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 dosing options
4. What do you know about this treatment with flexible dosing options?
5. Did you know about this product with a flexible dosing option?

Preheader Options

a. See dosing details below.

b. See dosing information for this new treatment option.

Write Your

NOW APPROVED

KEYTRUDA Qlex®
pembrolizumab and hyaluronidase-pmph
50 mg/1,000 U/mL subcutaneous injection

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

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

Selected Safety Information

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

Severe 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 its ligands, PD-L1 and PD-L2, blocking the PD-1/PD-L1 and PD-L2 pathways, thereby inhibition of the immune response, potentially including immune-mediated adverse reactions, which are immune-mediated adverse reactions. Immune-mediated adverse reactions may be severe or fatal. Left untreated or unmanaged, immune-mediated adverse reactions involving more than one body system can rapidly become life-threatening or fatal. Most of these immune-mediated adverse reactions resolve if recognized and treated promptly, but some may result in sequelae. Immune-mediated adverse reactions may mimic other medical conditions and flare upon rechallenge with immunosuppressant medications. Important immune-mediated adverse reactions include but are not limited to all possible severe and fatal immune-mediated adverse reactions.

Exposure to Some Selected Safety Information

Selected Safety Information continues below

KEYTRUDA QLEX can be administered in as little as 1 minute

IV	SC
30-minute infusion	1-minute injection
100 mg pembrolizumab and 2,000 U hyaluronidase	100 mg pembrolizumab and 2,000 U hyaluronidase
1-minute administration*	2-minute administration*
2.5-mL Vertavia syringe	4.8-mL injection volume

*Administration time does not include observation period. Actual clinic time may vary.

Tap screens to see administration sites

1 / 2

Give your patients a choice of where and how administer their treatment

Two injection sites options: abdomen or upper thigh

KEYTRUDA QLEX can only be administered by a healthcare professional

Tap screens to see dosing options

1 / 2

For the adjuvant treatment of RCC:

Treatment with KEYTRUDA QLEX should continue for a total of 9 mg/kg, up to 18 mg, or up to 18 months.

Patients receiving KEYTRUDA can switch to KEYTRUDA QLEX at their next scheduled dose.

Patients receiving KEYTRUDA QLEX can switch to KEYTRUDA at their next scheduled dose.

KEYTRUDA QLEX is administered under the skin (subcutaneously) in the abdomen. Do not administer intravenously.

For certain patients, treatment with KEYTRUDA QLEX offers more 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. Immune-mediated adverse reactions should be managed as soon as possible to avoid worsening of the underlying immune-mediated adverse reaction. Depending on the severity of the immune-mediated adverse reaction, withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX and administer corticosteroids. For severe or life-threatening immune-mediated adverse reactions, administer intravenous corticosteroids. Upon improvement to Grade 1 or baseline, initiate corticosteroid taper over at least 1 month. Consider administration of other systemic immunosuppressants in patients in whom systemic corticosteroids are not contraindicated and who have severe immune-mediated adverse reactions.

Immune-Mediated Pneumonitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated pneumonitis. The incidence is higher in patients who have received previous thoracic radiation. Immune-mediated pneumonitis occurred in 3.4% (127/3716) of patients receiving KEYTRUDA, including Grade 2 (1.1%), Grade 3 (1.0%), Grade 4 (0.1%), and Grade 5 (0.2%) deaths. Systemic corticosteroids were required in 0.9% (33/3716) of patients receiving KEYTRUDA, including Grade 3 (0.4%) and Grade 4 (0.1%) events, and were permanently discontinued for pneumonitis in 0.8% (28) and withholding in 0.8% (28) of patients. All patients who were withheld resumed KEYTRUDA after pneumonitis resolved to Grade 1 or less. With the administration of other immunosuppressants in the 34 patients, immune-mediated pneumonitis resolved in 21 patients. Of 21 patients receiving KEYTRUDA QLEX or KEYTRUDA, 14 (67%) had Grade 1 and two (9.5%), Grade 3 (1%), and Grade 5 (1%) events of pneumonitis.

Immune-Mediated Colitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated colitis, which may present with diarrhea. Cytomegalovirus infection/reactivation has been observed in immune-mediated colitis in patients treated with PD-1/PD-L1 blockade agents, including KEYTRUDA, consider testing infectious causes as clinically appropriate. Immune-mediated colitis occurred in 1.3% (48/3716) of patients receiving KEYTRUDA, including Grade 2 (0.3%), Grade 3 (0.7%), and Grade 4 (0.1%) events. Systemic corticosteroids were required in 69% (33/48) patients with immune-mediated colitis, and were permanently discontinued for immune-mediated colitis in 0.4% (14) and withholding in 0.6% (23) of patients. All patients who were withheld resumed KEYTRUDA after symptom improvement. With the administration of other immunosuppressants in the 23 patients, immune-mediated colitis resolved in 17 patients. Of 17 patients receiving KEYTRUDA QLEX or KEYTRUDA, 12 (71%) had Grade 3 (5.9%) and Grade 4 (5.9%) events of immune-mediated colitis.

Hepatitis/Hepatitis and Immune-Mediated Hepatitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated hepatitis. Immune-mediated hepatitis occurred in 0.7% (22/3716) of patients receiving KEYTRUDA, including Grade 3 (0.4%), Grade 4 (0.2%), and Grade 5 (0.1%) events. Systemic corticosteroids were required in 68% (15/22) of patients receiving KEYTRUDA, including Grade 3 (0.4%) events. Hepatitis resolved in 50% (11/22) of patients receiving KEYTRUDA. In patients with immune-mediated hepatitis, KEYTRUDA was permanently discontinued in 0.2% (5) and withheld in 0.2% (5) of patients. All patients who were withheld resumed KEYTRUDA after symptom improvement. With the administration of other immunosuppressants in the 11 patients, immune-mediated hepatitis resolved in 9 patients. Of 9 patients receiving KEYTRUDA QLEX or KEYTRUDA, 5 (56%) had Grade 3 (33%) and Grade 4 (22%) events of immune-mediated hepatitis.

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. Hormone replacement as indicated. Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity.
- Hypophysitis occurred in 0.6% (21/3716) of patients receiving KEYTRUDA, including Grade 3 (0.1%), Grade 4 (0.1%), and Grade 5 (0.1%) events. Systemic corticosteroids were required in 71% (15/21) of patients, and hormone replacerment in patients. Hypophysitis resolved in 43% (9/21) of patients. KEYTRUDA was permanently discontinued in 0.6% (19) and withheld in 0.1% (3) of patients. All patients who were withheld resumed KEYTRUDA after symptom improvement.

