This resource will be deployed with multiple subject lines and preheaders

Subject Line Options

1. Administration in just minutes is now an approved option
2. Administration in just minutes is now an option
3. Learn about a new treatment with flexible administration options
4. What do you know about this new treatment with flexible administration options?
5. Did you know about this new product with a flexible administration option?
6. NOW APPROVED: Find out more about this new treatment option
7. NOW APPROVED: Administration in just minutes is an option

Preheader Options

a. See administration details below.

b. See administration information for this new treatment option.

c. Scroll below to learn more.

d. See interactive content below.

US PDS-KEYTRUDA QLEX Rev Approved Closing Writing Compared

Write You

NOW APPROVED

KEYTRUDA Qlex®
pembrolizumab and hyaluronidase-pmph
Injection, 394 mg/2000 Units

KEYTRUDA QLEX is approved for use in adult patients across most cancer types, including those with KEYTRUDA® (pembrolizumab) injection 100 mg—whether alone or in combination with other therapies

One each indication for KEYTRUDA and KEYTRUDA QLEX: Adjuvant treatment of adult patients with renal cell carcinoma at a recurrence risk ≥ 10% as high risk of recurrence following nephrectomy or nephrectomy and resection of metastatic lesions

Selected Safety Information

Contraindications

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

Serious and Fatal Immune-Mediated Adverse Reactions

- KEYTRUDA and KEYTRUDA QLEX are monoclonal antibodies that belong to a class of immunotherapy agents that bind to the programmed death receptor-1 (PD-1) receptor and block the PD-1 ligand (PD-L1), blocking the PD-1/PD-L1 pathway. Blocking binding of PD-L1 to the receptor can overcome tumor-induced suppressive immunity, including peripheral immunosuppression, and may lead to immune-mediated adverse reactions. Immune-mediated adverse reactions may be severe or fatal, can occur at any time after starting treatment, and more than one body system may be affected. Monitor for signs and at any time after starting treatment of adverse reactions and depending on severity of important immune-mediated adverse reactions, withhold or permanently discontinue all possible severe and fatal immune-mediated adverse reactions.

Expand to See Selected Safety Information

Selected Safety Information continues below.

KEYTRUDA QLEX can be administered in as little as 1 minute

Subcutaneous injection over approximately 1 minute	Intravenous infusion over approximately 30 minutes
1-minute administration*	2-minute administration*
2.4 mL injection volume	4.8 mL injection volume

*Does not account for all aspects of preparation and other steps.

Tap arrows to see more.

Patients have the option to switch between KEYTRUDA QLEX and KEYTRUDA or KEYTRUDA QLEX to KEYTRUDA at their next scheduled dose

For certain patients, treatment with KEYTRUDA QLEX offers fewer administration steps

Learn more about clinical data for KEYTRUDA QLEX

Selected Safety Information (continued)

Serious and Fatal Immune-Mediated Adverse Reactions (continued)

- Immune-mediated adverse reactions 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 antibodies. Evaluate liver enzymes, creatinine, and clinical chemistries at baseline and periodically during treatment. In cases of suspected immune-mediated adverse reactions, initiate appropriate workup to exclude infectious causes, evaluate for etiology of adverse reaction, institute medical management consistent with generally accepted standards of care, and consider consultation with rheumatologist.
- Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity of the reaction. In general, if KEYTRUDA and KEYTRUDA QLEX are withheld because of an immune-mediated adverse reaction, corticosteroid therapy should be administered (1 mg/kg 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 immunosuppressant non-corticosteroid immunosuppressants in patients where corticosteroids are contraindicated or ineffective as corticosteroid therapy.

Immune-Mediated Pneumonitis

- ARTICLE and KEYTRUDA QLEX can cause immune-mediated pneumonitis. The first case of pneumonitis in the clinical trial program was fatal. Pneumonitis, including cases requiring hospitalization, occurred in 267/3740 (7.1%) patients receiving KEYTRUDA, including Grade 5 (0.1%), Grade 4 (0.2%), Grade 3 (1.7%), and Grade 2 (1.7%) patients. Systemic corticosteroids were required in 154/267 (58%) of these patients. Pneumonitis led to permanent discontinuation of KEYTRUDA in 39/267 (15%) patients and to withholding of KEYTRUDA in 51/267 (19%) patients. Pneumonitis resolved in 50% of patients with a median time to resolution of 6.1 months (range: 0.1+ to 27.4+ months). Pneumonitis resolved in 56% of patients with corticosteroids administered at the time of resolution and in 11% of patients with corticosteroids administered at the time of pneumonitis recurrence. Pneumonitis resolved in 58% of patients who did not receive systemic corticosteroids compared to 75% (12/16) of patients who received systemic corticosteroids at the time of pneumonitis onset. Immunosuppressive therapy was required in 7 patients for pneumonitis that resulted in permanent discontinuation of KEYTRUDA. Pneumonitis resolved in 4 of these 7 patients. Of patients who were administered KEYTRUDA after symptom resolution, pneumonitis recurred in 4 patients. Delay/interruption of dosing for pneumonitis was observed in 1.5% (55/3740) of patients receiving KEYTRUDA, including cases in 0.5% (19) of patients receiving corticosteroids for immune-mediated pneumonitis.

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 immune-mediated colitis, consider infectious etiologies.
- Immune-mediated colitis occurred in 1.7% (62/3740) of patients receiving KEYTRUDA, including Grade 4 (0.1%), Grade 3 (0.7%), and Grade 2 (0.8%) reactions. Systemic corticosteroids were required in 48/62 (77%) of these patients. Immunosuppressant therapy was required in 12/62 (19%) patients. This led to permanent discontinuation of KEYTRUDA in 7 patients and to withholding of KEYTRUDA in 20 patients. Of patients who were administered KEYTRUDA after symptom resolution, colitis recurred in 2 patients. Colitis resolved in 30% of the patients with a median time to resolution of 1.1+ months (range: 0.1+ to 22.1+ months). Colitis resolved in 50% of patients who were treated with corticosteroids at the time of colitis onset.

Immune-Mediated Hepatitis and Immune-Mediated Hepatitis with Liver Failure

- ARTICLE and KEYTRUDA QLEX can cause immune-mediated hepatitis. Immune-mediated hepatitis occurred in 0.7% (26/3740) of patients receiving KEYTRUDA, including Grade 4 (0.3%), Grade 3 (0.3%), and Grade 2 (0.1%) reactions. Systemic corticosteroids were required in 69% (18/26) of patients. Immunosuppressant therapy was required in 19% (5/26) of patients. This led to permanent discontinuation of KEYTRUDA in 4 patients and to withholding of KEYTRUDA in 4 patients. Of patients who were administered KEYTRUDA after symptom resolution, hepatitis recurred in 1 patient. Hepatitis resolved in 79% of patients with a median time to resolution of 1.4+ months (range: 0.1+ to 11.0+ months). Hepatitis resolved in 71% of patients who received corticosteroids at the time of hepatitis onset.

Immune-Mediated Hypophysitis and Hypophysitis with Endocrine Disorders

- ARTICLE and KEYTRUDA QLEX can cause immune-mediated hypophysitis. Hypophysitis could present with signs and symptoms of headache, visual field defects, and hypopituitarism. Hypophysitis can follow exposure to other PD-1/PD-L1 inhibitors, resulting in hypophysitis with a review of medical management of hypophysitis with other PD-1/PD-L1 inhibitors. This led to permanent discontinuation of KEYTRUDA and KEYTRUDA QLEX in 1 patient.
- Hypophysitis occurred in 0.3% (10/3740) of patients receiving KEYTRUDA, including Grade 3 (0.1%), Grade 2 (0.2%) reactions. Systemic corticosteroids were required in 7/10 (70%) patients and hormone replacement in 10/10 (100%) patients. This led to permanent discontinuation of KEYTRUDA in 1 patient and to withholding of KEYTRUDA in 1 patient. Hypophysitis resolved in 50% of patients with a median time to resolution of 2.1+ months (range: 0.1+ to 2.1+ months). Hypophysitis resolved in 50% of patients who received corticosteroids at the time of hypophysitis onset.

