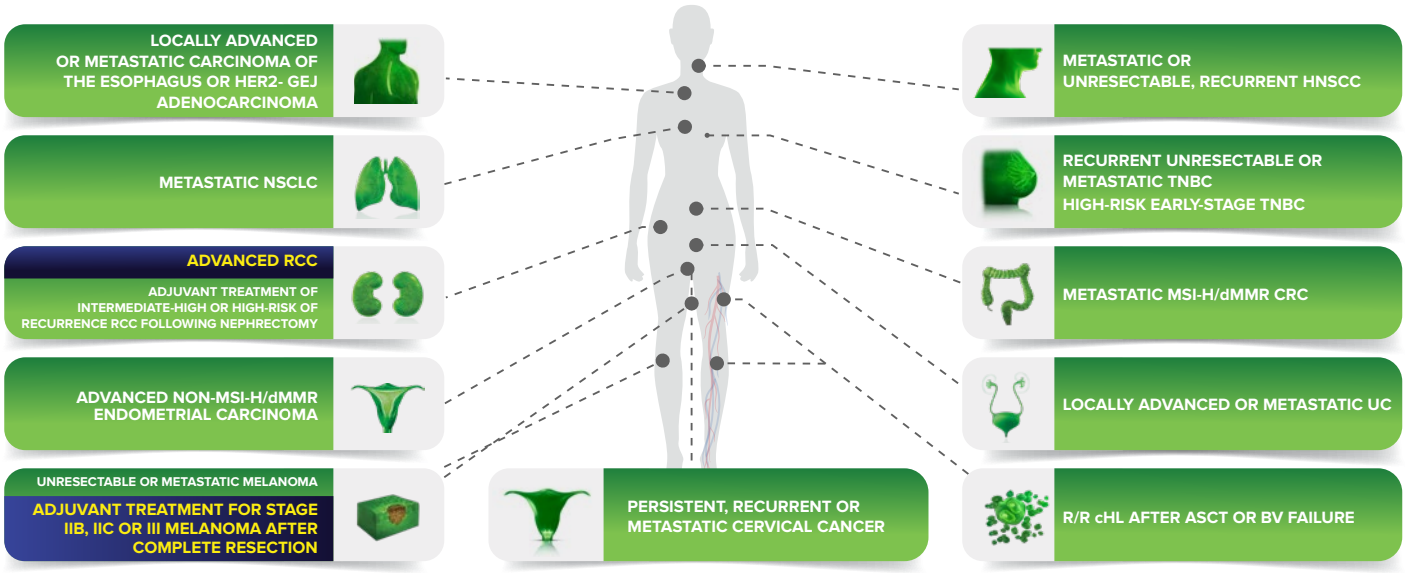
A Key to More Possibilities for Treating Your Patients

KEYTRUDA® is Approved for Certain Early-Stage and Advanced Cancers*

* For list of indications, please see KEYTRUDA® full prescribing information.

Approved for **22 INDICATIONS** across **11 TUMOUR TYPES**[1]



ASCT = autologous stem cell transplant; BV = brentuximab vedotin; CRC = colorectal cancer; GEJ = gastroesophageal junction; HNSCC = head and neck squamous cell carcinoma; MSI-H/dMMR = microsatellite instability high/mismatch repair deficient; NSCLC = non-small cell lung carcinoma; RCC = renal cell carcinoma; R/R cHL = relapsed or refractory classical hodgkin lymphoma; SCC = squamous cell carcinoma; TNBC = triple-negative breast cancer; UC = urothelial carcinoma

INDICATIONS

MELANOMA

KEYTRUDA® (pembrolizumab) is indicated for the treatment of patients with unresectable or metastatic melanoma.

NEW! **KEYTRUDA® as monotherapy is indicated for the adjuvant treatment of adult and pediatric (12 years and older) patients with Stage IIB, IIC or III melanoma who have undergone complete resection.**

NON-SMALL CELL LUNG CARCINOMA

KEYTRUDA®, in combination with pemetrexed and platinum chemotherapy, is indicated for the first-line treatment of patients with metastatic non-squamous non-small cell lung carcinoma (NSCLC), with no EGFR or ALK genomic tumor aberrations.

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

KEYTRUDA® as monotherapy is indicated for the first-line treatment of patients with NSCLC expressing PD-L1 [Tumour Proportion Score (TPS) ≥1%] as determined by a validated test, with no EGFR or ALK genomic tumor aberrations, and is:

- stage III where patients are not candidates for surgical resection or definitive chemoradiation, or
- metastatic

KEYTRUDA® as monotherapy is indicated for the treatment of patients with locally advanced or metastatic NSCLC whose tumors express PD-L1 with a ≥1% TPS as determined by a validated test and who have disease progression on or after platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on approved therapy for these aberrations prior to receiving KEYTRUDA®.

