KEYNOTE-024 5-Year OS Update: First-Line Pembrolizumab vs Platinum-Based Chemotherapy in Patients with Metastatic Non-Small-Cell Lung Cancer and PD-L1 Tumor Proportion Score ≥50%.

Presented at the European Society for Medical Oncology Virtual Congress 2020 (ESMO)
September 19 – 21, 2020.

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MSD

KEYTRUDA®
Pembrolizumab, MSD

CH-KEY-00580; created in March 2021.

KEYNOTE-024 (NCT02142738)[1]

- Outcomes with standard chemotherapy have been historically poor for patients with metastatic NSCLC[2]
- KEYNOTE-024 showed superiority of first-line pembrolizumab monotherapy versus platinum-based chemotherapy for metastatic NSCLC with PD-L1 TPS ≥50% and without sensitizing EGFR/ALK alterations[2] at 11.2 months median follow-up[a]
  - Primary endpoint:[b] PFS HR, 0.50 (95% CI, 0.37–0.68; P<0.001)[3]
  - Key secondary endpoint: OS HR, 0.60 (95% CI, 0.41–0.89; P=0.005)[3]
- The 5 years' follow-up reports updated efficacy and safety outcomes for
  - The ITT population
  - Patients who completed 35 cycles (2 years) of pembrolizumab therapy

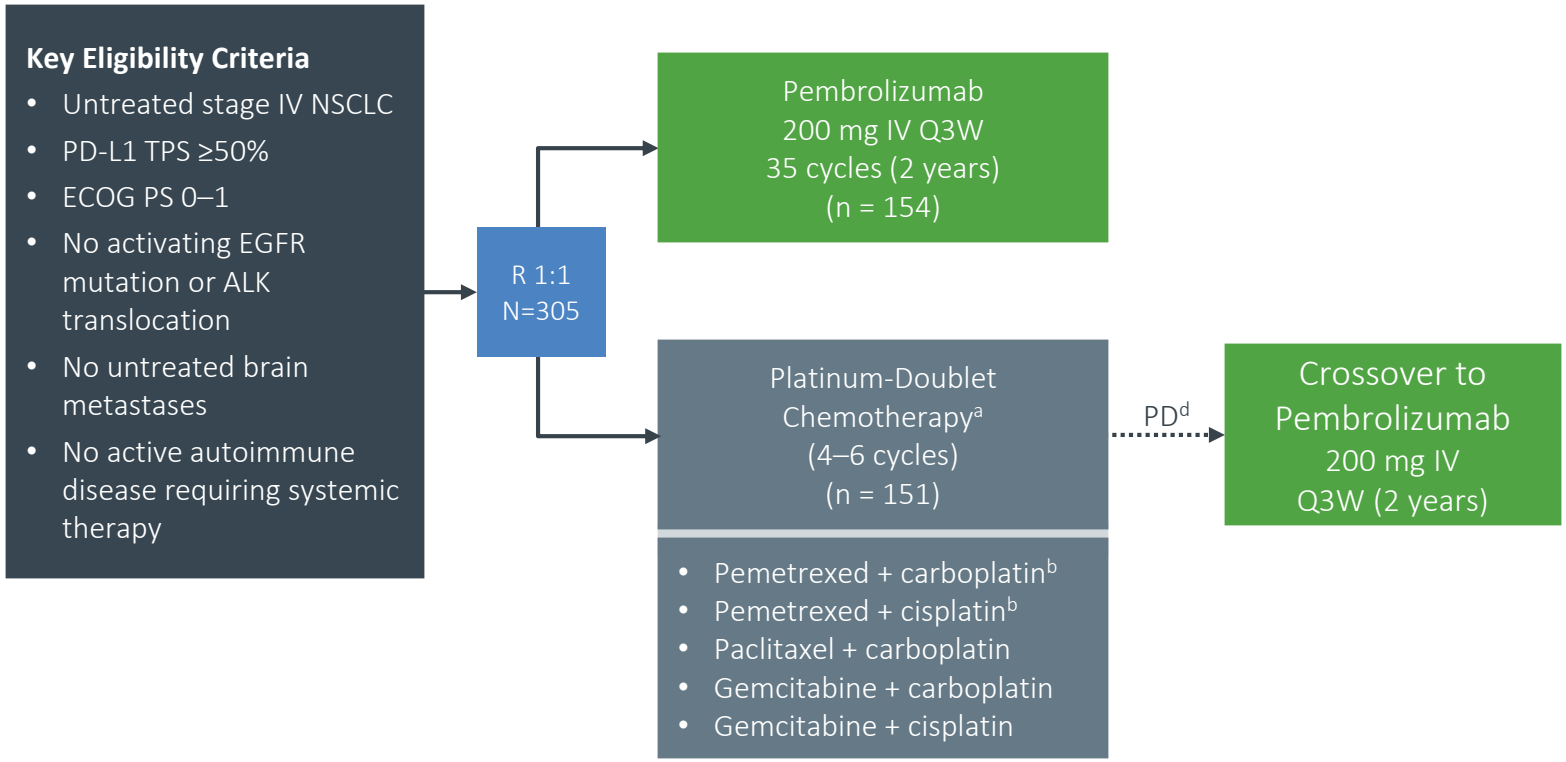
1. Brahmer JR, et al. LBA51 KEYNOTE-024 5-year OS update: First-line pembrolizumab (pembro) vs platinum-based chemotherapy (chemo) in patients (pts) with metastatic NSCLC and PD-L1 tumour proportion score ≥ 50 %. Ann Oncol. 2020;31(Suppl 4);S1181 – S1182.
2. Howlader N, et al (eds). SEER Cancer Statistics Review, 1975–2017, National Cancer Institute. https://seer.cancer.gov/csr/1975_2017/. 3. Reck M, et al., for the KEYNOTE-024 investigators. Pembrolizumab versus chemotherapy for PD-L1-positive non-small-cell lung cancer. N Engl J Med. 2016;375:1823–1833.
DOI:https://doi.org/10.1016/j.annonc.2020.08.2284 Presented at the European Society for Medical Oncology (ESMO) Virtual Congress 2020; 19 – 21 September 2020.

HR, hazard ratio; ITT, intent-to-treat; NSCLC, non–small-cell lung cancer; TPS, tumor proportion score.
a. Defined as median time from randomization to death or data cutoff.
b. Analyzed by RECIST version 1.1 per blinded, independent, central radiology review.
ALK: anaplastic lymphoma kinase; CI: confidence interval; EGFR: epidermal growth factor receptor; HR: hazard ratio; ITT: intention to treat; NSCLC: non-small cell lung cancer; OS: overall survival; PD-L1: programmed cell death ligand 1; PFS: progression free survival; TPS: tumor proportion score.

CH-KEY-00580; created in March 2021.

