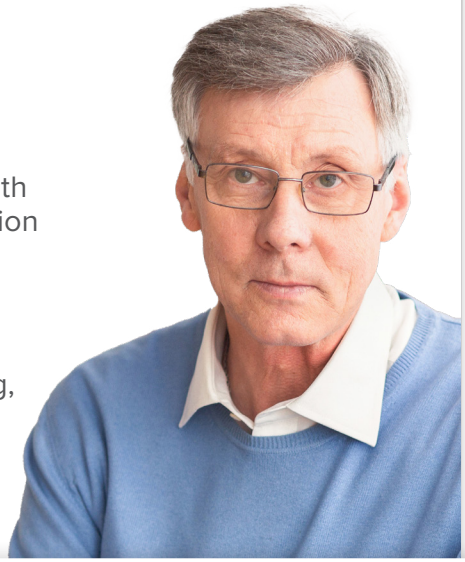
KEYTRUDA® (pembrolizumab) Injection 100 mg

KEYTRUDA Qlex™
pembrolizumab + berahyaluronidase alfa-pmph
Subcutaneous Injection | 165 mg + 2,000 units/mL

KEYTRUDA and KEYTRUDA QLEX are each indicated for the treatment of adult patients with unresectable or metastatic MSI-H or dMMR colorectal cancer (CRC) as determined by an FDA-authorized test.

Consider KEYTRUDA or KEYTRUDA QLEX as your first-line, single-IO treatment for certain patients with advanced MSI-H/dMMR CRC

JEREMY



- **Age:** 67 | **Gender:** Male
- **Diagnosis:** Advanced MSI-H CRC with a single unresectable metastatic lesion in the liver.
- **Social history:** Jeremy is a retired cashier who enjoys watching his favorite sports teams on TV, cooking, and taking long walks.

MSI-H = microsatellite instability-high;
dMMR = deficient DNA mismatch repair;
IO = immunotherapy.

DEBRA



- **Age:** 73 | **Gender:** Female
- **Diagnosis:** Advanced MSI-H CRC with several unresectable metastatic lesions in the liver.
- **Social history:** Prior to diagnosis, Debra enjoyed weekly family gatherings and her daily hobbies. Her caregiver provides consistent transportation for her appointments.

Hypothetical patients based on clinical trials.

SELECTED SAFETY INFORMATION

Contraindications

- KEYTRUDA QLEX is contraindicated in patients with known hypersensitivity to berahyaluronidase alfa, hyaluronidase or to any of its excipients.

Severe and Fatal Immune-Mediated Adverse Reactions

- KEYTRUDA and KEYTRUDA QLEX are monoclonal antibodies that belong to a class of drugs that bind to either the programmed death receptor-1 (PD-1) or the programmed death ligand 1 (PD-L1), blocking the PD-1/PD-L1 pathway, thereby removing inhibition of the immune response, potentially breaking peripheral tolerance and inducing immune-mediated adverse reactions. Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue, can affect more than one body system simultaneously, and can occur at any time after starting treatment or after discontinuation of treatment. Important immune-mediated adverse reactions listed here may not include all possible severe and fatal immune-mediated adverse reactions.

Selected Safety Information continues on next page

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Take a closer look at JEREMY



MEDICAL HISTORY

- **Initial presentation:** Fatigue and abdominal cramping for one month with more recent change in stool color (black). Upon further questioning, he admits to unintentional 10-lb weight loss over 6 months.
- **ECOG PS:** 0 | **Family history:** Colorectal cancer on father's side
- **Smoking history:** Former smoker (40 pack-year history)
- **Drinking history:** Moderate drinker (1-2 drinks per day)
- **Additional notes:** Currently being treated for hyperlipidemia

EXAMINATION

- During his exam, it was noted that Jeremy was a thin male with a BMI of 24 kg/m^2 who was not in acute distress. His abdomen was not distended, but he had tenderness in the right lower quadrant.

DIAGNOSTIC TESTING



Based on hypothetical patient

- **Colonoscopy:** Mass on the right side of the colon
- **Biopsy:** Moderately differentiated adenocarcinoma
- **NGS:** MSI-H
- **CT scan:** Confirmed mass on the right side of the colon and identified enlarged lymph nodes adjacent to the right-colon mass and a single large peri-portal metastasis of the liver. (Consulting hepatic surgeon felt the liver lesion was unresectable.)