Thyroid Disorders

- ARTICLE and KEYTRUDA QLEX can cause immune-mediated thyroid disorders. Thyroid disorders could present with any signs and symptoms of dysfunction. Thyroid disorders can follow exposure to other PD-1/PD-L1 inhibitors, resulting in thyroid disorders with a review of medical management of thyroid disorders with other PD-1/PD-L1 inhibitors. This led to permanent discontinuation of KEYTRUDA and KEYTRUDA QLEX in 1 patient.
- Thyroiditis occurred in 0.3% (10/3740) of patients receiving KEYTRUDA, including Grade 2 (0.2%) reactions. Thyroiditis led to permanent discontinuation of KEYTRUDA and KEYTRUDA QLEX in 1 patient.
- Hypothyroidism occurred in 8.2% (306/3740) of patients receiving KEYTRUDA, including Grade 3 (0.1%) and Grade 2 (7.1%) reactions. This led to permanent discontinuation of KEYTRUDA in 1% (3) and withholding in 0.3% (12) of patients. Hypothyroidism resolved in 21% of patients with a median time to resolution of 2.8+ months (range: 0.1+ to 22.1+ months). Hormone replacement was required in 87% of patients.
- Hyperthyroidism occurred in 3.2% (120/3740) of patients receiving KEYTRUDA, including Grade 3 (0.1%) and Grade 2 (1.1%) reactions. This led to permanent discontinuation of KEYTRUDA in 0.1% (2) and withholding in 0.3% (12) of patients. Hyperthyroidism resolved in 39% of patients with a median time to resolution of 1.4+ months (range: 0.1+ to 16.6+ months). Of patients with hyperthyroidism who received treatment with thyroid hormone inhibitors, 12% (3/25) of patients resolved compared to 40% (42/105) of patients who did not receive thyroid hormone inhibitors.

Type 1 Diabetes Mellitus (Old Name: Insulin-Dependent Diabetes Mellitus)

- ARTICLE and KEYTRUDA QLEX can cause immune-mediated hyperglycemia. Type 1 diabetes mellitus could present with acute symptoms of diabetes, including but not limited to diabetic ketoacidosis. Hyperglycemia can follow exposure to other PD-1/PD-L1 inhibitors, resulting in hyperglycemia with a review of medical management of hyperglycemia with other PD-1/PD-L1 inhibitors. This led to permanent discontinuation of KEYTRUDA and KEYTRUDA QLEX in 1 patient.
- Hyperglycemia occurred in 0.9% (34/3740) of patients receiving KEYTRUDA, including Grade 4 (0.1%), Grade 3 (0.4%), and Grade 2 (0.3%) reactions. Hyperglycemia resolved in 76% of patients.

Hypophysitis

- ARTICLE and KEYTRUDA QLEX can cause immune-mediated hypophysitis. Hypophysitis could present with acute symptoms of endocrinopathy, such as headache, photophobia, or visual field defects, with or without hypopituitarism. Initial hormone replacement may be adequate in some patients. This led to permanent discontinuation of KEYTRUDA and KEYTRUDA QLEX depending on severity.
- Hypophysitis occurred in 0.3% (10/3740) of patients receiving KEYTRUDA, including Grade 3 (0.1%), and Grade 2 (0.2%) reactions. Hypophysitis resolved in 50% of patients.

Adrenal Insufficiency

- ARTICLE and KEYTRUDA QLEX can cause immune-mediated adrenal insufficiency. For Grade 2 or higher, initiate hormone replacement therapy. Adrenal insufficiency can be clinically manifest as nonspecific signs and symptoms of other etiologies, such as immune-mediated adrenitis. This led to permanent discontinuation of KEYTRUDA and KEYTRUDA QLEX in 0.3% (12/3740) of patients receiving KEYTRUDA, including Grade 3 (0.1%), Grade 2 (0.2%), and Grade 1 (0.1%). Grade 3 (0.1%), Grade 2 (0.2%), and Grade 1 (0.1%) adrenal insufficiency were treated with systemic corticosteroids. Hormone replacement therapy was required in 10/12 (83%) of patients. This led to permanent discontinuation of KEYTRUDA in 1 patient and to withholding of KEYTRUDA in 3 patients. Of patients who were administered KEYTRUDA after symptom resolution, adrenal insufficiency recurred in 2 patients. Adrenal insufficiency resolved in 25% (3/12) of patients receiving KEYTRUDA and in 0% (0/9) of patients receiving KEYTRUDA and systemic corticosteroids.

Hypophysitis

- ARTICLE and KEYTRUDA QLEX can cause immune-mediated hypophysitis. Hypophysitis could present with acute symptoms of endocrinopathy, such as headache, photophobia, or visual field defects, with or without hypopituitarism. Initial hormone replacement may be adequate in some patients. This led to permanent discontinuation of KEYTRUDA and KEYTRUDA QLEX depending on severity.
- Hypophysitis occurred in 0.3% (10/3740) of patients receiving KEYTRUDA, including Grade 3 (0.1%), and Grade 2 (0.2%) reactions. Hypophysitis resolved in 50% of patients.

Uveitis and Iritis

- ARTICLE and KEYTRUDA QLEX can cause uveitis or iritis, which may occur in patients with a history of other autoimmune disease. Uveitis or iritis could present with blurred vision, photophobia, or pain. This led to permanent discontinuation of KEYTRUDA and KEYTRUDA QLEX depending on severity.
- Uveitis or iritis occurred in 0.3% (11/3740) of patients receiving KEYTRUDA, including Grade 3 (0.1%), Grade 2 (0.2%) reactions. Uveitis or iritis led to permanent discontinuation of KEYTRUDA in 0.1% (2) and withholding of KEYTRUDA in 0.1% (3) of patients. Uveitis or iritis resolved in 82% of patients with a median time to resolution of 1.1+ months (range: 0.1+ to 11.1+ months). Uveitis or iritis resolved in 67% of patients who received corticosteroids at the time of uveitis or iritis onset.

Pancreatitis, Including Acute Pancreatitis

- ARTICLE and KEYTRUDA QLEX can cause immune-mediated pancreatitis. Pancreatitis could present with signs and symptoms of abdominal pain, nausea, and vomiting. Pancreatitis can follow exposure to other PD-1/PD-L1 inhibitors, resulting in pancreatitis with a review of medical management of pancreatitis with other PD-1/PD-L1 inhibitors. This led to permanent discontinuation of KEYTRUDA and KEYTRUDA QLEX in 1 patient.
- Pancreatitis occurred in 0.3% (10/3740) of patients receiving KEYTRUDA, including Grade 3 (0.1%), Grade 2 (0.1%) reactions. Pancreatitis led to permanent discontinuation of KEYTRUDA and KEYTRUDA QLEX in 1 patient and to withholding of KEYTRUDA in 1 patient. Pancreatitis resolved in 67% of patients with a median time to resolution of 1.4+ months (range: 0.1+ to 1.4+ months). Pancreatitis resolved in 50% of patients who received corticosteroids at the time of pancreatitis onset.