KEYNOTE-024 – Study Design (NCT02142738)

- International, randomized, open-label, controlled, phase 3 trial



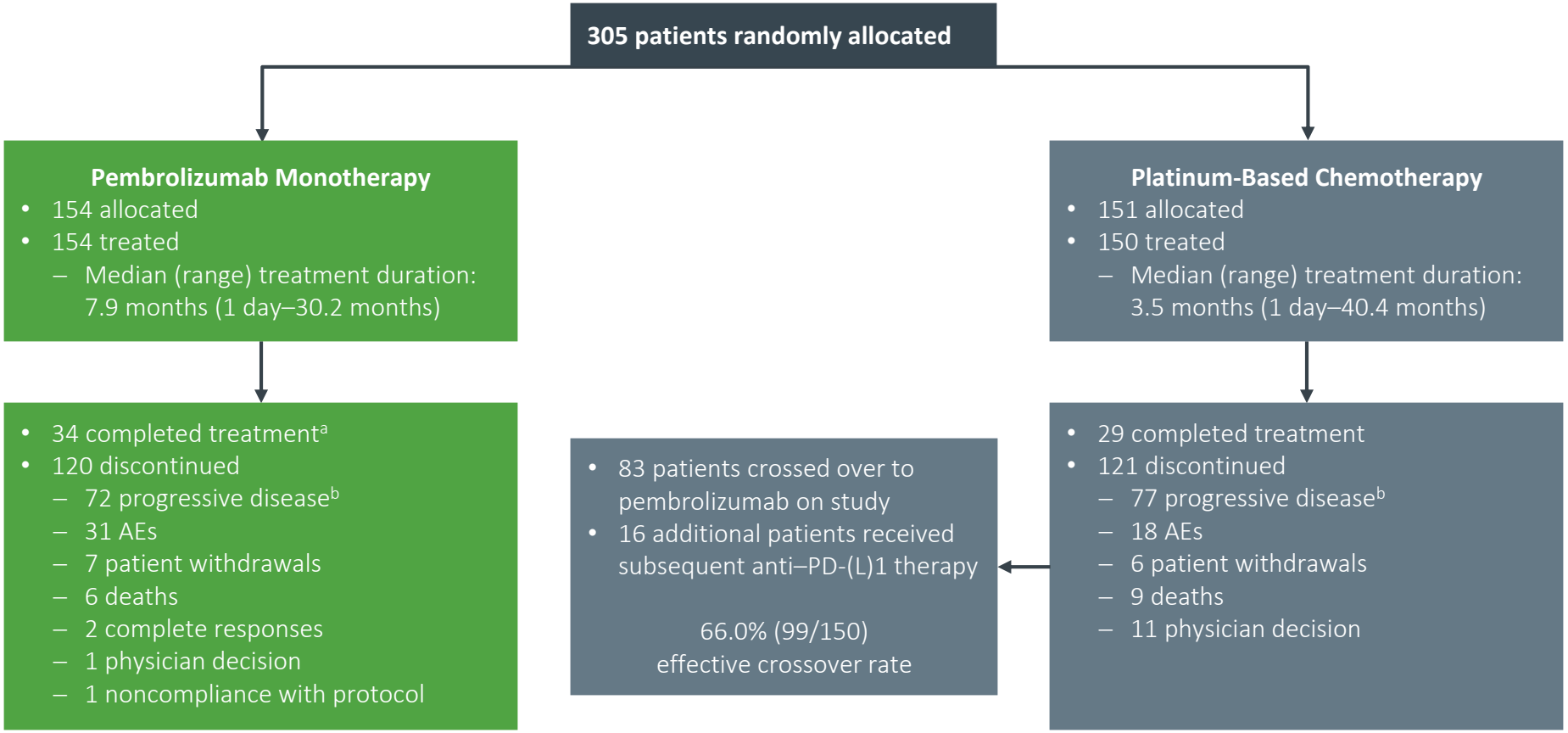
- **Primary end point:** PFS (RECIST v1.1 per blinded, independent, central review)
- **Key secondary end point:** OS
- **Secondary end points:** ORR, safety, PFS (RECIST v1.1 per investigator review)
- **Exploratory end point:** DOR

Adapted from Brahmer JR, et al. LBA51 KEYNOTE-024 5-year OS update: First-line pembrolizumab (pembro) vs platinum-based chemotherapy (chemo) in patients (pts) with metastatic NSCLC and PD-L1 tumour proportion score ≥ 50 %. Ann Oncol. 2020;31(Suppl 4);S1181 – S1182. DOI:https://doi.org/10.1016/j.annonc.2020.08.2284 Presented at the European Society for Medical Oncology (ESMO) Virtual Congress 2020; 19 – 21 September 2020.

a. Optional pemetrexed maintenance therapy for nonsquamous disease.
b. Permitted for nonsquamous disease only.
c. Patients randomized to pembrolizumab who completed 2 years of therapy or who stopped pembrolizumab after achieving CR and then had PD were eligible for a second course of pembrolizumab monotherapy.
d. Before the DMC recommendation and amendment 8, which permitted those in the chemotherapy arm to be offered pembrolizumab (based on interim analysis 2 data), patients were eligible for crossover when PD was confirmed by blinded, independent, central radiology review.
ALK: anaplastic lymphoma kinase; CR: complete response; DMC: data monitoring committee; DOR: duration of response; ECOG PS: Eastern Co-operative Oncology Group performance status; EGFR: epidermal growth factor receptor; IV: intravenous; NSCLC: non-small cell lung cancer; ORR: overall response rate; OS: overall survival; PD: progressive disease; PD-L1: programmed cell death ligand 1; PFS: progression free survival; R: randomization; Q3W: every three weeks; RECIST 1.1: Response Evaluation Criteria In Solid Tumors 1.1.

CH-KEY-00580; created in March 2021.