CC BY Zhang L, Liu Y, Ding Y, et al. Predictive value of intratumoral-metabolic heterogeneity derived from ^{18}F-FDG PET/CT in distinguishing microsatellite instability status of colorectal carcinoma. *Front Oncol.* 13:1065744. doi:10.3389/fonc2023.1065744

ECOG PS = Eastern Cooperative Oncology Group performance status; BMI = body mass index; NGS = next-generation sequencing; CT = computed tomography; CC BY = Creative Commons Attribution license.

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SELECTED SAFETY INFORMATION (*continued*)

Severe and Fatal Immune-Mediated Adverse Reactions (*continued*)

- Monitor patients closely for symptoms and signs that may be clinical manifestations of underlying immune-mediated adverse reactions. Early identification and management are essential to ensure safe use of anti–PD-1/PD-L1 treatments. Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. In cases of suspected immune-mediated adverse reactions, initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate.
- Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity of the immune-mediated adverse reaction. In general, if KEYTRUDA and KEYTRUDA QLEX require interruption or discontinuation, administer systemic corticosteroid therapy (1 to 2 mg/kg/day prednisone or equivalent) until improvement to Grade 1 or less. Upon improvement to Grade 1 or less, initiate corticosteroid taper and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants in patients whose adverse reactions are not controlled with corticosteroid therapy.

Selected Safety Information continues on next page

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What treatment would you consider for a patient with advanced MSI-H/dMMR CRC like Jeremy?



Jeremy's Diagnosis
Advanced MSI-H CRC with a single unresectable metastatic lesion in the liver.

Shared-Decision Discussion
Jeremy's medical oncologist recommended treatment with immunotherapy and discussed 2 potential treatments:

KEYTRUDA Dosing Information
- Either 200 mg Q3W or 400 mg Q6W
- Administered as a 30-minute intravenous infusion
- Continue treatment until disease progression, unacceptable toxicity, or for up to 24 months

Considerations:
Scheduling may sometimes be limited by infusion-chair availability.

OR

KEYTRUDA QLEX Dosing Information
- 1 minute for 2.4 mL Q3W (395mg pembrolizumab/4,800 units berahyaluronidase alfa)*
- 2 minutes for 4.8 mL Q6W (790mg pembrolizumab/9,600 units berahyaluronidase alfa)*
- KEYTRUDA QLEX must be administered by a healthcare provider
- Two subcutaneous injection site options, either the thigh or abdomen (avoiding the 5-cm area around the navel)
- Continue treatment until disease progression, unacceptable toxicity, or for up to 24 months

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

Considerations:
Subcutaneous administration may provide Jeremy with more scheduling options, since treatment would not depend on the availability of an infusion chair.

Q3W = every 3 weeks; Q6W = every 6 weeks.

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SELECTED SAFETY INFORMATION (*continued*)

Severe and Fatal Immune-Mediated Adverse Reactions (*continued*)

Immune-Mediated Pneumonitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated pneumonitis. The incidence is higher in patients who have received prior thoracic radiation. Immune-mediated pneumonitis occurred in 3.4% (94/2799) of patients receiving KEYTRUDA, including fatal (0.1%), Grade 4 (0.3%), Grade 3 (0.9%), and Grade 2 (1.3%) reactions. Systemic corticosteroids were required in 67% (63/94) of patients. Pneumonitis led to permanent discontinuation of KEYTRUDA in 1.3% (36) and withholding in 0.9% (26) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement; of these, 23% had recurrence. Pneumonitis resolved in 59% of the 94 patients. Immune-mediated pneumonitis occurred in 5% (13/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including fatal (0.4%), Grade 3 (2%), and Grade 2 (1.2%) adverse reactions.

Selected Safety Information continues on next page

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What treatment would you consider for a patient with advanced MSI-H/dMMR CRC like Jeremy?



Discussion Questions

What questions would you ask yourself to help Jeremy determine a treatment?

- How would you factor Jeremy's personal circumstances into your decision to recommend KEYTRUDA or KEYTRUDA QLEX?
- For certain patients like Jeremy, does treatment with KEYTRUDA QLEX offer flexibility in the site of care by not requiring an infusion chair?
- What other factors would you consider when making the decision to recommend KEYTRUDA or KEYTRUDA QLEX to Jeremy?

Treatment Decision

Since infusion chair availability may sometimes limit treatment scheduling for KEYTRUDA, Jeremy and his doctor elected to start treatment with KEYTRUDA QLEX.