HEAD AND NECK CANCER

KEYTRUDA®, in combination with platinum and fluorouracil (FU), is indicated for the first-line treatment of patients with metastatic or with unresectable, recurrent head and neck squamous cell carcinoma (HNSCC).

KEYTRUDA® as monotherapy is indicated for the first-line treatment of patients with metastatic or with unresectable, recurrent HNSCC whose tumors express PD-L1 [Combined Positive Score (CPS) ≥1] as determined by a validated test.

KEYTRUDA® as monotherapy is indicated for the treatment of patients with metastatic or unresectable recurrent HNSCC with disease progression on or after platinum-containing chemotherapy.

UROTHELIAL CARCINOMA

KEYTRUDA® is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.

KEYTRUDA® is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy and whose tumors express PD-L1 [Combined Positive Score (CPS) ≥ 10] as determined by a validated test.

This indication is approved based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

CLASSICAL HODGKIN LYMPHOMA

KEYTRUDA® as monotherapy is indicated for the treatment of adult and pediatric patients aged 3 years and older with relapsed or refractory classical Hodgkin lymphoma who have failed autologous stem cell transplant (ASCT) or following at least two prior therapies when ASCT is not a treatment option.

COLORECTAL CANCER

KEYTRUDA® as monotherapy is indicated for the first-line treatment of metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer (CRC) in adults.

CERVICAL CANCER

KEYTRUDA®, in combination with chemotherapy with or without bevacizumab, is indicated for the treatment of patients with persistent, recurrent, or metastatic cervical cancer whose tumors express PD-L1 (CPS ≥1) as determined by a validated test.

RENAL CELL CARCINOMA

KEYTRUDA®, in combination with axitinib, is indicated for the first-line treatment of patients with advanced renal cell carcinoma (RCC).

NEW! **KEYTRUDA®, in combination with lenvatinib, is indicated for the first-line treatment of patients with advanced RCC.**

KEYTRUDA®, as monotherapy, is indicated for the adjuvant treatment of patients with RCC at intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions.

ENDOMETRIAL CARCINOMA

KEYTRUDA®, in combination with lenvatinib, is indicated for the treatment of adult patients with advanced endometrial carcinoma that is not microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR), who have disease progression following prior platinum-based systemic therapy and are not candidates for curative surgery or radiation.

This indication is approved based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

ESOPHAGEAL CANCER

KEYTRUDA®, in combination with platinum and fluoropyrimidine based chemotherapy, is indicated for the first-line treatment of patients with locally advanced or metastatic carcinoma of the esophagus or HER2 negative gastroesophageal junction adenocarcinoma (tumor center 1 to 5 centimeters above the gastroesophageal junction) that is not amenable to surgical resection or definitive chemoradiation, in adults whose tumors express PD-L1 with a CPS ≥10, as determined by a validated test.

KEYTRUDA® is indicated for the treatment of patients with recurrent locally advanced or metastatic squamous cell carcinoma of the esophagus whose tumors express PD-L1 [Combined Positive Score (CPS) ≥10] as determined by a validated test, with disease progression after one prior line of systemic therapy.

TRIPLE-NEGATIVE BREAST CANCER

KEYTRUDA® is indicated for the treatment of adult patients with high-risk early-stage triple-negative breast cancer (TNBC) in combination with chemotherapy as neoadjuvant treatment, and then continued as monotherapy as adjuvant treatment after surgery.

KEYTRUDA®, in combination with chemotherapy, is indicated for the treatment of patients with locally recurrent unresectable or metastatic triple-negative breast cancer (TNBC) whose tumors express PD-L1 (CPS ≥10) as determined by a validated test.