KEYNOTE-024 – Disposition of Study Treatment

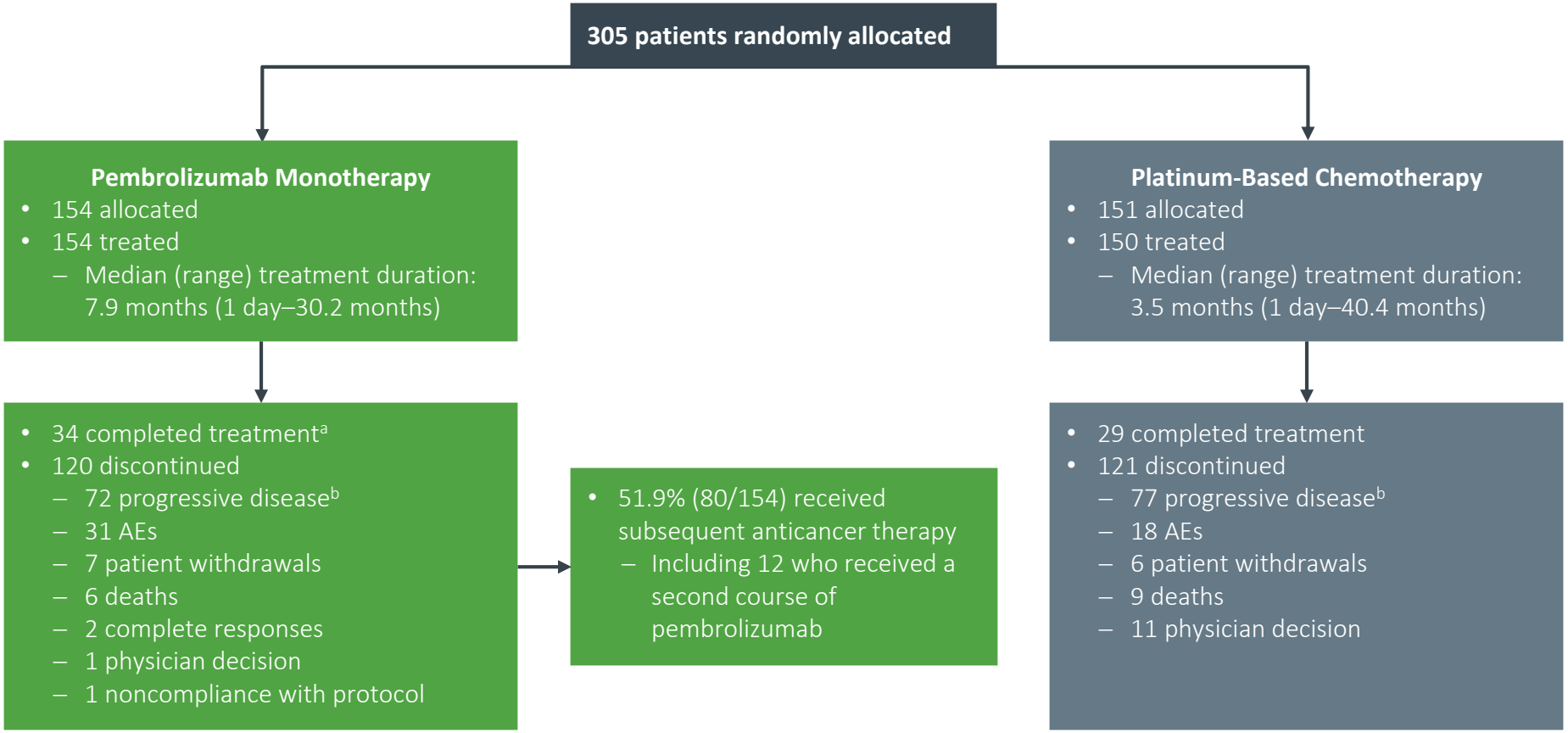


Adapted from Brahmer JR, et al. LBA51 KEYNOTE-024 5-year OS update: First-line pembrolizumab (pembro) vs platinum-based chemotherapy (chemo) in patients (pts) with metastatic NSCLC and PD-L1 tumour proportion score ≥ 50 %. Ann Oncol. 2020;31(Suppl 4);S1181 – S1182. DOI:https://doi.org/10.1016/j.annonc.2020.08.2284 Presented at the European Society for Medical Oncology (ESMO) Virtual Congress 2020; 19 – 21 September 2020.

a. Number of patients who completed treatment, as reported by investigator. b. Includes patients with clinical progression or progressive disease. Data cutoff: June 1, 2020.
AE: adverse event.

CH-KEY-00580; created in March 2021.

KEYNOTE-024 – Disposition of Study Treatment



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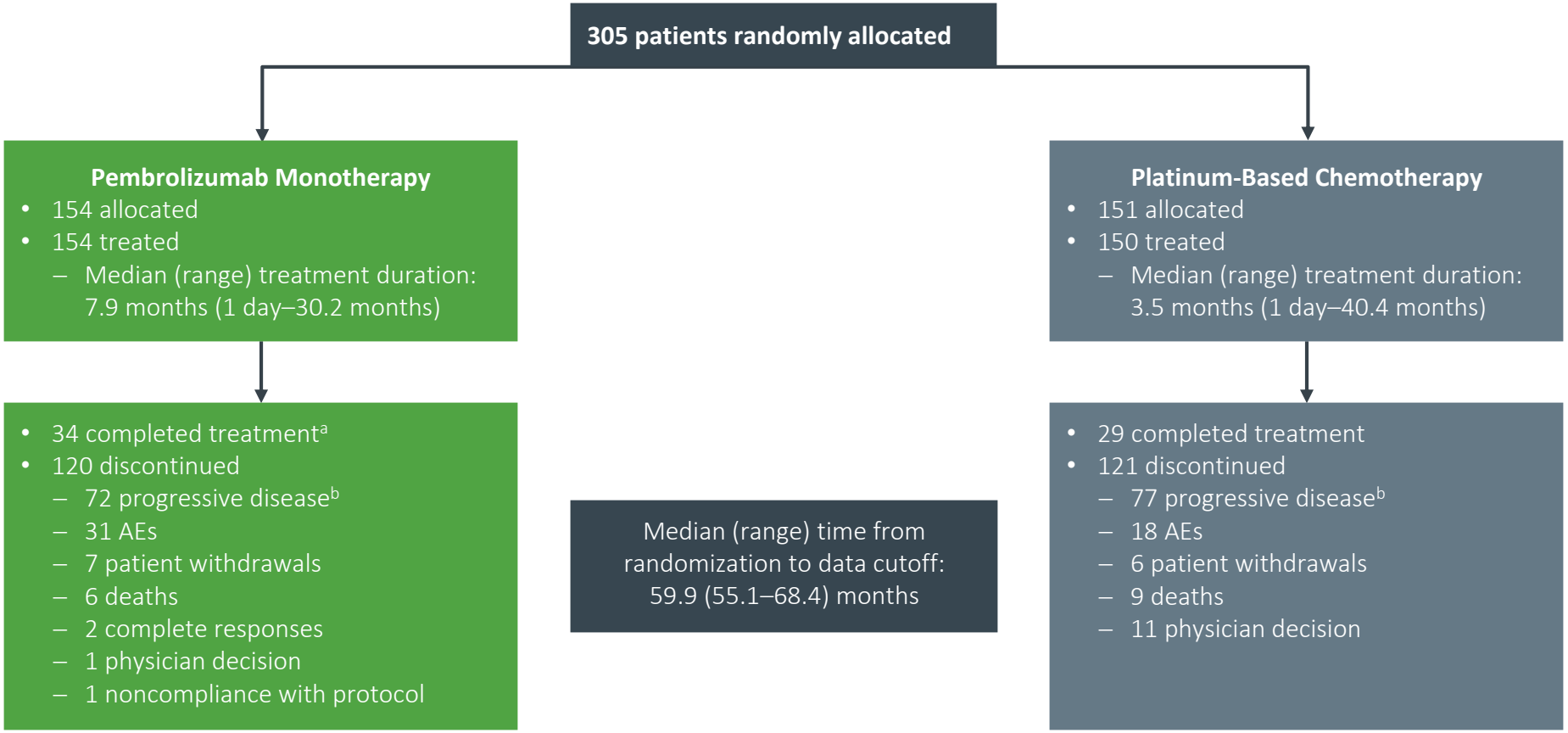

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a. Number of patients who completed treatment, as reported by investigator. b. Includes patients with clinical progression or progressive disease. Data cutoff: June 1, 2020.
AE: adverse event.