Learn more >

SELECTED SAFETY INFORMATION (*continued*)

Severe and Fatal Immune-Mediated Adverse Reactions (*continued*)

Immune-Mediated Colitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated colitis, which may present with diarrhea. Cytomegalovirus infection/reactivation has been reported in patients with corticosteroid-refractory immune-mediated colitis. In cases of corticosteroid-refractory colitis, consider repeating infectious workup to exclude alternative etiologies.
- Immune-mediated colitis occurred in 1.7% (48/2799) of patients receiving KEYTRUDA, including Grade 4 (<0.1%), Grade 3 (1.1%), and Grade 2 (0.4%) reactions. Systemic corticosteroids were required in 69% (33/48); additional immunosuppressant therapy was required in 4.2% of patients. Colitis led to permanent discontinuation of KEYTRUDA in 0.5% (15) and withholding in 0.5% (13) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement; of these, 23% had recurrence. Colitis resolved in 85% of the 48 patients. Immune-mediated colitis occurred in 1.2% (3/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 3 (0.8%) and Grade 2 (0.4%) adverse reactions.

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Selected Safety Information continues on next page

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SELECTED SAFETY INFORMATION (*continued*)

Severe and Fatal Immune-Mediated Adverse Reactions (*continued*)

Hepatotoxicity and Immune-Mediated Hepatitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated hepatitis. Immune-mediated hepatitis occurred in 0.7% (19/2799) of patients receiving KEYTRUDA, including Grade 4 (<0.1%), Grade 3 (0.4%), and Grade 2 (0.1%) reactions. Systemic corticosteroids were required in 68% (13/19) of patients; additional immunosuppressant therapy was required in 11% of patients. Hepatitis led to permanent discontinuation of KEYTRUDA in 0.2% (6) and withholding in 0.3% (9) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement; of these, none had recurrence. Hepatitis resolved in 79% of the 19 patients. Immune-mediated hepatitis occurred in 0.4% (1/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 2 (0.4%) adverse reactions.

Immune-Mediated Endocrinopathies

Adrenal Insufficiency

- KEYTRUDA and KEYTRUDA QLEX can cause primary or secondary adrenal insufficiency. For Grade 2 or higher, initiate symptomatic treatment, including hormone replacement as clinically indicated. Withhold KEYTRUDA and KEYTRUDA QLEX depending on severity. Adrenal insufficiency occurred in 0.8% (22/2799) of patients receiving KEYTRUDA, including Grade 4 (<0.1%), Grade 3 (0.3%), and Grade 2 (0.3%) reactions. Systemic corticosteroids were required in 77% (17/22) of patients; of these, the majority remained on systemic corticosteroids. Adrenal insufficiency led to permanent discontinuation of KEYTRUDA in <0.1% (1) and withholding in 0.3% (8) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. Adrenal insufficiency occurred in 2% (5/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 3 (0.4%) and Grade 2 (0.8%) adverse reactions.

Hypophysitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated hypophysitis. Hypophysitis can present with acute symptoms associated with mass effect such as headache, photophobia, or visual field defects. Hypophysitis can cause hypopituitarism. Initiate hormone replacement as indicated. Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity.
- Hypophysitis occurred in 0.6% (17/2799) of patients receiving KEYTRUDA, including Grade 4 (<0.1%), Grade 3 (0.3%), and Grade 2 (0.2%) reactions. Systemic corticosteroids were required in 94% (16/17) of patients; of these, the majority remained on systemic corticosteroids. Hypophysitis led to permanent discontinuation of KEYTRUDA in 0.1% (4) and withholding in 0.3% (7) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement.

Thyroid Disorders

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated thyroid disorders. Thyroiditis can present with or without endocrinopathy. Hypothyroidism can follow hyperthyroidism. Initiate hormone replacement for hypothyroidism or institute medical management of hyperthyroidism as clinically indicated. Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity.
- Thyroiditis occurred in 0.6% (16/2799) of patients receiving KEYTRUDA, including Grade 2 (0.3%). None discontinued, but KEYTRUDA was withheld in <0.1% (1) of patients.

Selected Safety Information continues on next page

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Take a closer look at DEBRA



MEDICAL HISTORY

- **Initial presentation:** Worsening weakness and fatigue over the past 2 months, but still able to complete light housework. Recent change in bowel habits with abdominal cramping over the past 2 months. Unintentional 10-lb weight loss over the past 6 months.
- **ECOG PS:** 1 | **Family history:** None | **Smoking history:** Former smoker
- **Drinking history:** Moderate drinker (1-2 drinks per day)
- **Additional notes:** Patient with history of well-controlled Type 2 diabetes, hypertension

EXAMINATION

- Abdomen with mild distention, moderate right-sided abdominal tenderness, palpable liver edge 3 fingerbreadths beneath costal margin. BMI of 26.0 kg/m^2.