Other Immune-Mediated Adverse Reactions

- The following clinically significant immune-mediated adverse reactions occurred at an incidence of 1% (38/3740) patients receiving KEYTRUDA: Guillain-Barré syndrome, myasthenic syndrome/myasthenia gravis, (including cases with fatal consequences), Bell's palsy, sarcoidosis, uveitis, iritis and other ocular inflammatory disorders, pituitary gland inflammation and damage, adrenal gland inflammation, hypophysitis, hypothyroidism, hyperthyroidism, type 1 diabetes mellitus, including cases presenting with diabetic ketoacidosis, Grade 3 Stevens-Johnson syndrome (SJS), Grade 3 erythema multiforme (EM), and other ocular disorders, hemolytic anemia, aplastic anemia, red blood cell (erythrocyte) aplasia, hemolytic uremic syndrome, leukocytoclasic vasculitis, Grade 3 uveitis, iritis and other ocular inflammatory disorders, and Grade 3 renal vasculitis. Withhold or permanently discontinue KEYTRUDA depending on severity of immune-mediated adverse reactions in combination with prednisone or equivalent up to 4 mg/kg/day prednisone or equivalent.
- Immune-mediated myocarditis, myositis/polymyositis, rhabdomyolysis (and associated sequelae, including renal failure), arrhythmia (including torsades de pointes and complete heart block), and myasthenic syndrome/myasthenia gravis (including exacerbation) have been reported for some of these adverse reactions. Cardiac/vascular: Myocarditis, pericarditis, vasculitis: Renal/urinary: Nephritis with renal dysfunction, nephritis, renal failure, and renal tubular acidosis: Endocrine: Hypophysitis, diabetes mellitus, diabetic ketoacidosis, adrenal insufficiency, hypothyroidism, hyperthyroidism, thyroiditis: Gastrointestinal: Pancreatitis, to include fatal cases, hepatitis, hepatitis with biliary cirrhosis, jaundice, colitis, perforation of small intestine, colitis with other complications, including toxic megacolon, Hepatobiliary/pancreas: Hepatitis, sclerosing cholangitis, hepatitis with biliary cirrhosis, cholecystitis: Musculoskeletal: Arthritis, myositis/polymyositis, rhabdomyolysis (and associated sequelae, including renal failure), arthralgia: Hematologic/Immune: Hemolytic anemia, aplastic anemia, hemolytic uremic syndrome, thrombocytopenia purpura, systemic lupus erythematosus, sarcoidosis, Guillain-Barré syndrome, myasthenic syndrome/myasthenia gravis (including exacerbation), hypophysitis, uveitis, conjunctivitis, eosinophilia, pancreatitis, gastritis, hepatitis, sialadenitis, colitis, serum sickness, urticaria, dermatitis, exfoliative dermatitis, Stevens-Johnson syndrome, erythema multiforme, drug reaction with eosinophilia and systemic symptoms, Sweet's syndrome, autoimmune neuropathies, consider a large-fibre neuropathy and small-fibre neuropathy, Parkinson's-like syndrome, severe skin reactions, other immune-mediated dermatologic adverse reactions. Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity of immune-mediated adverse reactions in combination with prednisone or equivalent up to 4 mg/kg/day prednisone or equivalent.

Hypersensitivity and Infusion- or Injection-Related Reactions

- ARTICLE and KEYTRUDA QLEX can cause severe or life-threatening hypersensitivity reactions, including anaphylaxis, and anaphylaxis. Monitor for signs and symptoms of hypersensitivity and anaphylaxis and, if anaphylaxis occurs, immediately and permanently discontinue KEYTRUDA and KEYTRUDA QLEX. Administer epinephrine and other appropriate treatments as clinically indicated.
- Hypersensitivity and anaphylaxis or infusion-related reactions occurred in 0.6% (21/3740) of patients receiving KEYTRUDA, including Grade 3 (0.1%) and Grade 2 (0.1%) reactions. Hypersensitivity and anaphylaxis or infusion-related reactions led to permanent discontinuation of KEYTRUDA in 0.1% (2) and withholding of KEYTRUDA in 0.1% (3) of patients. All patients who experienced a Grade 3 or higher hypersensitivity and anaphylaxis or infusion-related reaction had a fatal outcome. Immune-mediated pneumonitis, immune-mediated hepatitis with liver failure, and immune-mediated adrenal insufficiency occurred in 1 of the 21 patients. Immune-mediated pneumonitis occurred in 1 patient who received KEYTRUDA in combination with pemetrexed and platinum chemotherapy, including Grade 4 (0.4%) reactions. Of the 21 patients, 5 (0.1%) patients had a fatal outcome due to a hypersensitivity and anaphylaxis or infusion-related reaction. Immune-mediated pneumonitis, immune-mediated hepatitis with liver failure, and immune-mediated adrenal insufficiency occurred in 1 of the 5 patients. Immune-mediated pneumonitis occurred in 1 patient who received KEYTRUDA in combination with pemetrexed and platinum chemotherapy, including Grade 4 (0.4%) reactions. Immune-mediated hepatitis with liver failure occurred in 1 of the 5 patients. Immune-mediated adrenal insufficiency occurred in 1 of the 5 patients.

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 treatment. Transplant-related complications include hyperacute graft-versus-host-disease (GVHD), acute GVHD, chronic GVHD, hepatic veno-occlusive disease after non-myeloablative conditioning, and steroid-requiring febrile pneumonitis/pulmonary edema syndrome. Transplant complications may occur in the setting of corticosteroids and other therapies administered after anti-PD-1/PD-L1 treatment and prior to or after allogeneic HSCT.

Increased Mortality in Patients With Multiple Myeloma

- In trials in patients with multiple myeloma, PD-1/PD-L1 blockade in combination with a thalidomide analog plus dexamethasone resulted in increased mortality. Treatment of these patients with an anti-PD-1/PD-L1 antibody in combination is not recommended outside of controlled trials.

Embryo-Fetal Toxicity

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

Adverse Reactions

- Across 394 patients with advanced RCC treated with KEYTRUDA QLEX plus administered with pegilodecakin, axitinib, or pegylated interferon alfa-2b, serious adverse reactions occurred in 39% of patients. Serious adverse reactions in ≥ 2% of patients were pneumonitis (6.7%), pneumonitis (2.5%), and hepatitis (2.5%). Fatal adverse reactions occurred in 2.5% of patients with pneumonitis, pneumonitis, and hepatitis. Permanent discontinuation of KEYTRUDA due to adverse reactions occurred in 21% of patients. The most common adverse reactions (≥ 20%) were fatigue/asthenia (71%), musculoskeletal pain (51%), cutaneous reactions (48%), diarrhea (45%), nausea (41%), hypothyroidism (27%), dyspnea (27%), cough (25%), and hypertension (21%).

Please see the full Prescribing Information for complete information.

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

Before prescribing KEYTRUDA or KEYTRUDA QLEX, please read the full Prescribing Information for KEYTRUDA and KEYTRUDA QLEX. The Prescribing Information for KEYTRUDA and KEYTRUDA QLEX are not interchangeable.

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Mobile View - Expanded

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KEYTRUDA® Qlex™
pembrolizumab and vibrdamase alfa-vollen injection, 465 mg/5 mL

KEYTRUDA QLEX is approved for adult solid tumors that progress after at least one prior treatment in combination with other therapies

One such indication is KEYTRUDA® and KEYTRUDA QLEX is the adjuvant treatment of adult patients with melanoma (AJCC v8 staging) with lymph node involvement or metastatic disease, treated by resection, or following neoadjuvant treatment in combination with other therapies

Selected Safety Information

Contraindications

KEYTRUDA QLEX is contraindicated in patients with known hypersensitivity to vibrdamase alfa-vollen or hypersensitivity to any of its excipients.

Severe and Fatal Immune-Mediated Adverse Reactions

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated adverse reactions. These reactions can occur in any organ system or tissue. Immune-mediated adverse reactions initiated by KEYTRUDA may also occur after discontinuation of PD-1 or PD-L1 blocking antibodies. Immune-mediated adverse reactions, which in rare cases have been fatal, may involve any organ system or tissue, can affect more than one organ system at the same time, and can occur at any dose. Although immune-mediated reactions discussed in these sections include those that are attributed to PD-1 or PD-L1 blocking antibody-mediated adverse reactions, similar immune-mediated adverse reactions with and apart from those discussed here have been observed with immune-mediated adverse reactions. Early onset and higher incidence of severe reactions with prior or concomitant CTLA-4 antibody-mediated adverse reactions. Early, severe, and fatal immune-mediated adverse reactions have been observed in patients who received sequential or concurrent administration of KEYTRUDA and ipilimumab. Consider more frequent monitoring for adverse reactions during treatment in cases of suspected immune-mediated adverse reactions. Evaluate clinically suspected immune-mediated adverse reactions with appropriate management procedures, including appropriate consultations, based on severity of the adverse reaction. Consider withholding KEYTRUDA or permanently discontinuing KEYTRUDA or KEYTRUDA QLEX depending on severity of the immune-mediated adverse reaction. In general, if KEYTRUDA or KEYTRUDA QLEX interruption or discontinuation is required, administer systemic corticosteroids (1 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. Based on the severity of the adverse reaction, consider non-corticosteroid immunosuppressants in patients with persistent Grade 2 or 3 adverse reactions. Exceptions to these recommendations are noted under the individual adverse reactions below and in the text of the Dosage and Administration section. If prolonged administration of corticosteroids is required, consider prophylactic antimicrobial coverage. Immunosuppressants should not be administered to patients with active infection. Immune-mediated adverse reactions are not controlled with corticosteroid therapy.

Collapse

Selected Safety Information continues below

KEYTRUDA QLEX can be administered in as little as 1 minute

These not actual for all aspects of treatment decision. See PI for details.

Tap arrows to see more.