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KEYNOTE-024 – Patient baseline characteristics

Patient characteristics, n (%)	Pembrolizumab (n=154)	Chemotherapy (n=151)	35 Cycles (2 Years) of Pembrolizumab (n=39)[a]
Age, years, median (range)	64.5 (33–90)	66.0 (38–85)	61.0 (43–80)
Male	92 (59.7)	95 (62.9)	25 (64.1)
ECOG PS 1	99 (64.3)	98 (64.9)	23 (59.0)
East Asian enrollment site	21 (13.6)	19 (12.6)	8 (20.5)
Squamous histology	29 (18.8)	27 (17.9)[c]	2 (5.1)
Current/former smoker	149 (96.8)	132 (87.4)	37 (94.9)
Treated brain metastases	18 (11.7)	10 (6.6)	9 (23.1)
Prior neoadjuvant therapy	3 (1.9)	1 (0.7)	0
Prior adjuvant therapy	6 (3.9)	3 (2.0)	0

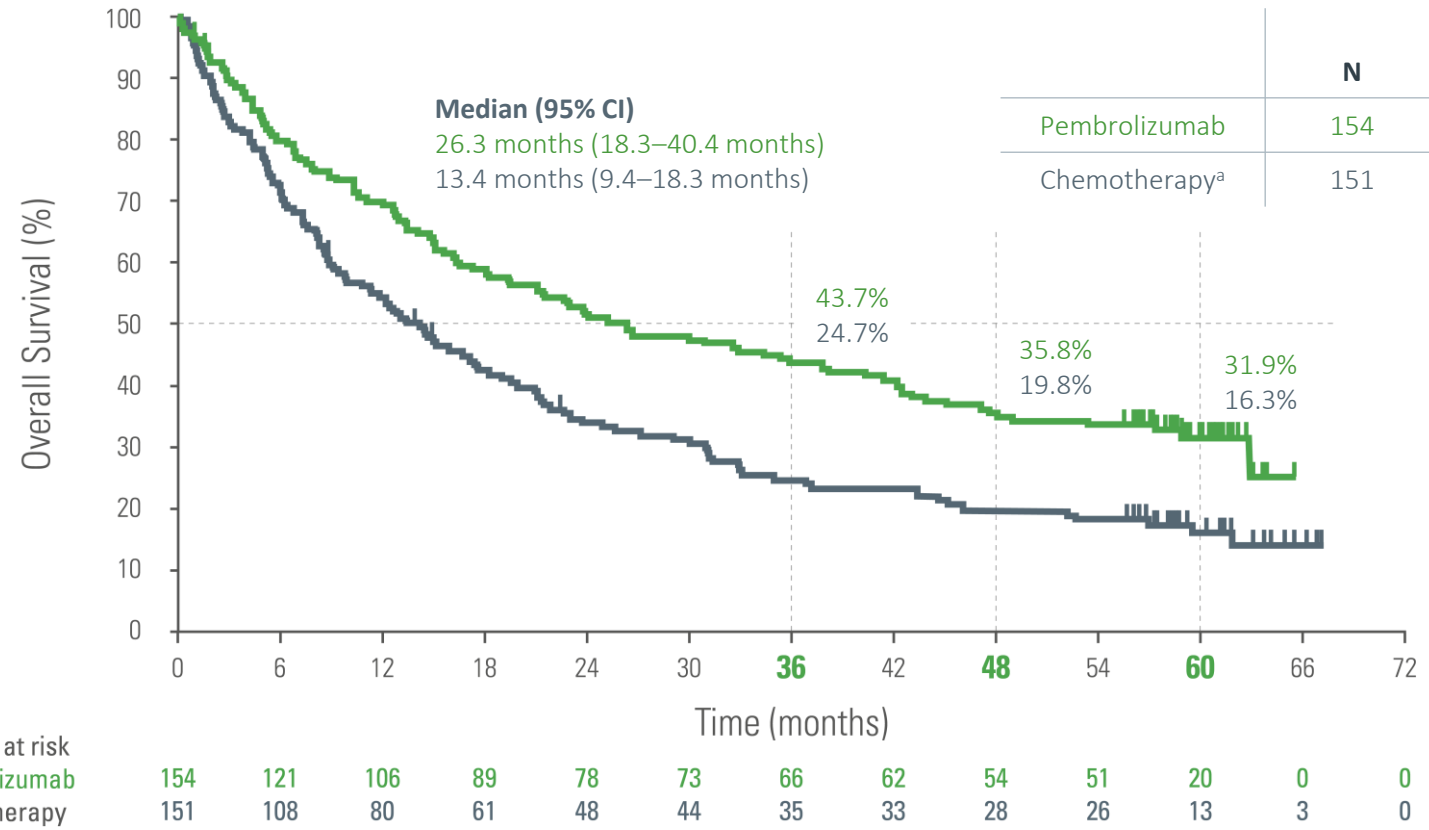
Adapted from Brahmer JR, et al. LBA51 KEYNOTE-024 5-year OS update: First-line pembrolizumab (pembro) vs platinum-based chemotherapy (chemo) in patients (pts) with metastatic NSCLC and PD-L1 tumour proportion score ≥ 50 %. Ann Oncol. 2020;31(Suppl 4);S1181 – S1182. DOI:https://doi.org/10.1016/j.annonc.2020.08.2284 Presented at the European Society for Medical Oncology (ESMO) Virtual Congress 2020; 19 – 21 September 2020.

a. Includes only those patients initially allocated to pembrolizumab who received 35 cycles (2 years) of pembrolizumab according to actual exposure assessment. b. Includes only those patients initially allocated to pembrolizumab who received a second course of pembrolizumab therapy according to actual exposure assessment. c. Includes patients with squamous cell carcinoma and poorly differentiated squamous cell carcinoma. Data in table are n (%), unless otherwise noted. Data cutoff: June 1, 2020.
ECOG PS: Eastern Co-operative Oncology Group performance status.

CH-KEY-00580; created in March 2021.