DIAGNOSTIC TESTING



Based on hypothetical patient

- **Colonoscopy:** A 5-cm, non-obstructive mass in ascending colon
- **Biopsy:** Moderately differentiated adenocarcinoma
- **NGS:** MSI-H
- **CT scan:** Right colonic mass, and multiple liver lesions of various sizes consistent with metastases

CC BY Liu J, Cao S, Imbach KJ, et al. Multi-scale signaling and tumor evolution in high-grade gliomas (CPTAC-Glioblastoma-CODEX) (Version 1) [MSB-09019]. *The Cancer Imaging Archive.* 2024. https://doi.org/10.7937/ce1t-ea12

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SELECTED SAFETY INFORMATION (*continued*)

Severe and Fatal Immune-Mediated Adverse Reactions (*continued*)

Immune-Mediated Endocrinopathies (*continued*)

Thyroid Disorders (continued)

- Hyperthyroidism occurred in 3.4% (96/2799) of patients receiving KEYTRUDA, including Grade 3 (0.1%) and Grade 2 (0.8%). It led to permanent discontinuation of KEYTRUDA in <0.1% (2) and withholding in 0.3% (7) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. Hypothyroidism occurred in 8% (237/2799) of patients receiving KEYTRUDA, including Grade 3 (0.1%) and Grade 2 (6.2%). It led to permanent discontinuation of KEYTRUDA in <0.1% (1) and withholding in 0.5% (14) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. The majority of patients with hypothyroidism required long-term thyroid hormone replacement.
- Thyroiditis occurred in 0.4% (1/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 2 (0.4%). Hyperthyroidism occurred in 8% (20/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 2 (3.2%). Hypothyroidism occurred in 14% (35/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 2 (11%).

Selected Safety Information continues on next page

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What treatment would you consider for a patient with advanced MSI-H/dMMR CRC like Debra?



Debra's Diagnosis
Advanced MSI-H CRC with several unresectable metastatic lesions in the liver.

Shared-Decision Discussion
Debra's medical oncologist recommended treatment with immunotherapy and discussed 2 potential treatments:

KEYTRUDA Dosing Information
- Either 200 mg Q3W or 400 mg Q6W
- Administered as a 30-minute intravenous infusion
- Continue treatment until disease progression, unacceptable toxicity, or for up to 24 months

Considerations:
KEYTRUDA has been used as a 1L treatment for advanced MSI-H/dMMR CRC since 2020.

OR

KEYTRUDA QLEX Dosing Information
- 1 minute for 2.4 mL Q3W (395mg pembrolizumab/4,800 units berahyaluronidase alfa)*
- 2 minutes for 4.8 mL Q6W (790mg pembrolizumab/9,600 units berahyaluronidase alfa)*
- KEYTRUDA QLEX must be administered by a healthcare provider
- Two subcutaneous injection site options, either the thigh or abdomen (avoiding the 5-cm area around the navel)
- Continue treatment until disease progression, unacceptable toxicity, or for up to 24 months

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

Considerations:
KEYTRUDA QLEX requires substantially less time to administer than a 30-minute IV infusion of KEYTRUDA.

1L = first line; IV = intravenous.

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SELECTED SAFETY INFORMATION (*continued*)

Severe and Fatal Immune-Mediated Adverse Reactions (*continued*)

Immune-Mediated Endocrinopathies (*continued*)

Type 1 Diabetes Mellitus (DM), Which Can Present With Diabetic Ketoacidosis

- Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Initiate treatment with insulin as clinically indicated. Withhold KEYTRUDA and KEYTRUDA QLEX depending on severity. Type 1 DM occurred in 0.2% (6/2799) of patients receiving KEYTRUDA. It led to permanent discontinuation in <0.1% (1) and withholding of KEYTRUDA in <0.1% (1) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. Type 1 DM occurred in 0.4% (1/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy.

Immune-Mediated Nephritis With Renal Dysfunction

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated nephritis.
- Immune-mediated nephritis occurred in 0.3% (9/2799) of patients receiving KEYTRUDA, including Grade 4 (<0.1%), Grade 3 (0.1%), and Grade 2 (0.1%) reactions. Systemic corticosteroids were required in 89% (8/9) of patients. Nephritis led to permanent discontinuation of KEYTRUDA in 0.1% (3) and withholding in 0.1% (3) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement; of these, none had recurrence. Nephritis resolved in 56% of the 9 patients.

