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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KEYNOTE-024 (NCT02142738)¹

- Outcomes with standard chemotherapy have been historically poor for patients with metastatic NSCLC²
- 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 alterations² at 11.2 months median follow-up⁸
  - Primary endpoint:³ 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

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HR, hazard ratio; ITT, intent-to-treat; NSCLC, non-small-cell lung cancer; TPS, tumour 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: tumour proportion score.
Key Eligibility Criteria
- Untreated stage IV NSCLC
- PD-L1 TPS ≥50%
- ECOG PS 0–1
- No activating EGFR mutation or ALK translocation
- No untreated brain metastases
- No active autoimmune disease requiring systemic therapy

Platinum-Douplet Chemotherapy
- (4–6 cycles)
- (n = 151)
  - Pemetrexed + carboplatin
  - Pemetrexed + cisplatin
  - Paclitaxel + carboplatin
  - Gemcitabine + carboplatin
  - Gemcitabine + cisplatin

Pembrolizumab
- 200 mg IV Q3W
- 35 cycles (2 years)
- (n = 154)

Crossover to Pembrolizumab
- 200 mg IV Q3W (2 years)

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 Cooperative 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.

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
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.

305 patients randomly allocated

- Pembrolizumab Monotherapy
  - 154 allocated
  - 154 treated
    - Median (range) treatment duration: 7.9 months (1 day–30.2 months)
  - 34 completed treatment\(^a\)
  - 120 discontinued
    - 72 progressive disease\(^b\)
    - 31 AEs
    - 7 patient withdrawals
    - 6 deaths
    - 2 complete responses
    - 1 physician decision
    - 1 noncompliance with protocol

- Platinum-Based Chemotherapy
  - 151 allocated
  - 150 treated
    - Median (range) treatment duration: 3.5 months (1 day–40.4 months)
  - 29 completed treatment
  - 121 discontinued
    - 77 progressive disease\(^b\)
    - 18 AEs
    - 6 patient withdrawals
    - 9 deaths
    - 11 physician decision

\(^a\) 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.
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 tumor 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.

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  - 1 physician decision
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- 51.9% (80/154) received subsequent anticancer therapy
  - Including 12 who received a second course of pembrolizumab

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- 151 allocated
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- 151 allocated
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- 29 completed treatment
- 121 discontinued
  - 77 progressive disease
  - 18 AEs
  - 6 patient withdrawals
  - 9 deaths
  - 11 physician decision

Median (range) time from randomization to data cutoff: 59.9 (55.1–68.4) months

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. AEs: adverse event.
### KEYNOTE-024 – Patient baseline characteristics

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

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

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.

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Events, n (%)</th>
<th>HR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pembrolizumab</td>
<td>154</td>
<td>103 (66.9)</td>
<td>0.62 (0.48–0.81)</td>
</tr>
<tr>
<td>Chemotherapy</td>
<td>151</td>
<td>123 (81.5)</td>
<td></td>
</tr>
</tbody>
</table>

Median (95% CI)
26.3 months (18.3–40.4 months)
13.4 months (9.4–18.3 months)
KEYNOTE-024 – Progression-free Survival, ITT population

Kaplan-Meier estimates of PFS 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.

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.

<table>
<thead>
<tr>
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<th>N</th>
<th>Events, n (%)</th>
<th>HR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pembrolizumab</td>
<td>154</td>
<td>126 (81.8)</td>
<td>0.50 (0.39–0.65)</td>
</tr>
<tr>
<td>Chemotherapy</td>
<td>151</td>
<td>141 (93.4)</td>
<td></td>
</tr>
</tbody>
</table>

Median (95% CI)
7.7 months (6.1–10.2 months)
5.5 months (4.2–6.2 months)
KEYNOTE-024 – Objective Response, ITT population

Objective Response by RECIST v1.1 per Investigator Review

- Pembrolizumab (n=154):
  - 46.1% ORR
  - 4.5% CR
  - 41.6% PR

- Chemotherapy (n=151):
  - 31.1% ORR
  - 0% CR
  - 31.1% PR

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

- Pembrolizumab: 29.1 months*
- Chemotherapy: 6.3 months**

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.
KEYNOTE-024 – Treatment Duration and Time to Response\textsuperscript{a}

35 Cycles (2 Years) of Pembrolizumab Completed

- 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.
- 3 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.

<table>
<thead>
<tr>
<th>Objective response, n (%)</th>
<th>32 (82)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Best objective response, n (%)</td>
<td></td>
</tr>
<tr>
<td>Complete response</td>
<td>4 (10)</td>
</tr>
<tr>
<td>Partial response</td>
<td>28 (72)</td>
</tr>
<tr>
<td>Stable disease</td>
<td>6 (15)</td>
</tr>
<tr>
<td>Progressive disease</td>
<td>1 (3)</td>
</tr>
</tbody>
</table>

- 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 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.

\textsuperscript{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.
\textsuperscript{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.

KEYNOTE-024 – Adverse Events

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


- **Pembrolizumab**
- **Chemotherapy**
- **35 Cycles (2 Years) of Pembrolizumab**

\(^a\) 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. AEs, adverse events.
KEYNOTE-024 – Summary and Conclusions

- 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.


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

- 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.  

- KEYTRUDA®, in combination with carboplatin and either paclitaxel or nab-paclitaxel, is indicated for first-line treatment of patients with metastatic squamous NSCLC.  

- 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®.
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 (rPMBCL) 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/exciipients. PR: immune mediated adverse reactions: e.g. Pneumonitis (including fatal cases), colitis, hepatitis, nephritis, endocrinopathies (including hypophysitis, type 1 diabetes mellitus, thyroid disorders), hematomatous 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 (H SCT): 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, dyspea, cough, dysphonia, diarrhoea, abdominal pain, nausea, stomatitis, vomiting, constipation, alanine aminotransferase increased, aspartate aminotransferase increased, palmar-plantar erythrodysesthesia 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, Werf testrasse 4, 6005 Lucerne, Switzerland. (V17.0); CH-KEY-00084.

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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.


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

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