Thyroid Disorders

- KEYTRUDA and KEYTRUDA QLEX can cause thyroid disorders. Thyroid disorders generally occur more frequently with combinations containing KEYTRUDA, including hypothyroidism, hyperthyroidism, and thyroiditis. Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity.
- Thyroiditis occurred in 0.3% (10/3716) of patients receiving KEYTRUDA, including Grade 2 (0.1%) events. Hypothyroidism occurred in 10% (374/3716) of patients receiving KEYTRUDA, including Grade 3 (0.1%) and Grade 4 (0.8%) events. Hypothyroidism resulted in hormone replacement in 8.1% (302) of patients. Hyperthyroidism occurred in 3.1% (115/3716) of patients receiving KEYTRUDA, including Grade 3 (0.2%) and Grade 4 (0.1%) events. Systemic corticosteroids were required in 0.4% (15/3716) of patients receiving KEYTRUDA. Thyroid disorders resolved in 0.4% (15/3716) of patients receiving KEYTRUDA. KEYTRUDA was permanently discontinued in 0.7% (27) and withheld in 0.3% (12) of patients. All patients who were withheld resumed KEYTRUDA after symptom improvement. Of these, none had Grade 3 or 4 events of hypothyroidism, hyperthyroidism, or thyroiditis.
- Hypothyroidism can be preceded by thyrotoxicosis and/or hyperthyroidism, which may be transient. Initiate hormone replacement as indicated. Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity.
- Hyperthyroidism occurred in 0.4% (14/3716) of patients receiving KEYTRUDA, including Grade 3 (0.1%) events. Systemic corticosteroids were required in 0.2% (7/3716) of patients receiving KEYTRUDA. Hyperthyroidism resolved in 0.2% (7/3716) of patients receiving KEYTRUDA. KEYTRUDA was permanently discontinued in 0.1% (2/3716) of patients. All patients who were withheld resumed KEYTRUDA after symptom improvement.

Adrenal Insufficiency

- KEYTRUDA and KEYTRUDA QLEX can cause adrenal insufficiency, primary and secondary. Adrenal insufficiency occurred in 0.6% (21/3716) of patients receiving KEYTRUDA, including Grade 3 (0.3%) and Grade 4 (0.1%) events. Systemic corticosteroids were required in 0.9% (19/21) of patients receiving KEYTRUDA, and hormone replacement in 0.4% (12/3716) of patients receiving KEYTRUDA. Adrenal insufficiency resolved in 0.2% (5/3716) of patients receiving KEYTRUDA. KEYTRUDA was permanently discontinued for adrenal insufficiency in 0.2% (6) and withheld in 0.3% (10) of patients. All patients who were withheld resumed KEYTRUDA after symptom improvement. With the administration of other immunosuppressants in the 10 patients, adrenal insufficiency resolved in 7 patients. Of 7 patients receiving KEYTRUDA QLEX or KEYTRUDA, 4 (57%) had Grade 3 (29%) and Grade 4 (14%) events of adrenal insufficiency.
- Hypophysitis can be preceded by thyrotoxicosis and/or hyperthyroidism, which may be transient. Initiate hormone replacement as indicated. Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity.

Diabetes Mellitus, Type 1, Immune-Mediated

- Monitor patients for hyperglycemia or other signs and symptoms of diabetes mellitus treated with insulin as clinically appropriate. Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity. Administer insulin as clinically appropriate. Immune-mediated hypophosphatemia, initiate hormone replacement as clinically appropriate. Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity.
- Diabetes mellitus, type 1, occurred in 0.3% (10/3716) of patients receiving KEYTRUDA, including Grade 3 (0.1%) and Grade 4 (0.1%) events. Diabetes mellitus resulted in 0.3% (10/3716) of patients receiving KEYTRUDA. KEYTRUDA was permanently discontinued for diabetes mellitus, type 1, in 0.1% (2) and withheld in 0.1% (2) of patients. All patients who were withheld resumed KEYTRUDA after symptom improvement. Of these, 0% had Grade 3 or 4 events of diabetes mellitus, type 1, in patients receiving KEYTRUDA.

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%), Grade 4 (0.1%), and Grade 5 (0.1%) events. Systemic corticosteroids were required in 0.3% (8/2799) of patients. KEYTRUDA was permanently discontinued in 0.1% (2/2799) of patients. All patients who were withheld resumed KEYTRUDA after symptom improvement. Of these, none had Grade 3 or 4 events of immune-mediated nephritis in 100% of the 2 patients.

Immune-Mediated Dermatologic Adverse Reactions

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated rash or dermatitis, including exfoliative dermatitis, including Stevens-Johnson syndrome, drug rash with eosinophilia and systemic symptoms, and toxic epidermal necrolysis, that can be life-threatening. Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity. Administer corticosteroids and, if severe or life-threatening, consider hospitalization for treatment.
- Immune-mediated rash or dermatitis occurred in 0.9% (26/2799) of patients receiving KEYTRUDA, including Grade 3 (0.1%) events. Systemic corticosteroids were required in 0.4% (12/2799) of patients receiving KEYTRUDA. Immune-mediated rash or dermatitis resolved in 0.3% (8/2799) of patients receiving KEYTRUDA. KEYTRUDA was permanently discontinued for immune-mediated rash or dermatitis in 0.1% (2) and withheld in 0.4% (12) of patients. All patients who were withheld resumed KEYTRUDA after symptom improvement. Of these, none had Grade 3 or 4 events of immune-mediated rash or dermatitis in patients receiving KEYTRUDA.