Selected Safety Information continues on next page

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What treatment would you consider for a patient with advanced MSI-H/dMMR CRC like Debra?



Discussion Questions

What questions would you ask yourself to help Debra determine a treatment?

- How would you factor Debra's personal circumstances into your decision to recommend KEYTRUDA or KEYTRUDA QLEX?
- Do Debra's personal preferences for treatment administration affect your prescribing decision?
- What other factors would you consider when making the decision to recommend KEYTRUDA or KEYTRUDA QLEX to Debra?

Treatment Decision

Debra has the ability to get to an infusion center regularly, so she and her doctor decided to start with KEYTRUDA. Patients have the option to switch from KEYTRUDA to KEYTRUDA QLEX—or KEYTRUDA QLEX to KEYTRUDA—at their next scheduled dose.

- 1 minute for 2.4 mL Q3W (395mg pembrolizumab/4,800 units berahyaluronidase alfa)*
- 2 minutes for 4.8 mL Q6W (790mg pembrolizumab/9,600 units berahyaluronidase alfa)*
- KEYTRUDA QLEX must be administered by a healthcare provider
- Two subcutaneous injection site options, either the thigh or abdomen (avoiding the 5-cm area around the navel)

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

Learn more >

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SELECTED SAFETY INFORMATION (*continued*)

Severe and Fatal Immune-Mediated Adverse Reactions (*continued*)

Immune-Mediated Dermatologic Adverse Reactions

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated rash or dermatitis. Exfoliative dermatitis, including Stevens-Johnson syndrome, drug rash with eosinophilia and systemic symptoms, and toxic epidermal necrolysis, has occurred with anti–PD-1/PD-L1 treatments. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate nonexfoliative rashes. Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity.
- Immune-mediated dermatologic adverse reactions occurred in 1.4% (38/2799) of patients receiving KEYTRUDA, including Grade 3 (1%) and Grade 2 (0.1%) reactions. Systemic corticosteroids were required in 40% (15/38) of patients. These reactions led to permanent discontinuation in 0.1% (2) and withholding of KEYTRUDA in 0.6% (16) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement; of these, 6% had recurrence. The reactions resolved in 79% of the 38 patients. Immune-mediated dermatologic adverse reactions occurred in 1.6% (4/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 4 (0.8%) and Grade 3 (0.8%) adverse reactions.

Selected Safety Information continues on next page

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SELECTED SAFETY INFORMATION (*continued*)

Severe and Fatal Immune-Mediated Adverse Reactions (*continued*)

Other Immune-Mediated Adverse Reactions

- The following clinically significant immune-mediated adverse reactions occurred at an incidence of <1% (unless otherwise noted) in patients who received KEYTRUDA, KEYTRUDA QLEX, or were reported with the use of other anti–PD-1/PD-L1 treatments. Severe or fatal cases have been reported for some of these adverse reactions. *Cardiac/Vascular*: Myocarditis, pericarditis, vasculitis; *Nervous System*: Meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia gravis (including exacerbation), Guillain-Barré syndrome, nerve paresis, autoimmune neuropathy; *Ocular*: Uveitis, iritis and other ocular inflammatory toxicities can occur. Some cases can be associated with retinal detachment. Various grades of visual impairment, including blindness, can occur. If uveitis occurs in combination with other immune-mediated adverse reactions, consider a Vogt-Koyanagi-Harada-like syndrome, as this may require treatment with systemic steroids to reduce the risk of permanent vision loss; *Gastrointestinal*: Pancreatitis, to include increases in serum amylase and lipase levels, gastritis (2.8%), duodenitis; *Musculoskeletal and Connective Tissue*: Myositis/polymyositis, rhabdomyolysis (and associated sequelae, including renal failure), arthritis (1.5%), polymyalgia rheumatica; *Endocrine*: Hypoparathyroidism; *Hematologic/Immune*: Hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenic purpura, solid organ transplant rejection, other transplant (including corneal graft) rejection; *Other*: Myocarditis-Myositis-Myasthenia Gravis (or Myasthenia-Like) Overlap syndrome, reported as the co-occurrence of either two or all three adverse reactions.