Patients have the option to switch from KEYTRUDA to KEYTRUDA QLEX — or KEYTRUDA QLEX to KEYTRUDA — in their next scheduled dose

For certain patients, treatment with KEYTRUDA QLEX offers flexibility by not requiring an infusion chair

Learn more about clinical data for KEYTRUDA QLEX

Selected Safety Information (continued)

Severe and Fatal Immune-Mediated Adverse Reactions (continued)

- Immune-mediated pneumonitis occurred in 4 patients (0.4%) treated with pembrolizumab or underlying immune-mediated adverse reaction in 2 patients (0.2%) treated with pembrolizumab and in 2 patients with severe immune-mediated colitis. Evaluate liver enzymes, creatinine, and clinical status to confirm etiology of pneumonitis before treatment or concomitant immunosuppressant administration. Administer corticosteroids, initiate appropriate workup to exclude infectious pneumonitis, and initiate, if clinically warranted, antibiotics or antifungals as appropriate.

Immune-Mediated Pneumonitis

KEYTRUDA and KEYTRUDA QLEX can cause pneumonitis, defined as CTCAE v4.0 Grade 2 or higher, and fatal pneumonitis occurred in 2.1% (61/2876) of patients treated with KEYTRUDA, including Grade 5 (1.7 fatal cases [0.1%]) and Grade 3 (0.7%) reactions. Systemic corticosteroids were required in 0.8% (23/2876) of patients. Pneumonitis led to permanent discontinuation of KEYTRUDA in 0.7% (19/2876) of patients and withholding in 0.9% (26/2876) of patients. Of patients who were treated with corticosteroids for pneumonitis, 74% (17/23) had resolution of pneumonitis. Pneumonitis resolved in 38% (23/61) of patients, including 13% (8/61) of patients with Grade 3 pneumonitis, 100% (1/1) of patients with Grade 5 pneumonitis, and in patients who were treated with corticosteroids for a median of 2.1 months (range: 0.3 to 20.4 months). Pneumonitis resolved in 38% (8/21) of patients with Grade 2 pneumonitis. Of patients who were withheld from KEYTRUDA for pneumonitis, 42% (11/26) had resolution of pneumonitis. Of patients who were treated with KEYTRUDA for pneumonitis, 2.1% (2/95) of patients had pneumonitis with a fatal outcome. Pneumonitis occurred in 3.8% (9/238) of patients with melanoma treated with KEYTRUDA, including Grade 3 (2.1%) and Grade 2 (1.7%) pneumonitis. Pneumonitis occurred in 1.8% (4/224) of patients with melanoma treated with KEYTRUDA and ipilimumab, including Grade 3 (1.3%) and Grade 2 (0.4%) pneumonitis. Pneumonitis occurred in 1.9% (5/263) of patients with melanoma treated with ipilimumab and KEYTRUDA QLEX, including Grade 3 (1.1%) and Grade 2 (0.8%) pneumonitis. Pneumonitis occurred in 1.9% (5/263) of patients with melanoma treated with ipilimumab and KEYTRUDA, including Grade 3 (1.1%) and Grade 2 (0.8

Bender Dummy - Dummy

NOW APPROVED

KEYTRUDA Qlex®
pembrolizumab + lenvatinib for advanced endometrial cancer

KEYTRUDA QLEX is approved for use in adult patients across most solid tumor indications for which KEYTRUDA intravenous injection 200 mg whether alone or in combination with chemotherapy.

The most indications for KEYTRUDA and KEYTRUDA QLEX is the approved dose of KEYTRUDA 200 mg every three weeks (Q3W) or intermittently for up to 24 months, in combination with platinum-based chemotherapy, or following radiotherapy and resection of resectable tumors.

Selected Safety Information

Contraindications

KEYTRUDA QLEX is contraindicated in patients with severe hypersensitivity to any of its components. Hypersensitivity to KEYTRUDA was observed.

Severe and Fatal Immune-Mediated Adverse Reactions

- KEYTRUDA and KEYTRUDA QLEX are monoclonal antibodies that belong to a class of immunotherapy drugs. The immunological basis underlying the adverse reactions is the ability of agent (PD-1) blocking the PD-1 pathway to unleash a patient's T-lymphocyte immune response against tumor cells. Immune-mediated adverse reactions, including inflammatory reactions, can be expected with PD-1 blockade and can mimic those seen with other immune-mediated therapies and may involve any organ system or tissue, can affect more than one organ system at the same time, and can occur in any patient treated with KEYTRUDA QLEX.
- Immune-mediated adverse reactions may be misdiagnosed as other medical conditions and should be ruled out. Monitor for signs and symptoms of adverse reactions and treat immune-mediated adverse reactions.
- Monitor patients closely for symptoms and signs that may be immune-mediated adverse reactions. Early diagnosis and treatment of these adverse reactions may prevent more severe reactions. Depending on the type and severity of a suspected adverse reaction, withhold or permanently discontinue KEYTRUDA or ±PD-1 blockade, and initiate corticosteroids and, if appropriate, other immunosuppressants. Upon improvement to ≤ Grade 1, resume ±PD-1 blockade and taper corticosteroids over ≥ 1 month. Administer immunosuppressants in patients with ≤ Grade 1 immune-mediated adverse reactions not controlled with corticosteroids or hormone replacement therapy.

Selected Safety Information continues below

KEYTRUDA QLEX can be administered in as little as 1 minute

*Does not account for 10 seconds of treatment. Actual time may vary.

Selected Safety Information (continued)

Immune-Mediated Pneumonitis

- KEYTRUDA and KEYTRUDA QLEX can cause fatal or life-threatening pneumonitis. Pneumonitis occurred in patients treated with PD-1 blockade, including KEYTRUDA, and has been reported in other malignancies treated with other PD-1 blockade therapies.
- Pneumonitis occurred in 1.1% (2/179) patients receiving KEYTRUDA, including Grade 3 (0.7%), Grade 4 (0.2%), and Grade 5 (0.2%) pneumonitis. Pneumonitis resulting in permanent discontinuation of KEYTRUDA occurred in 0.6% (1/179) patients. Pneumonitis resulting in withholding of KEYTRUDA occurred in 0.6% (1/179) patients. Pneumonitis resolved in 50% (1/2) patients with a median duration of 2.1 months (range: 0.5 months, 3.7 months) after last dose of KEYTRUDA. Pneumonitis resolved in 50% (1/2) patients with corticosteroids. Pneumonitis occurred in 1.1% (2/179) of patients with cancer of the endometrium treated with KEYTRUDA in combination with chemotherapy, including Grade 3 (0.6%) and Grade 4 (0.6%) pneumonitis.

Selected Safety Information continues below

Give your patients a choice of where you administer their treatment

Two subcutaneous injection sites available in healthcare settings

KEYTRUDA QLEX must be administered in a healthcare provider's office

Important Dosage and Administration Information

- KEYTRUDA QLEX has different recommended dosage and administration instructions than KEYTRUDA intravenous.
- Administer KEYTRUDA QLEX at a dose of 2,000 mg pembrolizumab and 2,000 U of vibrelizumab, according the 3 in one step administration.
- Inject into healthy skin and never into areas that are tender, bruised, red, or lumpy or hard.
- Do not administer into a vein or at least 2.5 cm from the previous injection site.
- During treatment with KEYTRUDA QLEX, do not administer other medications for administration via SC or IM injection at the same injection site.
- Do not administer KEYTRUDA QLEX intravenously.

Patients have the option to switch from KEYTRUDA to KEYTRUDA QLEX or KEYTRUDA QLEX to KEYTRUDA at their next scheduled dose

For certain patients, treatment with KEYTRUDA QLEX offers flexibility by not requiring an infusion chair

Learn more about clinical data for KEYTRUDA QLEX

Selected Safety Information (continued)

Immune-Mediated Colitis

- KEYTRUDA and KEYTRUDA QLEX can cause fatal or life-threatening immune-mediated colitis, which occurred in patients treated with PD-1 blockade.
- Cytomegalovirus infection/reactivation has been observed in patients with steroid-refractory immune-mediated colitis. In the reported cases of colitis in patients with cancer, complete diagnostic evaluation for infectious causes should be performed.
- Immune-mediated colitis occurred in 1.1% (2/179) patients receiving KEYTRUDA, including Grade 3 (0.7%) Grade 4 (0.1%), and Grade 5 (0.2%) immune-mediated colitis. Immune-mediated colitis resulting in permanent discontinuation of KEYTRUDA occurred in 0.6% (1/179) patients. Immune-mediated colitis resulting in withholding of KEYTRUDA occurred in 0.6% (1/179) patients. Immune-mediated colitis resolved in 50% (1/2) patients with a median duration of 1.3 months (range: 1.3 months, 1.3 months) after last dose of KEYTRUDA. Immune-mediated colitis occurred in 1.1% (2/179) of patients with cancer of the endometrium treated with KEYTRUDA in combination with chemotherapy, including Grade 3 (0.6%) and Grade 4 (0.6%) immune-mediated colitis.