Immune-Mediated Adverse Reactions Affecting Other Organs

- The following clinically significant immune-mediated adverse reactions occurred at an incidence of 1% (1/99) or less in patients who received KEYTRUDA QLEX or KEYTRUDA QLEX or were reported with the use of other anti-PD-1/PD-L1 blocking antibodies in clinical trials or have reported to date of these adverse reactions with KEYTRUDA: Myocarditis, pancreatitis, vasculitis, Nervous System Disorders: Guillain-Barré syndrome, meningitis, myasthenic syndrome/myasthenia gravis, encephalitis, myelitis and neuritis, sarcoidosis, Ocular Bank syndrome, uveitis, iridocyclitis, chorioretinitis, pancreatic islets, bile and other acinar cell immune-mediated adverse reactions, cases can be associated with clinical sequelae including diabetes, Type 1 diabetes mellitus, hypophysitis, hypophysitis, exocrinopathies, Cushing syndrome, adrenal insufficiency, hypophysitis, hypothyroidism, hyperthyroidism, thyroiditis, Graves' disease, cases can be associated with clinical sequelae including hypothyroidism, hypophysitis, hypothyroidism, hypophysitis, exocrinopathies, Ocular Bank syndrome, uveitis, iridocyclitis, chorioretinit

Mirella Text - Expanded

NOW APPROVED

KEYTRUDA Qlex

pembrolizumab + vibrazyme (berahyaluronidase alfa)

KEYTRUDA QLEX is approved for use in adult patients with advanced solid tumor indications for intravenous pembrolizumab injection 100 mg/ml **rather than or in combination with other therapies**

One such indication for KEYTRUDA and KEYTRUDA QLEX is the adjuvant treatment of adult patients with stage III melanoma with lymphonodal involvement or metastatic disease who have undergone complete resection, or following neoadjuvant treatment for unresectable or metastatic disease.

Selected Safety Information

Contraindications

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

Severe and Fatal Immune-Mediated Adverse Reactions

• KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated adverse reactions, a class of drugs that bind to either PD-1 or PD-L1 and PD-L2 and block the PD-1/PD-L1 and PD-L2 immune checkpoint pathway. Blocking PD-1 and PD-L1 pathways thereby removing immune cell inhibitory signals may potentially increase peripheral immune cell activity and immune-mediated adverse reactions. Immune-mediated adverse reactions which may be severe or fatal, can occur at any time during treatment or after stopping treatment and affect any organ system, but most often involve the skin, lungs, colon, liver, endocrine glands, and kidneys. Most of these adverse reactions will resolve after stopping treatment or after administration of corticosteroids or immunosuppressants. Immune-mediated adverse reactions of possible severe and fatal immune-mediated adverse reactions include:

• Immune-mediated pneumonitis and signs that may be clinical pneumonitis, including cases of fatal immune-mediated adverse reactions. Early diagnosis and treatment may be especially critical with pneumonitis, which can progress to severe or life-threatening respiratory failure. Monitor patients for signs and symptoms of pneumonitis, such as new or worsening cough, chest pain, shortness of breath, or hypoxia. Evaluate suspected pneumonitis with appropriate imaging. Based on severity of pneumonitis, withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX, administer corticosteroids, and if no improvement after starting corticosteroid treatment, administer other immunosuppressants (equivalent) until improvement to Grade 1 or baseline. Upon improvement to Grade 1 or baseline, begin tapering corticosteroids and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants for Grade 3 or Grade 4 pneumonitis. Permanently discontinue KEYTRUDA and KEYTRUDA QLEX for Grade 3 or Grade 4 pneumonitis.

• Immune-mediated colitis, which may present initially as diarrhea. Monitor for signs and symptoms of diarrhea, cramping, and abdominal pain. Based on severity of diarrhea or colitis, withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX, administer corticosteroids, and if no improvement after starting corticosteroid treatment, administer other immunosuppressants (equivalent) until improvement to Grade 1 or baseline. Upon improvement to Grade 1 or baseline, begin tapering corticosteroids and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants for Grade 3 or Grade 4 colitis. Permanently discontinue KEYTRUDA and KEYTRUDA QLEX for Grade 3 or Grade 4 colitis.

Collapse

Selected Safety Information continues below

KEYTRUDA QLEX can be administered in as little as 1 minute

SCM	SCP
2 fixed dose injections	2 fixed dose injections
Administered by healthcare professional	Administered by healthcare professional
"Passive" administration	"Passive" administration
2.4 mL injection volume	4.8 mL injection volume

These are accurate for all aspects of treatment (Keytruda and Vibrazyme)

Tap arrows to see administration steps

Back | Next

For the adjuvant treatment of RCC:

Treatment with KEYTRUDA QLEX can be administered in as little as 1 minute, regardless of patient footing, or up to 15 minutes footing

Patients receiving KEYTRUDA can switch to KEYTRUDA QLEX at their next scheduled dose

Patients receiving KEYTRUDA QLEX can switch to KEYTRUDA at their next scheduled dose

"KEYTRUDA QLEX is administered over a fixed dose of 2 injections (syringes) that are administered intravenously"

For certain patients, treatment with KEYTRUDA QLEX offers more 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 of hypophysitis (inflammation of underlying anterior pituitary gland) including unusual moderate/severe headache, Data dysfunction or other signs and symptoms of hypopituitarism (hypopituitarism, adrenal insufficiency, and other hormonal deficiencies, such as hypothyroidism, hypogonadism, and diabetes insipidus) and hypophysitis-related mass effect (such as headache, visual disturbances, and other neurological signs and symptoms). Based on severity of hypophysitis, withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX, administer corticosteroids, and if no improvement after starting corticosteroid treatment, administer other immunosuppressants (equivalent) until improvement to Grade 1 or baseline. Upon improvement to Grade 1 or baseline, begin tapering corticosteroids and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants for Grade 3 or Grade 4 hypophysitis. Permanently discontinue KEYTRUDA and KEYTRUDA QLEX for Grade 3 or Grade 4 hypophysitis.

• Immune-mediated hepatitis and immune-mediated hepatitis associated with chemotherapy, including cases of fatal immune-mediated adverse reactions. Early detection of immune-mediated hepatitis is critical for initiating appropriate management. Monitor patients for biochemical changes in liver function, including elevations in aminotransferase and bilirubin, prior to and periodically during treatment with KEYTRUDA and KEYTRUDA QLEX, and based on clinical assessment of liver function. Based on severity of hepatitis, withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX, administer corticosteroids, and if no improvement after starting corticosteroid treatment, administer other immunosuppressants (equivalent) until improvement to Grade 1 or baseline. Upon improvement to Grade 1 or baseline, begin tapering corticosteroids and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants for Grade 3 or Grade 4 hepatitis. Permanently discontinue KEYTRUDA and KEYTRUDA QLEX for Grade 3 or Grade 4 hepatitis.