Selected Safety Information about KEYTRUDA®

Contraindications: None. **Precautions:** • Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue, including the following: immune-mediated pneumonitis, immune-mediated colitis, immune-mediated hepatitis, immune-mediated nephritis, immune-mediated endocrinopathies, immune-mediated severe skin reactions; transplant- related adverse reactions and infusion-related reactions. Withhold or permanently discontinue based on severity and type of reaction. When KEYTRUDA is given with axitinib, liver enzymes need to be monitored before initiation and periodically throughout treatment. Treatment of patients with multiple myeloma with a PD-1 or PD-L1 blocking antibody in combination with a thalidomide analogue plus dexamethasone is not recommended outside of controlled clinical trials. **Adverse reactions:** Most common adverse reactions (reported in ≥ 20% of patients) were: KEYTRUDA as a single agent: pruritus, pyrexia, cough, dyspnea, constipation and abdominal pain, vomiting, anemia, headache, diarrhea, rash, decreased appetite and hypothyroidism. KEYTRUDA in combination with chemotherapy: fatigue, asthenia, nausea, constipation, diarrhea, decreased appetite, rash, vomiting, alopecia, arthralgia, pyrexia, mucosal inflammation, stomatitis, weight loss, neutropenia and pyrexia. KEYTRUDA in combination with chemotherapy with or without bevacizumab: anemia. KEYTRUDA in combination with axitinib: diarrhea, hypertension, fatigue, hypothyroidism, decreased appetite, palmar-plantar erythrodysaesthesia syndrome, nausea, ALT increased, AST increased, dysphonia, cough and constipation. KEYTRUDA in combination with lenvatinib: fatigue, musculoskeletal pain, hypertension, hemorrhagic events, diarrhea, nausea, stomatitis, vomiting, abdominal pain, constipation, decreased appetite, hypomagnesemia, hypothyroidism, decreased weight, headache, urinary tract infection, proteinuria, dysphonia, dyspnea, cough, palmar-plantar erythrodysesthesia syndrome and rash. **Indications: Melanoma** KEYTRUDA (pembrolizumab) is indicated for the treatment of patients with unresectable or metastatic melanoma. KEYTRUDA as monotherapy is indicated for the adjuvant treatment of adult and pediatric (12 years and older) patients with Stage IIB, IIC or III melanoma who have undergone complete resection. **Non-Small Cell Lung Cancer** KEYTRUDA, in combination with pemetrexed and platinum chemotherapy, is indicated for the first-line treatment of patients with metastatic non-squamous non-small cell lung carcinoma (NSCLC), with no EGFR or ALK genomic tumor aberrations. KEYTRUDA, in combination with carboplatin and either paclitaxel or nab-paclitaxel, is indicated for the first-line treatment of patients with metastatic squamous NSCLC. KEYTRUDA as monotherapy is indicated for the first-line treatment of patients with NSCLC expressing PD-L1 [Tumor Proportion Score (TPS) ≥1%] as determined by a validated test, with no EGFR or ALK genomic tumor aberrations, and is: • stage III where patients are not candidates for surgical resection or definitive chemoradiation, or • metastatic. KEYTRUDA as monotherapy is indicated for the treatment of patients with locally advanced or metastatic NSCLC whose tumors express PD-L1 with a ≥1% TPS as determined by a validated test and who have disease progression on or after platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on approved therapy for these aberrations prior to receiving KEYTRUDA. **Head and Neck Cancer** KEYTRUDA, in combination with platinum and fluorouracil (FU), is indicated for the first-line treatment of patients with metastatic or with unresectable, recurrent head and neck squamous cell carcinoma (HNSCC). KEYTRUDA as monotherapy is indicated for the first-line treatment of patients with metastatic or with unresectable, recurrent HNSCC whose tumors express PD-L1 [Combined Positive Score (CPS) ≥1] as determined by a validated test. KEYTRUDA as monotherapy is indicated for the treatment of patients with metastatic or unresectable recurrent HNSCC with disease progression on or after platinum-containing chemotherapy. **Urothelial Carcinoma** KEYTRUDA is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. KEYTRUDA is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy and whose tumors express PD-L1 [Combined Positive Score (CPS) ≥ 10] as determined by a validated test. This indication is approved based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. **Classical Hodgkin Lymphoma (cHL)** KEYTRUDA as monotherapy is indicated for the treatment of adult and pediatric patients aged 3 years and older with relapsed or refractory classical Hodgkin lymphoma who have failed autologous stem cell transplant (ASCT), or following at least two prior therapies when ASCT is not a treatment option. **Colorectal Cancer** KEYTRUDA as monotherapy is indicated for the first-line treatment of metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer (CRC) in adults. **Cervical Cancer** KEYTRUDA, in combination with chemotherapy with or without bevacizumab, is indicated for the treatment of patients with persistent, recurrent, or metastatic cervical cancer whose tumors express PD-L1 (CPS ≥1) as determined by a validated test. **Renal Cell Carcinoma** KEYTRUDA, in combination with axitinib, is