Hepatitis and Immune-Mediated Hepatitis

- KEYTRUDA and KEYTRUDA QLEX can cause fatal or life-threatening hepatitis, including autoimmune hepatitis. Hepatitis occurred in 1.7% (3/179) patients receiving KEYTRUDA, including Grade 3 (1.1%), and Grade 4 (0.7%) immune-mediated hepatitis. Immune-mediated hepatitis occurred in 0.6% (1/179) of patients. Hepatitis resulting in permanent discontinuation of KEYTRUDA occurred in 0.6% (1/179) of patients. Hepatitis resulting in withholding of KEYTRUDA occurred in 0.6% (1/179) of patients. Hepatitis resolved in 75% of patients with a median duration of 2.1 months (range: 1.3 months, 2.8 months) after last dose of KEYTRUDA. Immune-mediated hepatitis occurred in 0.6% (1/179) of patients with cancer of the endometrium treated with KEYTRUDA in combination with chemotherapy, including Grade 3 (0.6%) and Grade 4 (0.6%) immune-mediated hepatitis.

Immune-Mediated Endocrinopathies

Adrenal Insufficiency

- KEYTRUDA and KEYTRUDA QLEX can cause primary or secondary adrenal insufficiency. For Grade 2 or higher adrenal insufficiency, initiate symptomatic treatment, including hormone replacement as clinically indicated. Withhold KEYTRUDA and KEYTRUDA QLEX depending on severity. Adrenal insufficiency occurred in 0.5% (1/179) of patients receiving KEYTRUDA, including Grade 3 (0.5%) adrenal insufficiency. Adrenal insufficiency resulting in permanent discontinuation of KEYTRUDA occurred in 0.5% (1/179) of patients. Adrenal insufficiency resulting in withholding of KEYTRUDA occurred in 0.5% (1/179) of patients. Adrenal insufficiency resolved in 100% of patients with a duration of 1.3 months after last dose of KEYTRUDA. Adrenal insufficiency occurred in 0.5% (1/179) of patients with cancer of the endometrium treated with KEYTRUDA in combination with chemotherapy, including Grade 3 (0.5%) adrenal insufficiency.

Hypophysitis

- KEYTRUDA and KEYTRUDA QLEX can cause hypophysitis. Hypophysitis occurred in 0.5% (1/179) patients receiving KEYTRUDA, including Grade 3 (0.5%) hypophysitis. Hypophysitis resulting in permanent discontinuation of KEYTRUDA occurred in 0.5% (1/179) patients. Hypophysitis resulting in withholding of KEYTRUDA occurred in 0.5% (1/179) patients. Hypophysitis resolved in 100% of patients with a duration of 1.3 months after last dose of KEYTRUDA. Hypophysitis occurred in 0.5% (1/179) of patients with cancer of the endometrium treated with KEYTRUDA in combination with chemotherapy, including Grade 3 (0.5%) hypophysitis.

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- 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 manage hyperthyroidism with thionamides as clinically indicated. Withhold KEYTRUDA and KEYTRUDA QLEX depending on severity. Immune-mediated thyroid disorders occurred in 7.8% (14/179) patients receiving KEYTRUDA, including Grade 3 (0.6%) thyroiditis. Immune-mediated hypothyroidism occurred in 7.3% (13/179) patients.
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Type 1 Diabetes Mellitus (DM), Where Onset Was Preceded With Diabetic Ketoacidosis

- Type 1 diabetes mellitus, including cases in other type and unspecified diabetes mellitus, can occur after KEYTRUDA treatment. Withhold KEYTRUDA and KEYTRUDA QLEX depending on severity. Type 1 DM occurred in 0.1% (1/179) of patients receiving KEYTRUDA. Type 1 DM resulting in permanent discontinuation of KEYTRUDA occurred in 0.1% (1/179) of patients. All patients who were diagnosed with Type 1 DM required insulin for glycemic control. Type 1 diabetes mellitus occurred in 0.1% (1/179) of patients with cancer of the endometrium treated with KEYTRUDA in combination with chemotherapy. The majority of patients with immune-mediated endocrinopathy received hormone replacement.
- Thyroiditis occurred in 0.6% (1/181) of patients with cancer of the endometrium in combination with chemotherapy, including Grade 2 (0.6%) thyroiditis. Hypothyroidism occurred in 4.0% (20/181) of patients receiving KEYTRUDA in combination with chemotherapy, including Grade 3 (0.6%) hypothyroidism. Hyperthyroidism occurred in 3.3% (6/181) of patients receiving KEYTRUDA Grade 3 (0.6%) hyperthyroidism.

Immune-Mediated Nephritis With Renal Dysfunction

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated nephritis. Immune-mediated nephritis occurred in 0.5% (1/179) patients receiving KEYTRUDA. Immune-mediated nephritis resulting in permanent discontinuation of KEYTRUDA occurred in 0.5% (1/179) patients. Immune-mediated nephritis resolved in 100% (1/1) patients. Immune-mediated nephritis occurred in 0.5% (1/179) of patients with cancer of the endometrium treated with KEYTRUDA in combination with chemotherapy, including Grade 3 (0.5%) immune-mediated nephritis.

Immune-Mediated Dermatologic Adverse Reactions

- KEYTRUDA and KEYTRUDA QLEX can cause severe immune-mediated dermatologic adverse reactions, including Stevens-Johnson syndrome, drug rash with eosinophilia and systemic symptoms, and toxic epidermal necrolysis. Withhold KEYTRUDA and KEYTRUDA QLEX depending on severity and treat suspected severe cutaneous adverse reactions with corticosteroids. Severe cutaneous adverse reactions occurred in 0.6% (1/179) patients receiving KEYTRUDA. Severe cutaneous adverse reactions resulting in permanent discontinuation of KEYTRUDA occurred in 0.6% (1/179) patients. All patients who developed severe cutaneous adverse reactions required hospitalization. Severe cutaneous adverse reactions resolved in 100% (1/1) patients. Severe cutaneous adverse reactions occurred in 0.6% (1/179) of patients with cancer of the endometrium treated with KEYTRUDA in combination with chemotherapy, including Grade 3 (0.6%) Toxic epidermal necrolysis.

Other Immune-Mediated Adverse Reactions

- Other clinically important immune-mediated adverse reactions can occur in patients treated with KEYTRUDA and KEYTRUDA QLEX. Immune-mediated adverse reactions affecting the following organ systems or tissues have been reported in patients treated with other PD-1 blockade therapies: Myocarditis, pancreatitis, uveitis, Guillain-Barré syndrome, myasthenic syndrome, myelitis, myositis, vasculitis, sarcoidosis, hemolytic anemia, aplastic anemia, hemolytic uremic syndrome, thrombocytopenia, adrenalitis, hypophysitis, nephritis, pituitary inflammation, hypothyroidism, hyperthyroidism, type 1 diabetes mellitus, and other endocrinopathies, arthritis, polymyalgia rheumatica, myelitis, and demyelinating lesions of central nervous system (CNS) and peripheral nervous system (PNS) lesions, including Guillain-Barré syndrome, myasthenic syndrome, and demyelination. Depending on the affected organ and severity of the adverse reaction, withhold KEYTRUDA and KEYTRUDA QLEX and initiate corticosteroids. Upon improvement to ≤ Grade 1, taper corticosteroids over ≥ 1 month. Administer immunosuppressants in patients with ≤ Grade 1 immune-mediated adverse reactions not controlled with corticosteroids or hormone replacement therapy.