• Immune-mediated nephritis and renal dysfunction, including cases of fatal immune-mediated adverse reactions. Monitor patients for changes in serum creatinine and urine output prior to and periodically during treatment with KEYTRUDA and KEYTRUDA QLEX. Based on severity of nephritis, withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX, administer corticosteroids, and if no improvement after starting corticosteroid treatment, administer other immunosuppressants (equivalent) until improvement to Grade 1 or baseline. Upon improvement to Grade 1 or baseline, begin tapering corticosteroids and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants for Grade 3 or Grade 4 nephritis with renal dysfunction. Permanently discontinue KEYTRUDA and KEYTRUDA QLEX for Grade 3 or Grade 4 nephritis with renal dysfunction.

• Immune-mediated premature ovarian failure. Monitor patients for signs and symptoms of ovarian failure. Based on severity of ovarian failure, withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX.

• Immune-mediated hypothyroidism. Hypothyroidism can follow hyperthyroidism. Initiate hormone replacement for hypothyroidism in patients with endocrinopathy as clinically indicated. Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity.

• Thyroiditis, including cases of fatal thyroiditis, which may be preceded by or concurrent with other immune-mediated adverse reactions. Early diagnosis and treatment may be critical for initiating appropriate management. Monitor patients for biochemical changes in thyroid function, including thyroid stimulating hormone (TSH), free thyroxine (fT4), and free triiodothyronine (fT3) prior to and periodically during treatment with KEYTRUDA and KEYTRUDA QLEX. Based on severity of thyroiditis, withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX, administer corticosteroids, and if no improvement after starting corticosteroid treatment, administer other immunosuppressants (equivalent) until improvement to Grade 1 or baseline. Upon improvement to Grade 1 or baseline, begin tapering corticosteroids and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants for Grade 3 or Grade 4 thyroiditis. Permanently discontinue KEYTRUDA and KEYTRUDA QLEX for Grade 3 or Grade 4 thyroiditis.

• Immune-mediated hyperthyroidism. Initiate treatment with a thyroid hormone synthesis inhibitor as clinically indicated. Based on severity of hyperthyroidism, withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX, administer corticosteroids, and if no improvement after starting corticosteroid treatment, administer other medications as clinically indicated. Upon improvement to Grade 1 or baseline, begin tapering corticosteroids and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants for Grade 3 or Grade 4 hyperthyroidism. Permanently discontinue KEYTRUDA and KEYTRUDA QLEX for Grade 3 or Grade 4 hyperthyroidism.

• Immune-mediated diabetes mellitus, including diabetic ketoacidosis. Monitor patients for signs and symptoms of diabetes. Based on severity of diabetes, withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX. Administer insulin for Type 1 DM and initiate management of hyperglycemia in accordance with standard of care for Type 2 DM. Permanently discontinue KEYTRUDA and KEYTRUDA QLEX for Type 1 DM associated with diabetic ketoacidosis.

• Immune-mediated adrenal insufficiency, including cases of fatal immune-mediated adverse reactions. Monitor patients for signs and symptoms of adrenal insufficiency. Based on severity of adrenal insufficiency, withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX, administer corticosteroids, and if no improvement after starting corticosteroid treatment, administer other immunosuppressants (equivalent) until improvement to Grade 1 or baseline. Upon improvement to Grade 1 or baseline, begin tapering corticosteroids and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants for Grade 3 or Grade 4 adrenal insufficiency. Permanently discontinue KEYTRUDA and KEYTRUDA QLEX for Grade 3 or Grade 4 adrenal insufficiency.

• Immune-mediated myocarditis, which may be fatal. Based on severity of myocarditis, withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX, administer corticosteroids, and if no improvement after starting corticosteroid treatment, administer other immunosuppressants (equivalent) until improvement to Grade 1 or baseline. Upon improvement to Grade 1 or baseline, begin tapering corticosteroids and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants for Grade 3 or Grade 4 myocarditis. Permanently discontinue KEYTRUDA and KEYTRUDA QLEX for Grade 3 or Grade 4 myocarditis.

• Immune-mediated rash, including severe cases with or without systemic involvement, including Stevens-Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN), and drug rash with eosinophilia and systemic symptoms (DRESS) syndrome, which may be life-threatening. Based on severity of rash, withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX, administer corticosteroids, and if no improvement after starting corticosteroid treatment, administer other immunosuppressants (equivalent) until improvement to Grade 1 or baseline. Upon improvement to Grade 1 or baseline, begin tapering corticosteroids and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants for Grade 3 or Grade 4 rash. Permanently discontinue KEYTRUDA and KEYTRUDA QLEX for Grade 3 or Grade 4 rash.

• Immune-mediated pancreatitis, including cases of fatal immune-mediated adverse reactions. Monitor patients for signs and symptoms of pancreatitis, such as new or worsening pain in the abdomen, back, or joints. Based on severity of pancreatitis, withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX, administer corticosteroids, and if no improvement after starting corticosteroid treatment, administer other immunosuppressants (equivalent) until improvement to Grade 1 or baseline. Upon improvement to Grade 1 or baseline, begin tapering corticosteroids and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants for Grade 3 or Grade 4 pancreatitis. Permanently discontinue KEYTRUDA and KEYTRUDA QLEX for Grade 3 or Grade 4 pancreatitis.

• Immune-mediated uveitis, iridocyclitis, and choroiditis, which may be associated with ocular symptoms, such as blurred vision, floaters, or flash ocular focus. Based on severity of uveitis, iridocyclitis, or choroiditis, withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX, administer corticosteroids, and if no improvement after starting corticosteroid treatment, administer other immunosuppressants (equivalent) until improvement to Grade 1 or baseline. Upon improvement to Grade 1 or baseline, begin tapering corticosteroids and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants for Grade 3 or Grade 4 uveitis, iridocyclitis, and choroiditis. Permanently discontinue KEYTRUDA and KEYTRUDA QLEX for Grade 3 or Grade 4 uveitis, iridocyclitis, and choroiditis.

• Immune-mediated myasthenia gravis, including cases of fatal immune-mediated adverse reactions. Monitor patients for signs and symptoms of myasthenia gravis. Based on severity of myasthenia gravis, withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX, administer corticosteroids, and if no improvement after starting corticosteroid treatment, administer other immunosuppressants (equivalent) until improvement to Grade 1 or baseline. Upon improvement to Grade 1 or baseline, begin tapering corticosteroids and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants for Grade 3 or Grade 4 myasthenia gravis. Permanently discontinue KEYTRUDA and KEYTRUDA QLEX for Grade 3 or Grade 4 myasthenia gravis.