indicated for the first-line treatment of patients with advanced renal cell carcinoma (RCC). KEYTRUDA, in combination with lenvatinib, is indicated for the first-line treatment of patients with advanced RCC. KEYTRUDA, as monotherapy, is indicated for the adjuvant treatment of patients with RCC at intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions. **Endometrial Carcinoma** KEYTRUDA, in combination with lenvatinib, is indicated for the treatment of adult patients with advanced endometrial carcinoma that is not microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR), who have disease progression following prior platinum-based systemic therapy and are not candidates for curative surgery or radiation. This indication is approved based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. **Esophageal Cancer** KEYTRUDA, in combination with platinum and fluoropyrimidine based chemotherapy, is indicated for the first-line treatment of patients with locally advanced or metastatic carcinoma of the esophagus or HER2 negative gastroesophageal junction adenocarcinoma (tumor center 1 to 5 centimeters above the gastroesophageal junction) that is not amenable to surgical resection or definitive chemoradiation, in adults whose tumors express PD-L1 with a CPS ≥10, as determined by a validated test. KEYTRUDA is indicated for the treatment of patients with recurrent locally advanced or metastatic squamous cell carcinoma of the esophagus whose tumors express PD-L1 [Combined Positive Score (CPS) ≥10] as determined by a validated test, with disease progression after one prior line of systemic therapy. **Triple-Negative Breast Cancer** KEYTRUDA is indicated for the treatment of adult patients with high-risk early-stage triple-negative breast cancer (TNBC) in combination with chemotherapy as neoadjuvant treatment, and then continued as monotherapy as adjuvant treatment after surgery. KEYTRUDA, in combination with chemotherapy, is indicated for the treatment of patients with locally recurrent unresectable or metastatic TNBC whose tumors express PD-L1 (CPS ≥10) as determined by a validated test. **Dosing: Patient Selection** If specified in the indication, select patients for treatment with KEYTRUDA based on the presence of positive PD-L1 expression, MSI-H or dMMR tumor status [see Indications], PD-L1 expression should be evaluated using the PD-L1 IHC 22C3 pharmDx® kit or equivalent. MSI or MMR tumor status should be evaluated using a validated test. **Recommended** Dosing KEYTRUDA is administered as an intravenous infusion over 30 minutes. The recommended dose of KEYTRUDA in adults is either: • 200mg every 3 weeks or • 400mg every 6 weeks. For use in combination, see the prescribing information for the concomitant therapies. When administering KEYTRUDA as part of a combination with intravenous chemotherapy, KEYTRUDA should be administered first. For RCC patients treated with KEYTRUDA in combination with axitinib, see the prescribing information regarding dosing of axitinib. When used in combination with KEYTRUDA, dose escalation of axitinib above the initial 5 mg dose may be considered at intervals of six weeks or longer [see Clinical Studies]. For endometrial carcinoma and RCC patients treated with KEYTRUDA in combination with lenvatinib, the recommended initial dose of lenvatinib is 20 mg orally once daily until disease progression, unacceptable toxicity, or for KEYTRUDA, up to 24 months in patients without disease progression. Patients should be treated with KEYTRUDA until disease progression or unacceptable toxicity. Atypical responses (i.e., an initial transient increase in tumor size or small new lesions within the first few months followed by tumor shrinkage) have been observed. Clinically stable patients with initial evidence of disease progression should remain on treatment until disease progression is confirmed. For adjuvant treatment of melanoma or RCC, KEYTRUDA should be administered for up to one year or until disease recurrence or unacceptable toxicity. For the neoadjuvant and adjuvant treatment of high-risk early-stage TNBC, patients should be treated with neoadjuvant KEYTRUDA in combination with chemotherapy for 8 doses of 200 mg every 3 weeks or 4 doses of 400 mg every 6 weeks or until disease progression that precludes definitive surgery or unacceptable toxicity, followed by adjuvant treatment with KEYTRUDA as monotherapy for 9 doses of 200 mg every 3 weeks or 5 doses of 400 mg every 6 weeks or until disease recurrence or unacceptable toxicity. Patients who experience disease progression that precludes definitive surgery or unacceptable toxicity related to KEYTRUDA as neoadjuvant treatment in combination with chemotherapy should not receive KEYTRUDA monotherapy as adjuvant treatment. For the complete list of indications, please see prescribing information.

Before prescribing KEYTRUDA®, please consult the full prescribing information. Full prescribing information is available upon request.

Reference: 1. KEYTRUDA Local Product Circular. Available at: Product Search, National Pharmaceutical Regulatory Agency. Available at: https://quest3plus.bpfk.gov.my/pmo2/index.php

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MY-KEY-00863 Jun/2023

For Healthcare Professionals Only.

KEYTRUDA® (pembrolizumab) Injection 100 mg