Selected Safety Information continues below

Selected Safety Information (continued)

Immune-Mediated Cholecystitis

- KEYTRUDA and KEYTRUDA QLEX can cause fatal or life-threatening immune-mediated cholecystitis, which occurred in patients treated with PD-1 blockade.
- Cholecystitis was observed exacerbation has been observed in patients with cholecystitis following immune-mediated adverse reactions with KEYTRUDA and other PD-1 blockade therapies.
- Immune-mediated cholecystitis occurred in 0.6% (1/179) patients receiving KEYTRUDA, including Grade 3 (0.6%) Grade 5 (0.1%), and Grade 5 (0.1%) immune-mediated cholecystitis. Immune-mediated cholecystitis resulting in permanent discontinuation of KEYTRUDA occurred in 0.6% (1/179) patients. Immune-mediated cholecystitis resolved in 100% (1/1) patients with a duration of 1.3 months after last dose of KEYTRUDA. Immune-mediated cholecystitis occurred in 0.6% (1/179) of patients with cancer of the endometrium treated with KEYTRUDA in combination with chemotherapy, including Grade 3 (0.6%) and Grade 5 (0.6%) immune-mediated cholecystitis.

Infusion Related Reactions

- Severe infusion reactions have been observed in patients treated with other PD-1 blockade therapies. Discontinue KEYTRUDA and KEYTRUDA QLEX for severe or life-threatening infusion reactions.

Complications of Allogeneic Hematopoietic Stem Cell Transplantation (HSCT)

- Fatal and other serious complications can occur in patients who receive allogeneic HSCT before or after KEYTRUDA and KEYTRUDA QLEX. Transplant-related complications include hyperacute graft-versus-host-disease (GVHD), acute GVHD, chronic GVHD, hepatic veno-occlusive disease after reduced intensity conditioning, and steroid-requiring febrile pneumonitis/pulmonary infiltrates without infection. Some complications have occurred in patients treated with PD-1 blockade. PD-1PD-1 blockade and allogeneic HSCT administered to patients with hematologic malignancies can be associated with unexpected severe acute graft-versus-host-disease (GVHD), graft-versus-host-disease (GVHD) after stem cell transplantation.

Increased Mortality in Patients With Multiple Myeloma

- In trials in patients with multiple myeloma, PD-1 blockade plus a thalidomide analog plus dexamethasone has shown increased mortality. Treatment of these patients with an anti-PD-1 antibody in combination in no recommendation cannot be ruled out.

Embryofetal Toxicity

- Based on its mechanism of action, KEYTRUDA and KEYTRUDA QLEX can cause fetal harm when administered to a pregnant woman. Advise pregnant females of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment and for 4 months after last dose.

Adverse Reactions

- In KEYNOTE-775, when KEYTRUDA is not an approved component of chemotherapy in metastatic non-small cell lung cancer (NSCLC), adverse reactions occurred in 20% of patients receiving KEYTRUDA and in 19% of patients who received placebo. The most common (≥ 20%) adverse reactions in patients receiving KEYTRUDA were musculoskeletal pain (27%), fatigue/asthenia (26%), nausea (23%), diarrhea (21%), rash (21%), and hypothyroidism (20%). The most common (≥ 2 patients) laboratory abnormalities were decreased hemoglobin (2%), decreased sodium (2%), and decreased lymphocytes (2%).
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Selected Safety Information continues below

Selected Safety Information (continued)

Immune-Mediated Pneumonitis

- KEYTRUDA and KEYTRUDA QLEX can cause fatal or life-threatening pneumonitis. Pneumonitis occurred in patients treated with PD-1 blockade, including KEYTRUDA, and has been reported in other malignancies treated with other PD-1 blockade therapies.
- Pneumonitis occurred in 1.1% (2/179) patients receiving KEYTRUDA, including Grade 3 (0.7%), Grade 4 (0.2%), and Grade 5 (0.2%) pneumonitis. Pneumonitis resulting in permanent discontinuation of KEYTRUDA occurred in 0.6% (1/179) patients. Pneumonitis resulting in withholding of KEYTRUDA occurred in 0.6% (1/179) patients. Pneumonitis resolved in 50% (1/2) patients with a median duration of 2.1 months (range: 0.5 months, 3.7 months) after last dose of KEYTRUDA. Pneumonitis resolved in 50% (1/2) patients with corticosteroids. Pneumonitis occurred in 1.1% (2/179) of patients with cancer of the endometrium treated with KEYTRUDA in combination with chemotherapy, including Grade 3 (0.6%) and Grade 4 (0.6%) pneumonitis.

Hepatitis and Immune-Mediated Hepatitis

- KEYTRUDA and KEYTRUDA QLEX can cause fatal or life-threatening hepatitis, including autoimmune hepatitis. Hepatitis occurred in 1.7% (3/179) patients receiving KEYTRUDA, including Grade 3 (1.1%), and Grade 4 (0.7%) immune-mediated hepatitis. Immune-mediated hepatitis occurred in 0.6% (1/179) of patients. Hepatitis resulting in permanent discontinuation of KEYTRUDA occurred in 0.6% (1/179) of patients. Hepatitis resulting in withholding of KEYTRUDA occurred in 0.6% (1/179) of patients. Hepatitis resolved in 75% of patients with a duration of 2.1 months (range: 1.3 months, 2.8 months) after last dose of KEYTRUDA. Immune-mediated hepatitis occurred in 0.6% (1/179) of patients with cancer of the endometrium treated with KEYTRUDA in combination with chemotherapy, including Grade 3 (0.6%) and Grade 4 (0.6%) immune-mediated hepatitis.

Immune-Mediated Endocrinopathies

Adrenal Insufficiency

- KEYTRUDA and KEYTRUDA QLEX can cause primary or secondary adrenal insufficiency. For Grade 2 or higher adrenal insufficiency, initiate symptomatic treatment, including hormone replacement as clinically indicated. Withhold KEYTRUDA and KEYTRUDA QLEX depending on severity. Adrenal insufficiency occurred in 0.5% (1/179) of patients receiving KEYTRUDA, including Grade 3 (0.5%) adrenal insufficiency. Adrenal insufficiency resulting in permanent discontinuation of KEYTRUDA occurred in 0.5% (1/179) of patients. Adrenal insufficiency resulting in withholding of KEYTRUDA occurred in 0.5% (1/179) of patients. Adrenal insufficiency resolved in 100% of patients with a duration of 1.3 months after last dose of KEYTRUDA. Adrenal insufficiency occurred in 0.5% (1/179) of patients with cancer of the endometrium treated with KEYTRUDA in combination with chemotherapy, including Grade 3 (0.5%) adrenal insufficiency.

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Thyroid Disorders

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Type 1 Diabetes Mellitus (DM), Where Onset Was Preceded With Diabetic Ketoacidosis

- Type 1 diabetes mellitus, including cases in other type and unspecified diabetes mellitus, can occur after KEYTRUDA treatment. Withhold KEYTRUDA and KEYTRUDA QLEX depending on severity. Type 1 DM occurred in 0.1% (1/179) of patients receiving KEYTRUDA. Type 1 DM resulting in permanent discontinuation of KEYTRUDA occurred in 0.1% (1/179) of patients. All patients who were diagnosed with Type 1 DM required insulin for glycemic control. Type 1 diabetes mellitus occurred in 0.1% (1/179) of patients with cancer of the endometrium treated with KEYTRUDA in combination with chemotherapy. The majority of patients with immune-mediated endocrinopathy received hormone replacement.
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Selected Safety Information continues below

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Desktop View

NOW APPROVED

KEYTRUDA Qlex®
pembrolizumab + berahyaluronidase alfa-pmph
Solution/vial-vial | 50 mg / 2000 units

KEYTRUDA QLEX is approved for use in adult patients across most solid tumor indications for KEYTRUDA® (pembrolizumab) Injection 100 mg—whether alone or in combination with other therapies

One such indication for KEYTRUDA and KEYTRUDA QLEX is the adjuvant treatment of adult patients with renal cell carcinoma (RCC) at intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions.

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.

Expand to See Selected Safety Information

Selected Safety Information continues below.

KEYTRUDA QLEX can be administered in as little as 1 minute

Q3W	Q6W
SUBQ 1 MINUTE	SUBQ 1 MINUTE
pembrolizumab 395 mg and berahyaluronidase alfa 4,000 units	pembrolizumab 790 mg and berahyaluronidase alfa 8,000 units
1-minute administration*	**2-minute administration***
2.4 mL injection volume	4.8 mL injection volume

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

Tap arrows to see more.