• Immune-mediated vasculitis, including cases of fatal immune-mediated adverse reactions. Based on severity of vasculitis, withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX, administer corticosteroids, and if no improvement after starting corticosteroid treatment, administer other immunosuppressants (equivalent) until improvement to Grade 1 or baseline. Upon improvement to Grade 1 or baseline, begin tapering corticosteroids and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants for Grade 3 or Grade 4 vasculitis. Permanently discontinue KEYTRUDA and KEYTRUDA QLEX for Grade 3 or Grade 4 vasculitis.

• Immune-mediated nephrogenic diabetes insipidus, which may be life-threatening. Based on severity of nephrogenic diabetes insipidus, withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX. Administer supportive care and hormone replacement as clinically indicated.

• Immune-mediated hypophysitis (inflammation of the anterior pituitary gland) which may be life-threatening. Based on severity of hypophysitis, withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX, administer corticosteroids, and if no improvement after starting corticosteroid treatment, administer other immunosuppressants (equivalent) until improvement to Grade 1 or baseline. Upon improvement to Grade 1 or baseline, begin tapering corticosteroids and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants for Grade 3 or Grade 4 hypophysitis. Permanently discontinue KEYTRUDA and KEYTRUDA QLEX for Grade 3 or Grade 4 hypophysitis.

• Immune-mediated hypophysitis (inflammation of the anterior pituitary gland) which may be life-threatening. Based on severity of hypophysitis, withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX, administer corticosteroids, and if no improvement after starting corticosteroid treatment, administer other immunosuppressants (equivalent) until improvement to Grade 1 or baseline. Upon improvement to Grade 1 or baseline, begin tapering corticosteroids and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants for Grade 3 or Grade 4 hypophysitis. Permanently discontinue KEYTRUDA and KEYTRUDA QLEX for Grade 3 or Grade 4 hypophysitis.

Immune-Mediated Pneumonitis

• KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated pneumonitis, a class of drugs that bind to either PD-1 or PD-L1 and PD-L2 and block the PD-1/PD-L1 and PD-L2 immune checkpoint pathway. Blocking PD-1 and PD-L1 pathways thereby removing immune cell inhibitory signals may potentially increase peripheral immune cell activity and immune-mediated adverse reactions. Immune-mediated adverse reactions which may be severe or fatal, can occur at any time during treatment or after stopping treatment and affect any organ system, but most often involve the skin, lungs, colon, liver, endocrine glands, and kidneys. Most of these adverse reactions will resolve after stopping treatment or after administration of corticosteroids or immunosuppressants. Immune-mediated adverse reactions of possible severe and fatal immune-mediated adverse reactions include:

• Immune-mediated pneumonitis and signs that may be clinical pneumonitis, including cases of fatal immune-mediated adverse reactions. Early diagnosis and treatment may be especially critical with pneumonitis, which can progress to severe or life-threatening respiratory failure. Monitor patients for signs and symptoms of pneumonitis, such as new or worsening cough, chest pain, shortness of breath, or hypoxia. Evaluate suspected pneumonitis with appropriate imaging. Based on severity of pneumonitis, withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX, administer corticosteroids, and if no improvement after starting corticosteroid treatment, administer other immunosuppressants (equivalent) until improvement to Grade 1 or baseline. Upon improvement to Grade 1 or baseline, begin tapering corticosteroids and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants for Grade 3 or Grade 4 pneumonitis. Permanently discontinue KEYTRUDA and KEYTRUDA QLEX for Grade 3 or Grade 4 pneumonitis.

Immune-Mediated Colitis

• KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated colitis, a class of drugs that bind to either PD-1 or PD-L1 and PD-L2 and block the PD-1/PD-L1 and PD-L2 immune checkpoint pathway. Blocking PD-1 and PD-L1 pathways thereby removing immune cell inhibitory signals may potentially increase peripheral immune cell activity and immune-mediated adverse reactions. Immune-mediated adverse reactions which may be severe or fatal, can occur at any time during treatment or after stopping treatment and affect any organ system, but most often involve the skin, lungs, colon, liver, endocrine glands, and kidneys. Most of these adverse reactions will resolve after stopping treatment or after administration of corticosteroids or immunosuppressants. Immune-mediated adverse reactions of possible severe and fatal immune-mediated adverse reactions include:

• Immune-mediated colitis, which may present initially as diarrhea. Monitor for signs and symptoms of diarrhea, cramping, and abdominal pain. Based on severity of diarrhea or colitis, withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX, administer corticosteroids, and if no improvement after starting corticosteroid treatment, administer other immunosuppressants (equivalent) until improvement to Grade 1 or baseline. Upon improvement to Grade 1 or baseline, begin tapering corticosteroids and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants for Grade 3 or Grade 4 colitis. Permanently discontinue KEYTRUDA and KEYTRUDA QLEX for Grade 3 or Grade 4 colitis.

Immune-Mediated Hepatitis and Immune-Mediated Hepatitis with Chemotherapy

• KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated hepatitis, a class of drugs that bind to either PD-1 or PD-L1 and PD-L2 and block the PD-1/PD-L1 and PD-L2 immune checkpoint pathway. Blocking PD-1 and PD-L1 pathways thereby removing immune cell inhibitory signals may potentially increase peripheral immune cell activity and immune-mediated adverse reactions. Immune-mediated adverse reactions which may be severe or fatal, can occur at any time during treatment or after stopping treatment and affect any organ system, but most often involve the skin, lungs, colon, liver, endocrine glands, and kidneys. Most of these adverse reactions will resolve after stopping treatment or after administration of corticosteroids or immunosuppressants. Immune-mediated adverse reactions of possible severe and fatal immune-mediated adverse reactions include:

• Immune-mediated hepatitis, including cases of fatal immune-mediated adverse reactions. Early detection is critical for initiating appropriate management. Monitor patients for biochemical changes in liver function, including elevations in aminotransferase and bilirubin, prior to and periodically during treatment with KEYTRUDA and KEYTRUDA QLEX, and based on clinical assessment of liver function. Based on severity of hepatitis, withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX, administer corticosteroids, and if no improvement after starting corticosteroid treatment, administer other immunosuppressants (equivalent) until improvement to Grade 1 or baseline. Upon improvement to Grade 1 or baseline, begin tapering corticosteroids and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants for Grade 3 or Grade 4 hepatitis. Permanently discontinue KEYTRUDA and KEYTRUDA QLEX for Grade 3 or Grade 4 hepatitis.