Hypersensitivity and Infusion- or Administration-Related Reactions

- KEYTRUDA and KEYTRUDA QLEX can cause severe or life-threatening administration-related reactions, including hypersensitivity and anaphylaxis. With KEYTRUDA and KEYTRUDA QLEX, monitor for signs and symptoms of infusion- and administration-related systemic reactions including rigors, chills, wheezing, pruritus, flushing, rash, hypotension, hypoxemia, and fever. Infusion-related reactions have been reported in 0.2% of 2799 patients receiving KEYTRUDA. Interrupt or slow the rate of infusion for Grade 1 or Grade 2 reactions. For Grade 3 or Grade 4 reactions, stop infusion and permanently discontinue KEYTRUDA. Hypersensitivity and administration-related systemic reactions occurred in 3.2% (8/251) of patients receiving KEYTRUDA QLEX in combination with platinum doublet chemotherapy, including Grade 2 (2.8%). Interrupt injection (if not already fully administered) and resume if symptoms resolve for mild or moderate systemic reactions. For severe or life-threatening systemic reactions, stop injection and permanently discontinue KEYTRUDA QLEX.

Complications of Allogeneic Hematopoietic Stem Cell Transplantation (HSCT)

- Fatal and other serious complications can occur in patients who receive allogeneic HSCT before or after anti–PD-1/PD-L1 treatments. Transplant-related complications include hyperacute graft-versus-host disease (GVHD), acute and chronic GVHD, hepatic veno-occlusive disease after reduced intensity conditioning, and steroid-requiring febrile syndrome (without an identified infectious cause). These complications may occur despite intervening therapy between anti–PD-1/PD-L1 treatments and allogeneic HSCT. Follow patients closely for evidence of these complications and intervene promptly. Consider the benefit vs risks of using anti–PD-1/PD-L1 treatments prior to or after an allogeneic HSCT.

Selected Safety Information continues on next page

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SELECTED SAFETY INFORMATION (*continued*)

Increased Mortality in Patients With Multiple Myeloma

- In trials in patients with multiple myeloma, the addition of KEYTRUDA to a thalidomide analogue plus dexamethasone resulted in increased mortality. Treatment of these patients with an anti–PD-1/PD-L1 treatment in this combination is not recommended outside of controlled trials.

Embryofetal Toxicity

- Based on their mechanism of action, KEYTRUDA and KEYTRUDA QLEX can each cause fetal harm when administered to a pregnant woman. Advise women of this potential risk. In females of reproductive potential, verify pregnancy status prior to initiating KEYTRUDA or KEYTRUDA QLEX and advise them to use effective contraception during treatment and for 4 months after the last dose.

Adverse Reactions

- In study MK-3475A-D77, when KEYTRUDA QLEX was administered with chemotherapy in metastatic non–small cell lung cancer (NSCLC), serious adverse reactions occurred in 39% of patients. Serious adverse reactions in ≥1% of patients who received KEYTRUDA QLEX were pneumonia (10%), thrombocytopenia (4%), febrile neutropenia (4%), neutropenia (2.8%), musculoskeletal pain (2%), pneumonitis (2%), diarrhea (1.6%), rash (1.2%), respiratory failure (1.2%), and anemia (1.2%). Fatal adverse reactions occurred in 10% of patients including pneumonia (3.2%), neutropenic sepsis (2%), death not otherwise specified (1.6%), respiratory failure (1.2%), parotitis (0.4%), pneumonitis (0.4%), pneumothorax (0.4%), pulmonary embolism (0.4%), neutropenic colitis (0.4%), and seizure (0.4%). KEYTRUDA QLEX was permanently discontinued due to an adverse reaction in 16% of 251 patients. Adverse reactions which resulted in permanent discontinuation of KEYTRUDA QLEX in ≥2% of patients included pneumonia and pneumonitis. Dosage interruptions of KEYTRUDA QLEX due to an adverse reaction occurred in 45% of patients. Adverse reactions which required dosage interruption in ≥2% of patients included neutropenia, anemia, thrombocytopenia, pneumonia, rash, and increased aspartate aminotransferase. The most common adverse reactions (≥20%) were nausea (25%), fatigue (25%), and musculoskeletal pain (21%).
- The most common adverse reactions for KEYTRUDA (reported in ≥20% of patients) were fatigue, musculoskeletal pain, rash, diarrhea, pyrexia, cough, decreased appetite, pruritus, dyspnea, constipation, pain, abdominal pain, nausea, and hypothyroidism.

Lactation

- Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment and for 4 months after the last dose.

Before prescribing KEYTRUDA or KEYTRUDA QLEX, please read the additional Selected Safety Information throughout, and the accompanying Prescribing Information for KEYTRUDA and KEYTRUDA QLEX. The Medication Guides for KEYTRUDA and KEYTRUDA QLEX also are available.

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