KEYNOTE-024 – Overall Survival, ITT population

Kaplan-Meier estimates of OS



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

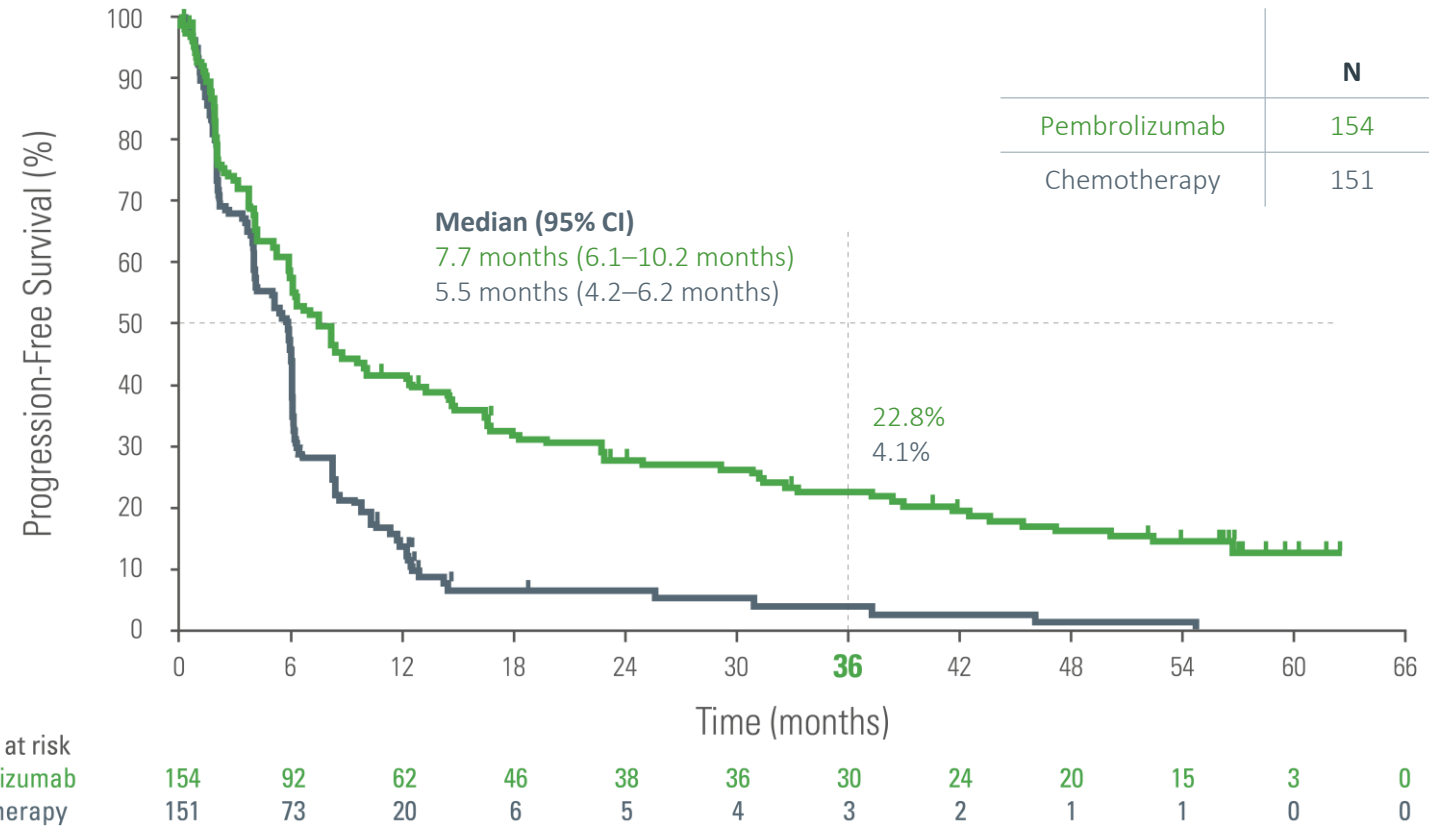
Adapted from Brahmer JR, et al. LBA51 KEYNOTE-024 5-year OS update: First-line pembrolizumab (pembro) vs platinum-based chemotherapy (chemo) in patients (pts) with metastatic NSCLC and PD-L1 tumour proportion score ≥ 50 %. Ann Oncol. 2020;31(Suppl 4);S1181 – S1182. DOI:https://doi.org/10.1016/j.annonc.2020.08.2284 Presented at the European Society for Medical Oncology (ESMO) Virtual Congress 2020; 19 – 21 September 2020.

a. Effective crossover rate from chemotherapy to anti–PD-(L)1 therapy, 66.0% (99 patients in total crossed over to anti–PD-[L]1 therapy: 83 patients crossed over to pembrolizumab during the study, and 16 patients received subsequent anti–PD-[L]1 therapy outside of crossover; patients may have received >1 subsequent anti–PD-[L]1 therapy). Data cutoff: June 1, 2020.
CI: confidence interval; HR: hazard ratio; ITT: intention to treat; PD-(L)1: programmed cell death receptor (ligand) 1.

CH-KEY-00580; created in March 2021.

KEYNOTE-024 – Progression-free Survival, ITT population

Kaplan-Meier estimates of PFS by RECIST v1.1 per Investigator Review[a]



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

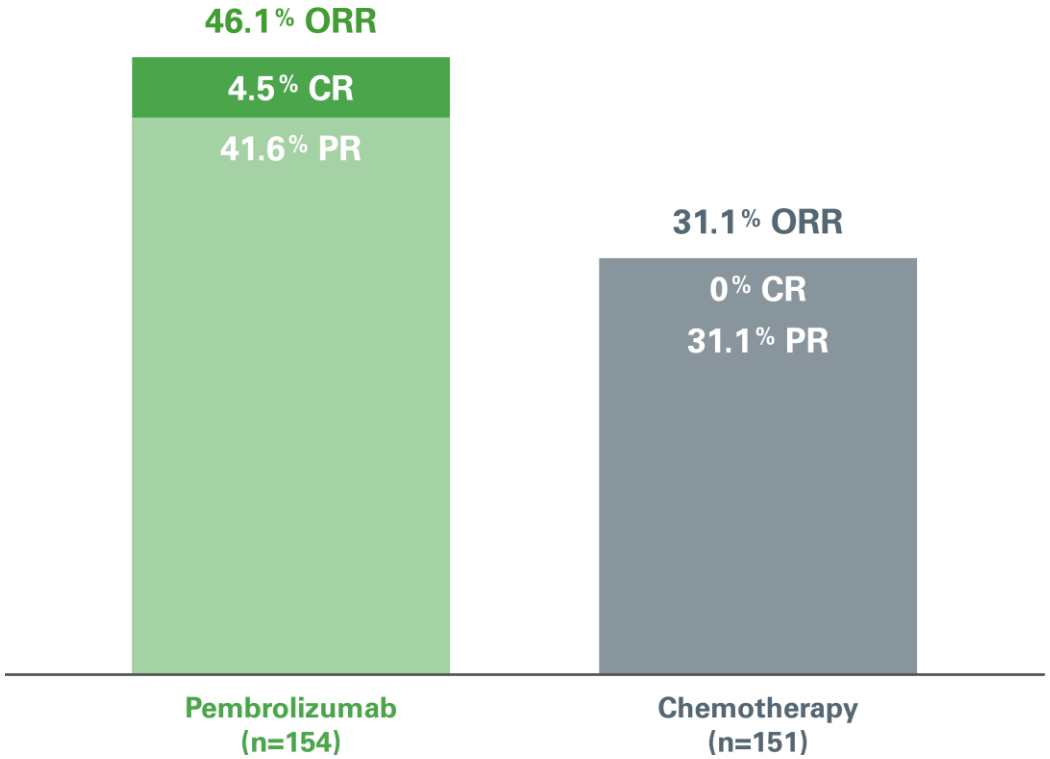
Adapted from Brahmer JR, et al. LBA51 KEYNOTE-024 5-year OS update: First-line pembrolizumab (pembro) vs platinum-based chemotherapy (chemo) in patients (pts) with metastatic NSCLC and PD-L1 tumour proportion score ≥ 50 %. Ann Oncol. 2020;31(Suppl 4);S1181 – S1182. DOI:https://doi.org/10.1016/j.annonc.2020.08.2284 Presented at the European Society for Medical Oncology (ESMO) Virtual Congress 2020; 19 – 21 September 2020.

