of administration:
Abdomen or thigh

LOW INJECTION VOLUME

2.4 mL Q3W
4.8 mL Q6W



Patients can switch from KEYTRUDA IV to KEYTRUDA SC, or from KEYTRUDA SC to KEYTRUDA IV, at their next scheduled dose[1]

*Does not account for all aspects of treatment. Actual clinic time may vary.

HCP, healthcare professional; IV, intravenous; SC, subcutaneous; Q3W, every 3 weeks; Q6W, every 6 weeks.

References

1. KEYTRUDA SC Summary of Product Characteristics.
2. KEYTRUDA Summary of Product Characteristics.
3. Davis JD, *et al. Clin Pharmacol Ther* 2024;115:422–439.
4. Connor RJ, *et al. J Pharmacol Toxicol Methods* 2020;106:106936.
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8. De Cock, *et al. Adv Ther* 2025; DOI: 10.1007/s12325-025-03365-7.
9. Casarini IA, *et al.* A Phase 2 study of participant-reported preference for pembrolizumab administered subcutaneously or intravenously. ESMO. 17–21 October 2025. Berlin, Germany. Poster: 3145P.

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