• Hepatitis associated with chemotherapy, including cases of fatal immune-mediated adverse reactions. Hepatitis occurred in 17% (2/12) of patients receiving KEYTRUDA in combination with chemotherapy, including Grade 3 (8.4%) and Grade 2 (8.4%) hepatitis.

Immune-Mediated Endocrinopathies

Adrenal Insufficiency

• KEYTRUDA and KEYTRUDA QLEX can cause primary or secondary adrenal insufficiency, a class of drugs that bind to either PD-1 or PD-L1 and PD-L2 and block the PD-1/PD-L1 and PD-L2 immune checkpoint pathway. Blocking PD-1 and PD-L1 pathways thereby removing immune cell inhibitory signals may potentially increase peripheral immune cell activity and immune-mediated adverse reactions. Immune-mediated adverse reactions which may be severe or fatal, can occur at any time during treatment or after stopping treatment and affect any organ system, but most often involve the skin, lungs, colon, liver, endocrine glands, and kidneys. Most of these adverse reactions will resolve after stopping treatment or after administration of corticosteroids or immunosuppressants. Immune-mediated adverse reactions of possible severe and fatal immune-mediated adverse reactions include:

• Adrenal insufficiency, including cases of fatal adrenal insufficiency. Adrenal insufficiency occurred in 0.8% (2/238) of patients receiving KEYTRUDA, including Grade 3 (0.4%) and Grade 2 (0.4%) adrenal insufficiency. Adrenal insufficiency occurred in 0.8% (2/238) of patients receiving KEYTRUDA in combination with chemotherapy, including Grade 3 (0.4%) and Grade 2 (0.4%) adrenal insufficiency.

Hypophysitis

• KEYTRUDA and KEYTRUDA QLEX can cause hypophysitis, a class of drugs that bind to either PD-1 or PD-L1 and PD-L2 and block the PD-1/PD-L1 and PD-L2 immune checkpoint pathway. Blocking PD-1 and PD-L1 pathways thereby removing immune cell inhibitory signals may potentially increase peripheral immune cell activity and immune-mediated adverse reactions. Immune-mediated adverse reactions which may be severe or fatal, can occur at any time during treatment or after stopping treatment and affect any organ system, but most often involve the skin, lungs, colon, liver, endocrine glands, and kidneys. Most of these adverse reactions will resolve after stopping treatment or after administration of corticosteroids or immunosuppressants. Immune-mediated adverse reactions of possible severe and fatal immune-mediated adverse reactions include:

• Hypophysitis occurred in 0.4% (1/238) of patients receiving KEYTRUDA, including Grade 3 (0.4%) hypophysitis. Hypophysitis occurred in 0.4% (1/238) of patients receiving KEYTRUDA in combination with chemotherapy, including Grade 3 (0.4%) hypophysitis.

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

• Monitor patients for hyperglycemia or other signs and symptoms of diabetes mellitus and initiate management in accordance with standard of care. Based on severity of Type 1 DM, withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX. Administer insulin for Type 1 DM and initiate management of hyperglycemia in accordance with standard of care for Type 2 DM. Permanently discontinue KEYTRUDA and KEYTRUDA QLEX for Type 1 DM associated with diabetic ketoacidosis.

• Type 1 DM developed in 0.2% (2/1019) of patients receiving KEYTRUDA, including Grade 2 (0.1%) Type 1 DM associated with diabetic ketoacidosis. Type 1 DM developed in 0.2% (2/1019) of patients receiving KEYTRUDA in combination with chemotherapy, including Grade 2 (0.1%) Type 1 DM associated with diabetic ketoacidosis.

Other Immune-Mediated Adverse Reactions

• The following immune-mediated adverse reactions have been reported with PD-1 or PD-L1 inhibitors, including severe or life-threatening cases, in patients treated with KEYTRUDA: Myocarditis, uveitis, iridocyclitis, choroiditis, polymyalgia rheumatica, Guillain-Barré syndrome, myasthenia gravis, vasculitis, sarcoidosis, hemolytic anemia, Myositis/polymyositis, rhabdomyolysis (and sequelae leading to renal failure), arthritis (1.1%), autoimmune hemolytic anemia, hemophagocytic lymphohistiocytosis, hemolysis, systemic inflammatory response syndrome, adrenal gland hemorrhage, adrenocorticotropic hypothesis syndrome, adrenomyeloneuropathy, autoimmune neuropathies, Guillain-Barré syndrome, autoimmune encephalitis, autoimmune thrombocytopenic purpura, and hemolytic uremic syndrome (thrombotic thrombocytopenic purpura, hemolytic uremic syndrome, and thrombotic microangiopathy).

Immune-Mediated Adverse Reactions Administration Related Reactions

• Administer corticosteroids, H1 receptor antagonists, and acetaminophen for premedication prior to administration initiated beginning, including subsequent administrations, as needed, for infusion reactions. Based on severity of infusion reactions, withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX. Administer corticosteroids, H1 receptor antagonists, and acetaminophen for infusion reactions including rapid onset of anaphylaxis, rash, flushing, dyspnea, chills, and rigors. Infusion reactions occurred in 0.2% (2/1019) patients receiving KEYTRUDA, including Grade 2 (0.1%) infusion reactions. Infusion reactions occurred in 0.2% (2/1019) patients receiving KEYTRUDA in combination with chemotherapy, including Grade 2 (0.1%) infusion reactions.

Immunogenicity and Administration Related Reactions

• Administer corticosteroids, H1 receptor antagonists, and acetaminophen for premedication prior to administration initiated beginning, including subsequent administrations, as needed, for infusion reactions. Based on severity of infusion reactions, withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX. Administer corticosteroids, H1 receptor antagonists, and acetaminophen for infusion reactions including rapid onset of anaphylaxis, rash, flushing, dyspnea, chills, and rigors. Infusion reactions occurred in 0.2% (2/1019) patients receiving KEYTRUDA, including Grade 2 (0.1%) infusion reactions. Infusion reactions occurred in 0.2% (2/1019) patients receiving KEYTRUDA in combination with chemotherapy, including Grade 2 (0.1%) 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 anti-PD (L1) (L2) or PD-1 or PD-L1 blocking antibodies. Complications include Graft-versus-host-disease (GVHD), hepatic veno-occlusive disease after myeloablative conditioning, and steroid-requiring febrile syndrome, among other immune-mediated reactions. These complications may occur despite intervening between PD-1 or PD-L1 blockade and allogeneic HSCT. Follow patients who undergo HSCT for these complications and intervene promptly. Consider the benefit of HSCT before using anti-PD (L1) or PD-1 blockade prior to or after allogeneic HSCT. Consider the risk of complications or toxicities in patients who have undergoing allogeneic HSCT.