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

For certain patients, treatment with KEYTRUDA QLEX offers flexibility by not requiring an infusion chair

Learn more about clinical data for KEYTRUDA QLEX

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 baseline. Confirm severity using CTCAE v4 or v5 unless otherwise specified 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.

Immune-Mediated Pneumonitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated pneumonitis. The incidence is higher in patients treated with PD-1/PD-L1 blockers. Immune-mediated pneumonitis occurred in 3.4% (362/799) 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% (83/94) of patients. Pneumonitis led to permanent discontinuation of KEYTRUDA in 1.3% (36) and withholding in 0.9% (29) 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.

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% (462/799) 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 75% 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.

Hepatotoxicity and Immune-Mediated Hepatitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated hepatitis. Immune-mediated hepatitis occurred in 0.7% (192/799) of patients receiving KEYTRUDA, including Grade 4 (0.3%), Grade 3 (0.3%), and Grade 2 (0.1%) reactions. Systemic corticosteroids were required in 92% (173/19) 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 0.2% (5) 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 or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity. Adrenal insufficiency occurred in 0.8% (22/799) 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 deficits. 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% (17/799) 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% (18/2799) of patients receiving KEYTRUDA, including Grade 2 (0.3%). None discontinued, but KEYTRUDA was withheld in <0.1% (1) of patients.
- 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. Hyperthyroidism occurred in 8% (237/2799) of patients receiving KEYTRUDA, including Grade 3 (0.1%) and Grade 2 (3.1%). Hypothyroidism led to permanent discontinuation of KEYTRUDA in 0.1% (3) 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 3 (3.2%). Hypothyroidism occurred in 14% (35/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 2 (11%).

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 diabetes mellitus 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% (2) 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.

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 0.8% (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.

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 inflammatory ocular disorders, including keratitis, which 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.

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 reactions, including chills, tremor, flushing, rash, pruritus, fever, nausea, vomiting, 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 who receive anti-PD-1/PD-L1 treatments prior to or after an allogeneic HSCT for early signs and symptoms of these complications. Consider the benefit-to-risk of using anti-PD-1/PD-L1 treatments prior to or after an allogeneic HSCT.

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-3475-037, 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%), pancitrop (0.4%), pneumonitis (0.4%), cardiac arrest (0.4%), cardiopulmonary failure (0.4%), cerebrovascular accident (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%).
- In KEYNOTE-564, when KEYTRUDA was administered as a single agent for the adjuvant treatment of renal cell carcinoma, serious adverse reactions occurred in 20% of patients receiving KEYTRUDA; the serious adverse reactions (≥1%) were acute kidney injury, adrenal insufficiency, pneumonia, colitis, and diabetic ketoacidosis (1% each). Fatal adverse reactions occurred in 0.8% of patients, including 1 case each of pneumonitis. Discontinuation of KEYTRUDA due to adverse reactions occurred in 21% of 488 patients; the most common (≥1%) were increased alanine aminotransferase (ALT) (1.6%), colitis (1%), and adrenal insufficiency (1%). The most common adverse reactions (≥20%) were musculoskeletal pain (41%), fatigue (40%), rash (30%), diarrhea (27%), pruritus (23%), and hypothyroidism (21%).

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 accompanying Prescribing Information for KEYTRUDA and KEYTRUDA QLEX. The Medication Guides for KEYTRUDA and KEYTRUDA QLEX also are available.

Give your patients a choice of where you administer their treatment

Two subcutaneous injection-site options: abdomen or thigh

KEYTRUDA QLEX must be administered by a healthcare provider.

Tap arrows to see more.

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Important Dosage and Administration Information

- KEYTRUDA QLEX has different recommended dosage and administration instructions than intravenous KEYTRUDA
- Administer KEYTRUDA QLEX as a subcutaneous injection into the thigh or abdomen, avoiding the 5 cm area around the navel
- Inject into healthy skin and never into areas where the skin is red, bruised, tender, or hard
- Ensure the injection site is at least 2.5 cm from the previous injection site
- During treatment with KEYTRUDA QLEX, do not administer other medications for subcutaneous use at the same time as KEYTRUDA QLEX
- Do not administer KEYTRUDA QLEX intravenously

Tap arrows to see more.

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KEYTRUDA Qlex™
pembrolizumab + berahyaluronidase alfa-pmph
Intravenous injection | 50 mg + 2,000 units/mL

KEYTRUDA QLEX is approved for use in adult patients across most solid tumor indications for KEYTRUDA® (pembrolizumab) injection 100 mg—whether alone or in combination with other therapies

One such indication for KEYTRUDA and KEYTRUDA QLEX is the adjuvant treatment of adult patients with renal cell carcinoma (RCC) at intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions.

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 induced by immunomodulatory monoclonal antibodies. 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.
- 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 infectious causes, withhold or permanently discontinue treatment depending on severity. Administer corticosteroids and, if needed, other immunosuppressants in patients whose adverse reactions are not controlled with corticosteroid therapy.

Collapse

Selected Safety Information continues below.

KEYTRUDA QLEX can be administered in as little as 1 minute

Q3W	Q6W
400 mg	800 mg
pembrolizumab 200 mg and berahyaluronidase alfa 8,000 units	pembrolizumab 400 mg and berahyaluronidase alfa 16,000 units
1-minute administration*	**2-minute administration***
2.4 mL injection volume	4.8 mL injection volume

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

Tap arrows to see more.

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

For certain patients, treatment with KEYTRUDA QLEX offers flexibility by not requiring an infusion chair

Learn more about clinical data for KEYTRUDA QLEX

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 infectious causes, withhold or permanently discontinue treatment depending on severity. Administer corticosteroids and, if needed, other immunosuppressants in patients whose adverse reactions are not controlled with corticosteroid therapy.
- Withhold or permanently discontinue KEYTRUDA QLEX depending on severity of the immune-mediated adverse reaction. In general, if KEYTRUDA QLEX requires 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.

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% (862/39) of patients receiving KEYTRUDA, including Grade 4 <0.1%), Grade 3 (1.1%), and Grade 2 (0.4%) reactions. Systemic corticosteroids were required in 85% (33/48); additional immunosuppressant therapy was required in 4.2% of patients. Colitis led to permanent discontinuation of KEYTRUDA in 0.9% (15) and withholding in 0.5% (13) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. Of these, none had recurrence. Colitis resolved in 85% of the 48 patients. Immune-mediated colitis occurred in 1.2% (32/61) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 3 (0.8%) and Grade 2 (0.4%) adverse reactions.

Hepatitis/only and Immune-Mediated Hepatitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated hepatitis. Immune-mediated hepatitis occurred in 0.7% (127/39) 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% (8) 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% (12/31) 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% (22/799) 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 of patients required long-term hormone replacement. 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% (32/31) 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% (172/799) 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 0.8% (192/799) of patients receiving KEYTRUDA, including Grade 2 (0.2%). None discontinued, but KEYTRUDA was withheld in <0.1% (1) of patients.
- Hypothyroidism occurred in 3.4% (862/799) of patients receiving KEYTRUDA, including Grade 3 (0.1%) and Grade 2 (3.3%) reactions. Hypothyroidism 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% (237/799) 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% (16) 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% (12/51) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 2 (0.4%). Hypothyroidism occurred in 8% (20/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 3 (0.4%) and Grade 2 (7.6%). Hypothyroidism occurred in 2% (2/51) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 2 (11%).

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% (5/2799) of patients receiving KEYTRUDA, including Grade 4 (<0.1%) and Grade 3 (0.1%) reactions. It led to permanent discontinuation of KEYTRUDA in <0.1% (1) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. Type 1 diabetes mellitus occurred in 0.4% (1/201) 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% (92/799) of patients receiving KEYTRUDA, including Grade 4 (<0.1%), Grade 3 (0.1%), and Grade 2 (0.1%) reactions. Systemic corticosteroids were required in 85% (78/92) of patients; of these, the majority required 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.

Immune-Mediated Dermatologic Adverse Reactions

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated rash or dermatitis. Exfoliative dermatitis, toxic epidermal necrolysis, and 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, 8% 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.

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: *Vascular*: Vasculitis, 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, iritis, or inflammatory ocular toxicities with ophthalmic 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 thrombocytopenia, solid organ transplant rejection, other transplant (including corneal graft) rejection.