a. Secondary endpoint; primary endpoint was PFS assessed per blinded, independent, central radiology review. Data cutoff: June 1, 2020.
CI: confidence interval; HR: hazard ratio; ITT: intention to treat.

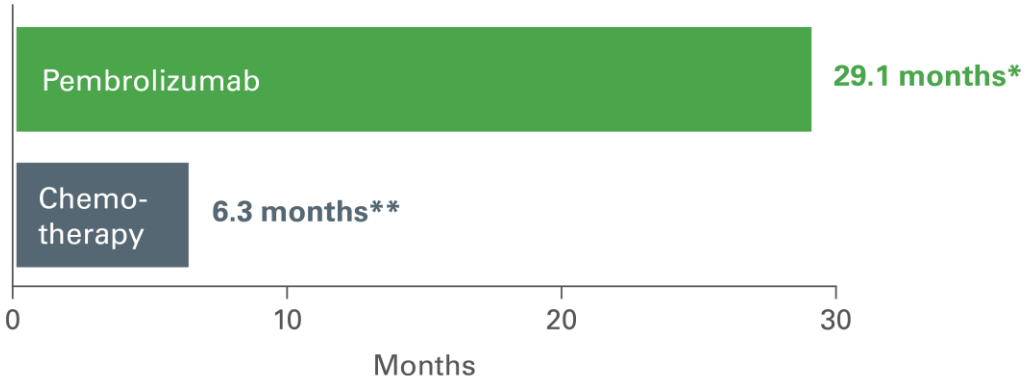
CH-KEY-00580; created in March 2021.

KEYNOTE-024 – Objective Response, ITT population

Objective Response by RECIST v1.1 per Investigator Review



Median Duration of Response by RECIST v1.1 per Investigator Review



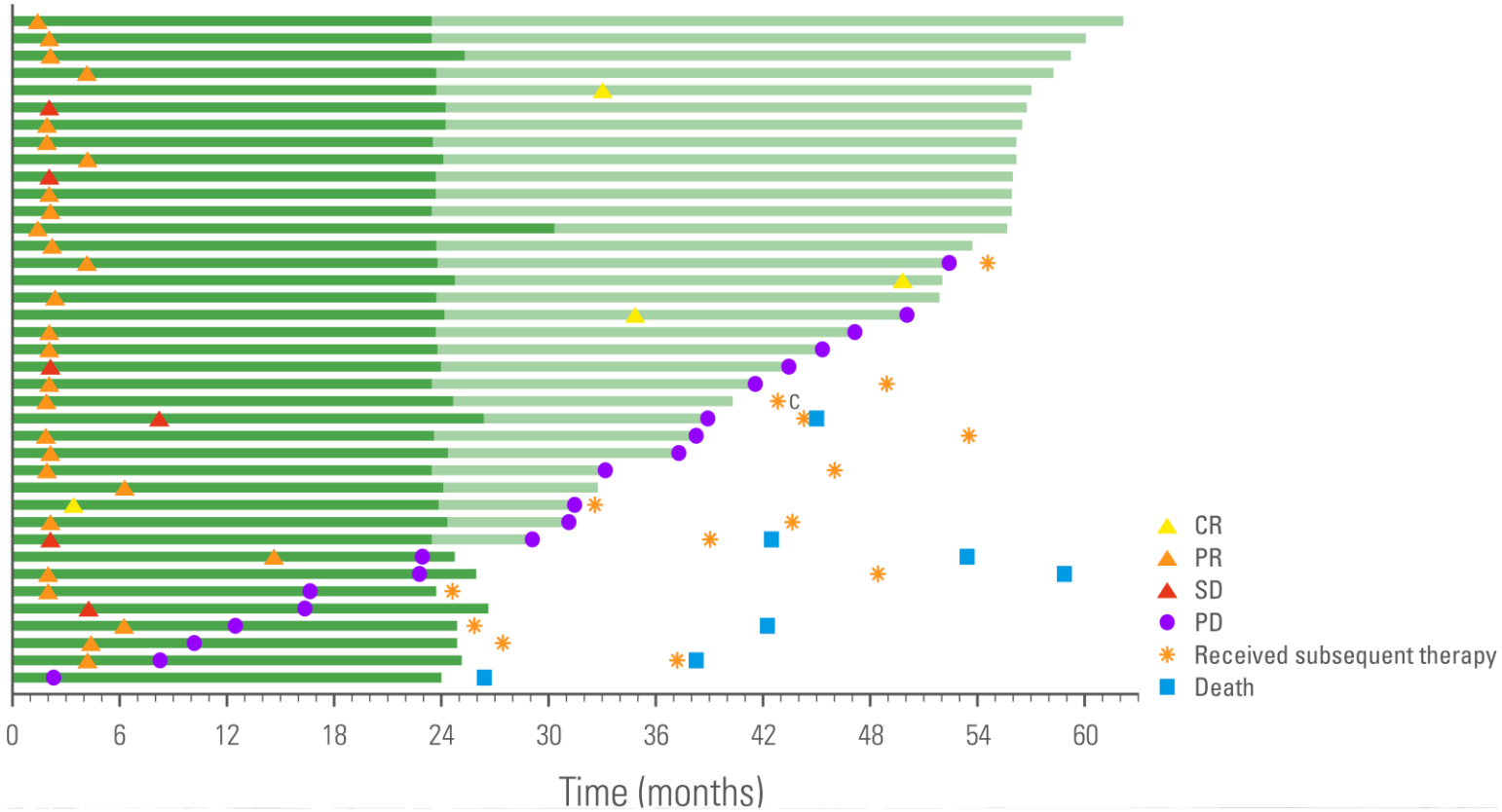
Adapted from Brahmer JR, et al. LBA51 KEYNOTE-024 5-year OS update: First-line pembrolizumab (pembro) vs platinum-based chemotherapy (chemo) in patients (pts) with metastatic NSCLC and PD-L1 tumour proportion score ≥ 50 %. Ann Oncol. 2020;31(Suppl 4);S1181 – S1182. DOI:https://doi.org/10.1016/j.annonc.2020.08.2284 Presented at the European Society for Medical Oncology (ESMO) Virtual Congress 2020; 19 – 21 September 2020.