Increased Mortality in Patients With Multiple Myeloma

• In patients with multiple myeloma, the addition of KEYTRUDA to a thalidomide analog plus dexamethasone resulted in increased mortality. Use of a PD-1/PD-L1 blockade in this combination is not recommended outside of controlled trials.

Embryofetal Toxicity

• Based on its 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

• In KEYNOTE-227, when KEYTRUDA was administered with platinum and pemetrexed for 4 cycles followed by KEYTRUDA monotherapy for up to a total of 35 cycles, serious adverse reactions occurred in 53% of patients. Serious adverse reactions in 2% or more of patients included pneumonitis (3%), pneumonia (2%), bronchopulmonary infection (2%), and pleural effusion (2%). Fatal adverse reactions occurred in 2% of patients, including pneumonitis (2 patients), bronchopulmonary infection (2 patients), and cardiorespiratory arrest (2 patients). Adverse reactions resulting in discontinuation of KEYTRUDA in 17% of patients included pneumonitis (2%), and pneumonia (2%). Adverse reactions resulting in interruption of KEYTRUDA in 51% of patients included pneumonitis (5%), and pneumonia (2%). Adverse reactions in patients treated with KEYTRUDA in combination with chemotherapy, including Grade 3 (4.4%) and Grade 2 (1.4%) pneumonitis.

• In KEYNOTE-189, when KEYTRUDA was administered in a fixed dose for 35 cycles in combination with pemetrexed and platinum chemotherapy, serious adverse reactions occurred in 65% of patients. Serious adverse reactions in 2% or more of patients included pneumonia (4%), and pleural effusion (2%). Fatal adverse reactions occurred in 2% of patients, including pneumonitis (2 patients), and cardiorespiratory arrest (2 patients). Adverse reactions resulting in discontinuation of KEYTRUDA in 14% of patients included pneumonitis (2%), and pneumonia (2%). Adverse reactions resulting in interruption of KEYTRUDA in 52% of patients included pneumonia (3%), and pneumonitis (2%).

• In KEYNOTE-671, when KEYTRUDA was administered with platinum and fluorouracil-based chemotherapy for 4 cycles followed by KEYTRUDA monotherapy for up to a total of 15 cycles, serious adverse reactions occurred in 59% of patients. Serious adverse reactions in 2% or more of patients included pneumonia (3%), and pulmonary embolism (2%). Fatal adverse reactions occurred in 2% of patients, including pneumonitis (2 patients), and pulmonary embolism (2 patients). Adverse reactions resulting in discontinuation of KEYTRUDA in 14% of patients included pneumonitis (2%), and myocarditis (2%). Adverse reactions resulting in interruption of KEYTRUDA in 51% of patients included pneumonitis (2%), and pneumonia (2%).

• In KEYNOTE-564, when KEYTRUDA was administered as a single agent for 1 year, serious adverse reactions occurred in 30% of patients. Serious adverse reactions in 2% or more of patients included diarrhea (2%), colitis (2%), pneumonitis (2%), and pulmonary embolism, colitis, and diarrhea (2%). Fatal adverse reactions occurred in 1% of patients, including pneumonitis (2 patients), and pulmonary embolism (2 patients). Adverse reactions resulting in discontinuation of KEYTRUDA in 19% of patients included pneumonitis (2%), colitis (2%), and diarrhea (2%). Adverse reactions resulting in interruption of KEYTRUDA in 41% of patients included pneumonitis (2%) and diarrhea (2%).

• In KEYNOTE-716, when KEYTRUDA was administered as a single agent for 1 year, serious adverse reactions occurred in 28% of patients. Serious adverse reactions in 2% or more of patients included diarrhea (2%), colitis (2%), and pneumonitis (2%). Fatal adverse reactions occurred in 2% of patients, including pneumonitis (2 patients), and colitis (2 patients). Adverse reactions resulting in discontinuation of KEYTRUDA in 19% of patients included pneumonitis (2%), and colitis (2%). Adverse reactions resulting in interruption of KEYTRUDA in 41% of patients included pneumonitis (2%), colitis (2%), and diarrhea (2%).

Lactation

• 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 review the complete prescribing information for KEYTRUDA and KEYTRUDA QLEX. The Selected Safety Information for KEYTRUDA QLEX also is available.

Review Copy - Dummy

NOW APPROVED

KEYTRUDA QLEX®
pembrolizumab + vibrezimkahialuronidase
injection, 2400 mg/20 mL

KEYTRUDA QLEX is approved for use in adult patients across all indications for intravenous KEYTRUDA[1] (pembrolizumab) 200 mg administered every 3 weeks or every 6 weeks regardless of prior therapy.

One such indication for KEYTRUDA and chemoradiotherapy (CRT) is adjuvant treatment of adult patients with resected esophageal (EC) or gastroesophageal junction (GEJ) adenocarcinoma high or intermediate risk of recurrence, defined as pathologic residual disease after neoadjuvant CRT.

One such indication for KEYTRUDA and chemotherapy is for treating resectable or borderline resectable locally advanced cervical cancer (LACC) as chemotherapy high or intermediate risk of recurrence, defined as pathologic residual disease after neoadjuvant chemotherapy.