Hypersensitivity and Infusion- or Administration-Related Reactions

- KEYTRUDA and KEYTRUDA QLEX can cause severe or life-threatening administration-related adverse reactions, including hypersensitivity and anaphylaxis. For 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% (82/51) of patients receiving KEYTRUDA QLEX in combination with platinum doublet chemotherapy, including Grade 2 (2.8%). Interrupt injection (if not administered as a single-agent) for administration-related systemic reactions or 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.

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-077, 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 31% of patients who received KEYTRUDA QLEX were pneumonia (10%), thrombocytopenia (4%), febrile neutropenia (4%), neutropenia (2.8%), musculoskeletal pain (2%), pneumonitis (2%), diarrhea (1.9%), 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-specified (0.8%), cardiac arrest (0.8%), hemoptysis (0.8%), multiple organ dysfunctions (0.8%), 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 201 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 46% of patients. Adverse reactions which required dosage interruption in ≥2% of patients included neutropenia, musculoskeletal pain, pneumonia, rash, ALT increased, aspartate aminotransferase. The most common adverse reactions (≥20%) were nausea (25%), fatigue (25%), and musculoskeletal pain (21%).
- In KEYNOTE-564, when KEYTRUDA was administered as a single-agent for the adjuvant treatment of renal cell carcinoma, serious adverse reactions occurred in 20% of patients receiving KEYTRUDA, the serious adverse reactions (≥1%) were acute kidney injury, adrenal insufficiency, pneumonia, colitis, and diabetic ketoacidosis (1% each). Fatal adverse reactions occurred in 0.2% including 3 case of pneumonia. Discontinuation of KEYTRUDA due to adverse reactions occurred in 21% of 488 patients; the most common (≥1%) were increased alanine aminotransferase (ALT) (1.6%), colitis (1%), and adrenal insufficiency (1%). The most common adverse reactions (≥20%) were musculoskeletal pain (31%), fatigue (40%), rash (30%), diarrhea (27%), pruritus (23%), and hypothyroidism (21%).

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 accompanying Prescribing Information for KEYTRUDA and KEYTRUDA QLEX. The Medication Guides for KEYTRUDA and KEYTRUDA QLEX also are available.

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KEYTRUDA QLex®
pembrolizumab and hyaluronidase-zzxfh
Subcutaneous injection | 160 mg – 2,400 units/mL

KEYTRUDA QLEX is approved for use in adult patients across most solid tumor indications for KEYTRUDA® (pembrolizumab) injection 100 mg—whether alone or in combination with other therapies

One such indication for KEYTRUDA and KEYTRUDA QLEX is the adjuvant treatment of adult patients with renal cell carcinoma (RCC) at intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions.

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 (PDL1), blocking the PD-1/PD-L1 pathway, thereby removing signals that can inhibit a patient's immune response, potentially 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 KEYTRUDA or KEYTRUDA QLEX. Immune-mediated reactions listed here may not include all possible severe and fatal immune-mediated adverse reactions.
- 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. For 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 corticosteroids (prednisone 1 mg/kg/day or 60 mg/day 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 below.

KEYTRUDA QLEX can be administered in as little as 1 minute

QTW	Q6W
1 vial + 1 syringe (1 dose)	1 vial + 1 syringe (1 dose)
pembrolizumab 200 mg and berahyaluronidase alfa 2,400 units	pembrolizumab 200 mg and berahyaluronidase alfa 2,400 units
1-minute administration*	**2-minute administration***
2.4 mL injection volume	4.8 mL injection volume

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

Selected Safety Information *(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% (847/2894) 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 71% (601/847) of patients. Pneumonitis led to permanent discontinuation of KEYTRUDA in 1.1% (36) and withholding in 0.5% (28) of patients. Of patients who were withheld from KEYTRUDA, 79% (22/28) had improvement, of these, 23% had recurrence. Pneumonitis resolved in 59% of the fatal patients. Immune-mediated pneumonitis occurred in 1% (13/291) 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 below.

Give your patients a choice of where you administer their treatment

Two subcutaneous injection-site options:
abdomen or thigh

KEYTRUDA QLEX must be administered by a healthcare provider.

Important Dosage and Administration Information

- KEYTRUDA QLEX has different recommended dosage and administration instructions than intravenous KEYTRUDA
- Administer KEYTRUDA QLEX as a subcutaneous injection into the thigh or abdomen, avoiding the 5 cm area around the navel
- Inject into healthy skin and never into areas where the skin is red, bruised, tender, or hard
- Ensure the injection site is at least 2.5 cm from the previous injection site
- During treatment with KEYTRUDA QLEX, do not administer other medications for subcutaneous use at the same time as KEYTRUDA QLEX
- Do not administer KEYTRUDA QLEX intravenously

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

For certain patients, treatment with KEYTRUDA QLEX offers flexibility by not requiring an infusion chair

Learn more about clinical data for KEYTRUDA QLEX

Selected Safety Information *(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 3 (0.4%) and Grade 2 (1.3%) 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% (13) 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.

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% (5) 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 50% of the 19 patients. Immune-mediated hepatitis occurred in 0.8% (2/251) 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 (0.5%), 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, neuroophthalmic defects, or hypopituitarism, including hypothyroidism. 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 0.2% (5) 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 0.8% (16/2799) of patients receiving KEYTRUDA, including Grade 2 (0.3%). None discontinued, but KEYTRUDA was withheld in <0.1% (1) of patients.
- 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 10% (220/2799) of patients receiving KEYTRUDA, including Grade 3 (0.1%) and Grade 2 (8.2%). It led to permanent discontinuation of KEYTRUDA in <0.1% (1) and withholding in 0.3% (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% (12/251) 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 3 (0.2%). Hypothyroidism occurred in 14% (35/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 2 (11%).

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 in 0.1% (3) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. Type 1 diabetes mellitus 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 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.

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. Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity. Immune-mediated rash or dermatitis occurred in 4.4% (38/2799) of patients receiving KEYTRUDA, including Grade 3 (1%) and Grade 2 (3.1%) 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, 5% 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.

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: Immune-mediated myocarditis, myositis/polymyositis, rhabdomyolysis (and associated sequelae), Vascular: Vasculitis, 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 types of uveitis/retinitis occur. Vision 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, duodenitis; Endocrine: Hypophysitis, diabetes insipidus; Musculoskeletal: Rhabdomyolysis (and associated sequelae), including renal failure, arthritis (1.5%), polymyalgia rheumatica; Endocrine: Hypophysitis, diabetes insipidus; Hematologic/Immune: Hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenic purpura, solid organ transport rejection, other transplant (including corneal graft) rejection.

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 reactions. Discontinue KEYTRUDA and KEYTRUDA QLEX for severe or life-threatening infusion-related reactions. 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 0.4% (12/2799) 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-to-risks of using anti-PD-1/PD-L1 treatments prior to or after an allogeneic HSCT.

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. Advise females of reproductive potential to use effective contraception during treatment with 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-077, 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 31% of patients who received KEYTRUDA QLEX were pneumonia (10%), thrombocytopenia (4%), febrile neutropenia (4%), neutropenia (2.8%), musculoskeletal pain (2%), pneumonitis (2%), diarrhea (1.8%), rash (1.8%), and acute kidney injury (1.8%). Fatal adverse reactions occurred in 10% of patients including pneumonia (3.2%), neutropenia sepsis (2%), death not otherwise specified (1.6%), respiratory failure (1.2%), pancitrifa (0.4%), pneumonitis (0.4%), pneumothorax (0.4%), pulmonary embolism (0.8%), neutropenic colitis (0.4%), and seizure (0.4%). KEYTRUDA QLEX was permanently discontinued due to an adverse reaction in 19% of patients with treatment withheld for adverse reactions and discontinuation of KEYTRUDA QLEX in 42% of patients included pneumonia and pneumonitis. Dosage interruptions of KEYTRUDA QLEX due to an adverse reaction occurred in 46% of patients. Adverse reactions which required dosage interruption in ≥2% of patients included neutropenia, anemia, thrombocytopenia, pneumonia, rash, and musculoskeletal pain. The most common adverse reactions (≥20%) were musculoskeletal pain (41%), fatigue (46%), rash (30%), diarrhea (27%), pruritus (23%), and hypothyroidism (21%).

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 accompanying Prescribing Information for KEYTRUDA and KEYTRUDA QLEX. The Medication Guides for KEYTRUDA and KEYTRUDA QLEX also are available.

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