«+», indicates response duration is censored. Data cutoff: June 1, 2020.
* Range: 2.2–60.8+ months. ** Range: 3.1–52.4 months.
DOR, duration of response; ITT: intention to treat.

CH-KEY-00580; created in March 2021.

KEYNOTE-024 – Treatment Duration and Time to Response[a]

35 Cycles (2 Years) of Pembrolizumab Completed



	n=39[b]
3-year OS rate from completion of pembrolizumab, %	81
Objective response, n (%)	32 (82)
Best objective response, n (%)	
Complete response	4 (10)
Partial response	28 (72)
Stable disease	6 (15)
Progressive disease	1 (3)

- At data cutoff, 18/39 patients (46%) were alive without PD or subsequent therapy for NSCLC per investigator assessment.
  - 1 patient developed a secondary malignancy and was treated accordingly.

Adapted from Brahmer JR, et al. LBA51 KEYNOTE-024 5-year OS update: First-line pembrolizumab (pembro) vs platinum-based chemotherapy (chemo) in patients (pts) with metastatic NSCLC and PD-L1 tumour proportion score ≥ 50 %. Ann Oncol. 2020;31(Suppl 4);S1181 – S1182. DOI:https://doi.org/10.1016/j.annonc.2020.08.2284 Presented at the European Society for Medical Oncology (ESMO) Virtual Congress 2020; 19 – 21 September 2020.

a. Dark green bars indicate first course treatment duration and light green bars indicate first course follow-up duration. Follow-up was defined as the time to progression or last non-progression assessment by investigator. Response was assessed by RECIST version 1.1 per investigator review.
b. 7 patients died, all due to PD; 2 did not receive any additional treatment. c. 1 patient developed a secondary malignancy. Data cutoff: June 1, 2020.
CR: complete response; NSCLC: non-small cell lung cancer; OS: overall survival; PD: progressive disease; PR: partial response; RECIST 1.1: Response Evaluation Criteria In Solid Tumors 1.1; SD: stable disease.

CH-KEY-00580; created in March 2021.

KEYNOTE-024 – Adverse Events

	Pembrolizumab (n=154)	Chemotherapy[a] (n=150)	35 Cycles (2 Years) of Pembrolizumab[a] (n=39)[a]
Treatment-related AEs, n (%)	118 (76.6)	135 (90.0)	34 (87.2)
Grade 3–5[b]	48 (31.2)	80 (53.3)	6 (15.4)
Serious	35 (22.7)	31 (20.7)	4 (10.3)
Led to discontinuation	21 (13.6)	16 (10.7)	0
Led to death	2 (1.3)	3 (2.0)	0
Immune-mediated AEs and infusion reactions, n (%)[c]	53 (34.4)	8 (5.3)	12 (30.8)
Grade 3–5	21 (13.6)	1 (0.7)	3 (7.7)
Led to death	1 (0.6)	0	0

Adapted from Brahmer JR, et al. LBA51 KEYNOTE-024 5-year OS update: First-line pembrolizumab (pembro) vs platinum-based chemotherapy (chemo) in patients (pts) with metastatic NSCLC and PD-L1 tumour proportion score ≥ 50 %. Ann Oncol. 2020;31(Suppl 4);S1181 – S1182. DOI:https://doi.org/10.1016/j.annonc.2020.08.2284 Presented at the European Society for Medical Oncology (ESMO) Virtual Congress 2020; 19 – 21 September 2020.

a. During treatment with the initially assigned therapy. b. 7 additional patients in the pembrolizumab arm and no additional patients in the chemotherapy arm had treatment-related grade 3–5 AEs since the initial publication of KEYNOTE-024 (Reck M, et al. N Engl J Med. 2016;375:1823–1833). There was no change since the updated analysis at 25.2 months median follow-up (Reck M, et al. J Clin Oncol. 2019;37:537–546). c. Irrespective of attribution to treatment by the investigator. Data cutoff: June 1, 2020.
AE: adverse event.

CH-KEY-00580; created in March 2021.

KEYNOTE-024 – Summary and Conclusions[1]

- With 5 years of follow-up, pembrolizumab continues to show meaningful improvements in OS and durable responses versus chemotherapy in KEYNOTE-024.
  - Despite the 66% effective crossover rate, the 5-year OS rate was approximately doubled in the pembrolizumab group (31.9% vs 16.3%) with a median DOR of 29.1 months in the pembrolizumab group.
- Incidence of any-grade and grade 3–5 treatment-related AEs was lower with pembrolizumab versus chemotherapy.
  - Long term treatment with pembrolizumab did not identify new safety signals.
- KEYNOTE-024 is the first phase 3 study to demonstrate 5-year efficacy for first-line immunotherapy and demonstrates that pembrolizumab monotherapy is an effective first-line treatment regimen in patients with metastatic NSCLC and PD-L1 TPS ≥50%.
  - These data confirm 5-year OS outcomes among previously untreated patients in the single-arm KEYNOTE-001 study.[2]

1. Brahmer JR, et al. LBA51 KEYNOTE-024 5-year OS update: First-line pembrolizumab (pembro) vs platinum-based chemotherapy (chemo) in patients (pts) with metastatic NSCLC and PD-L1 tumour proportion score ≥ 50 %. Ann Oncol. 2020;31(Suppl 4);S1181 – S1182.
2. Garon EB, et al. J Clin Oncol. 2019;37:2518-2527.

DOI:https://doi.org/10.1016/j.annonc.2020.08.2284 Presented at the European Society for Medical Oncology (ESMO) Virtual Congress 2020; 19 – 21 September 2020.

AE: adverse event; DOR, duration of response; NSCLC: non-small cell lung cancer; OS: overall survival; PD-L1: programmed cell death ligand 1.

CH-KEY-00580; created in March 2021.

KEYTRUDA® (pembrolizumab): Indication and Usage

- KEYTRUDA® as monotherapy is indicated for the first-line treatment of patients with metastatic non-small cell lung carcinoma (NSCLC) whose tumors express PD-L1 with a ≥50% tumor proportion score (TPS) as determined by a validated test, with no EGFR or ALK genomic tumor aberrations.[1]
- KEYTRUDA®, in combination with pemetrexed and platinum chemotherapy, is indicated for the first-line treatment of patients with metastatic non-squamous NSCLC, with no EGFR or ALK genomic tumor aberrations.[1]
- KEYTRUDA®, in combination with carboplatin and either paclitaxel or nab-paclitaxel, is indicated for first-line treatment of patients with metastatic squamous NSCLC.[1]
- KEYTRUDA® as monotherapy is indicated for the treatment of patients with advanced NSCLC whose tumors express PD-L1 with a ≥1% TPS as determined by a validated test and who have received platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have received prior therapy for these aberrations prior to receiving KEYTRUDA®.[1]

1. Professional information KEYTRUDA® (pembrolizumab), www.swissmedicinfo.ch. Accessed in March 2021.

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

CH-KEY-00580; created in March 2021.

Short Prescribing Information KEYTRUDA® (pembrolizumab)

KEYTRUDA®: C: pembrolizumab. **I** (adults): unresectable or metastatic melanoma; adjuvant treatment of completely resected melanoma stage III; metastatic non-small cell lung carcinoma (mNSCLC): 1st line: monotherapy for mNSCLC with tumours expressing PD-L1 with tumour proportion score (TPS) ≥50% without EGFR or ALK gen. tumour aberrations, for non-squamous mNSCLC in combination with pemetrexed and platinum chemotherapy without EGFR or ALK gen. tumour aberrations, as well as for squamous mNSCLC in combination with carboplatin and either paclitaxel or nab-paclitaxel, 2nd line: monotherapy for advanced metastatic NSCLC with tumours expressing PD-L1 with TPS ≥1% after chemotherapy and therapies for EGFR or ALK gen tumour aberrations; recurrent, not curatively treatable locally advanced or metastatic PD-L1 expressing head and neck squamous cell carcinoma (r/mHNSCC): 1st line: in combination with platinum and 5 fluorouracil (5-FU) chemotherapy, 2nd line: monotherapy for r/mHNSCC with tumours expressing PD-L1 with TPS ≥50% after platinum-containing chemotherapy; refractory or recurrent classic Hodgkin lymphoma (cHL) with at least 3 pretreatments; refractory or recurrent primary mediastinal B-cell lymphoma (rrPMBCL) with at least 2 prior lines of therapy (at least one with rituximab), if not eligible for autologous stem cell transplantation or after a relapse after transplantation; locally advanced or metastatic urothelial carcinoma after platinum-containing chemotherapy; monotherapy for the following tumors with high microsatellite instability (MSI-H) or deficient DNA mismatch repair (dMMR): for patients with unresectable or metastatic colorectal carcinoma (CRC) after previous fluoropyrimidine-based therapy in combination with irinotecan or oxaliplatin, for patients with metastatic endometrial carcinomas, gastric carcinomas, small intestinal carcinomas or cholangiocarcinomas who have progressed after standard therapy and who have no satisfactory treatment options available; 1st line: monotherapy for metastatic colorectal cancer (mCRC) with MSI-H or dMMR; 1st line: for advanced renal cell carcinoma (metastatic or recurrent) in combination with axitinib. **Po:** 200mg i.v. 30 min every 3 weeks; in combination administer KEYTRUDA® before chemotherapy; until disease progression or unacceptable toxicity; for the maximum course of treatment in clinical trials, please refer to the study description for the respective indication (see «Clinical efficacy» www.swissmedicinfo.ch), in adj. melanoma max. 12 mos. **CI:** hypersensitivity to active substance/excipients. **Pr:** immune mediated adverse reactions: e.g. Pneumonitis (including fatal cases), colitis, hepatitis, nephritis, endocrinopathies (including hypophysitis, type 1 diabetes mellitus, thyroid disorders), hematological toxicities, Hemophagocytic Lymphohistiocytosis (HLH), severe skin reactions (Stevens-Johnson syndrome and toxic epidermal necrolysis), myotoxicity (e.g. myositis including fatal progressions), Guillain-Barré syndrome, anaphylaxis; Transplantation/stem cell transplantation (HSCT): Graft-versus-Host-Disease (GvHD) and hepatic vein-occlusive disease (VOD); elevated liver enzymes when KEYTRUDA® is combined with axitinib (liver enzymes to be monitored before initiation of and throughout treatment); multiple myeloma: increased mortality when adding KEYTRUDA® to thalidomide analogue and dexamethasone. **IA:** none known/not investigated. **P/L:** not recommended, contraception. **UE:** in monotherapy: very common: anaemia, hypothyroidism, decreased appetite, headache, dyspnoea, cough, diarrhoea, abdominal pain, nausea, vomiting, constipation, rash, pruritus, musculoskeletal pain, arthralgia, fatigue, asthenia, oedema, pyrexia; in combination with chemotherapy: very common: anaemia, neutropenia, thrombocytopenia, hypokalaemia, decreased appetite, dizziness, headache, neuropathy peripheral, dysgeusia, dyspnoea, cough, diarrhoea, nausea, vomiting, constipation, abdominal pain, rash, alopecia, pruritus, musculoskeletal pain, arthralgia, blood creatinine increased, fatigue, asthenia, pyrexia, oedema; in combination with axitinib: very common: respiratory tract infections, hyperthyroidism, hypothyroidism, weight decreased, decreased appetite, headache, dysgeusia, hypertension, dyspnea, cough, dysphonia, diarrhea, abdominal pain, nausea, stomatitis, vomiting, constipation, alanine aminotransferase increased, aspartate aminotransferase increased, palmar-plantar erythrodysaesthesia syndrome, rash, pruritus, musculoskeletal pain, arthralgia, pain in extremity, proteinuria, blood creatinine increased, fatigue, asthenia, mucosal inflammation, pyrexia. **P:** 1 or 2 vial/s with 100mg/4ml. **C:** A. **MAH:** MSD Merck Sharp & Dohme AG, Werftestrasse 4, 6005 Lucerne, Switzerland. (V17.0); CH-KEY-00084.

Before prescribing, please consult the full prescribing information published on the homepage of Swissmedic (www.swissmedicinfo.ch).

CH-KEY-00580; created in March 2021.

References

- Brahmer JR, et al. LBA51 KEYNOTE-024 5-year OS update: First-line pembrolizumab (pembro) vs platinum-based chemotherapy (chemo) in patients (pts) with metastatic NSCLC and PD-L1 tumour proportion score ≥ 50 %. Ann Oncol. 2020;31(Suppl 4);S1181 – S1182. DOI:https://doi.org/10.1016/j.annonc.2020.08.2284 Presented at the European Society for Medical Oncology (ESMO) Virtual Congress 2020; 19 – 21 September 2020.
- Howlader N, Noone AM, Krapcho M, Miller D, Brest A, Yu M, Ruhl J, Tatalovich Z, Mariotto A, Lewis DR, Chen HS, Feuer EJ, Cronin KA (eds). SEER Cancer Statistics Review, 1975-2017, National Cancer Institute. Bethesda, MD, https://seer.cancer.gov/csr/1975_2017/, based on November 2019 SEER data submission, posted to the SEER web site, April 2020.
- Reck M, Rodríguez-Abreu D, Robinson AG, et al; for the KEYNOTE-024 investigators. Pembrolizumab versus chemotherapy for PD-L1-positive non-small-cell lung cancer. N Engl J Med. 2016;375(19):1823 – 1833. doi: 10.1056/NEJMoa1606774.
- Professional information KEYTRUDA® (pembrolizumab), www.swissmedicinfo.ch. Accessed in March 2021.

Reprints of cited literature can be requested at the address below.

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