Selected Safety Information

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

Severe and Fatal Immune-Mediated Adverse Reactions

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated adverse reactions in a wide of organ that tend to either affect the gastrointestinal (GI), liver, endocrine, lung, skin, kidney, musculoskeletal (MS), hematopoietic (HC), pathway. Severity, timeliness, and frequency of immune-mediated adverse reactions, following administration of immune checkpoint inhibitor mediated adverse reactions, immune-mediated adverse reactions may be severe or fatal. Can occur at any time after first dose and may manifest during treatment or after completing treatment. Monitor for signs and symptoms of immune-mediated adverse reactions and consider the severity of possible serious 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 minimize long-term sequelae. Withhold KEYTRUDA or KEYTRUDA QLEX and administer corticosteroids for moderate or severe immune-mediated adverse reactions. Upon resolution of the immune-mediated adverse reaction to a lower severity, initiate corticosteroids and, if applicable, resume KEYTRUDA or KEYTRUDA QLEX at a reduced dose. Permanently discontinue KEYTRUDA or KEYTRUDA QLEX for any immune-mediated adverse reaction that recurs in severe form. In most cases, KEYTRUDA or KEYTRUDA QLEX should be withheld or permanently discontinued if a diagnosis of immune-mediated adverse reaction is confirmed. Depending on severity of the immune-mediated adverse reaction, KEYTRUDA or KEYTRUDA QLEX may be resumed after resolution of the adverse reaction. Refer to the Prescribing Information for KEYTRUDA or KEYTRUDA QLEX for additional information on immune-mediated adverse reactions.

Selected Safety Information continued below

KEYTRUDA QLEX can be administered in as little as 1 minute

Takes an average of 6 weeks of treatment. Avoid skin lines, bruises, or tattoos.

Selected Safety Information (continued)

Immune-Mediated Pneumonitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated pneumonitis, defined as immune-mediated adverse reactions presenting as pneumonitis, interstitial lung disease, or pneumonitis. Fatal cases have occurred. Pneumonitis occurred in 2.1% (21/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX monotherapy, including Grade 3 (0.3%), Grade 4 (<0.1%), and Grade 5 (<0.1%) pneumonitis. Pneumonitis occurred in 5.8% (58/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with chemotherapy, including Grade 3 (1.7%), and Grade 5 (0.4%) pneumonitis. Pneumonitis occurred in 3.8% (38/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with axitinib, including Grade 3 (1.3%) and Grade 5 (0.3%) pneumonitis. Pneumonitis occurred in 5.1% (51/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with lenvatinib, including Grade 3 (1.7%), Grade 4 (<0.1%), and Grade 5 (0.4%) pneumonitis. Pneumonitis occurred in 3.5% (35/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with pemetrexed and platinum chemotherapy, including Grade 3 (1.4%) and Grade 5 (0.3%) pneumonitis.

Immune-Mediated Colitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated colitis, defined as immune-mediated adverse reactions presenting as colitis or diarrhea. Colitis occurred in 1.2% (12/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX monotherapy, including Grade 3 (0.4%), and Grade 5 (0.1%). Colitis occurred in 1.3% (13/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with chemotherapy, including Grade 3 (0.6%) and Grade 5 (0.1%) colitis. Colitis occurred in 2.1% (21/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with axitinib, including Grade 3 (0.7%), and Grade 5 (0.1%) colitis. Colitis occurred in 1.7% (17/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with lenvatinib, including Grade 3 (0.7%) and Grade 5 (0.1%) colitis. Colitis occurred in 1.0% (10/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with pemetrexed and platinum chemotherapy, including Grade 3 (0.4%) and Grade 5 (0.1%) colitis.

Immune-Mediated Hepatitis and Immune-Mediated Hepatitis with Elevated Transaminases and Total Bilirubin

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated hepatitis, defined as immune-mediated adverse reactions presenting as hepatitis, hepatitis with elevated transaminases or hepatitis with elevated total bilirubin. Hepatitis occurred in 0.6% (6/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX monotherapy, including Grade 3 (0.2%), Grade 4 (<0.1%), and Grade 5 (0.1%) hepatitis. Hepatitis occurred in 0.6% (6/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with chemotherapy, including Grade 3 (0.2%) and Grade 5 (0.1%) hepatitis. Hepatitis occurred in 1.1% (11/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with axitinib, including Grade 3 (0.4%) and Grade 5 (0.1%) hepatitis. Hepatitis occurred in 0.8% (8/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with lenvatinib, including Grade 3 (0.4%) and Grade 5 (0.1%) hepatitis. Hepatitis occurred in 0.7% (7/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with pemetrexed and platinum chemotherapy, including Grade 3 (0.3%) and Grade 5 (0.1%) hepatitis.

Immune-Mediated Adrenal Insufficiency

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated hypophysitis, defined as immune-mediated adverse reactions presenting as hypophysitis, hypophysitis with pituitary hormone deficiency, or hypopituitarism. Hypophysitis occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX monotherapy, including Grade 3 (0.1%) and Grade 5 (0.1%) hypophysitis. Hypophysitis occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with axitinib, including Grade 3 (0.1%) and Grade 5 (0.1%) hypophysitis. Hypophysitis occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with lenvatinib, including Grade 3 (0.1%) and Grade 5 (0.1%) hypophysitis. Hypophysitis occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with pemetrexed and platinum chemotherapy, including Grade 3 (0.1%) and Grade 5 (0.1%) hypophysitis.

Immune-Mediated Hypophysitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated hypophysitis, defined as immune-mediated adverse reactions presenting as hypophysitis, hypophysitis with pituitary hormone deficiency, or hypopituitarism. Hypophysitis occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX monotherapy, including Grade 3 (0.1%) and Grade 5 (0.1%) hypophysitis. Hypophysitis occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with axitinib, including Grade 3 (0.1%) and Grade 5 (0.1%) hypophysitis. Hypophysitis occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with lenvatinib, including Grade 3 (0.1%) and Grade 5 (0.1%) hypophysitis. Hypophysitis occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with pemetrexed and platinum chemotherapy, including Grade 3 (0.1%) and Grade 5 (0.1%) hypophysitis.

Immune-Mediated Adrenal Insufficiency

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated adrenal insufficiency. For cases in Cohort 1 where adrenal insufficiency was assessed, immune-mediated adrenal insufficiency occurred in 0.4% (4/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX monotherapy, including Grade 3 (0.2%) and Grade 5 (0.1%) adrenal insufficiency. For cases in Cohort 1 where adrenal insufficiency was assessed, immune-mediated adrenal insufficiency occurred in 0.4% (4/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with axitinib, including Grade 3 (0.2%) and Grade 5 (0.1%) adrenal insufficiency. For cases in Cohort 1 where adrenal insufficiency was assessed, immune-mediated adrenal insufficiency occurred in 0.4% (4/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with lenvatinib, including Grade 3 (0.2%) and Grade 5 (0.1%) adrenal insufficiency. For cases in Cohort 1 where adrenal insufficiency was assessed, immune-mediated adrenal insufficiency occurred in 0.4% (4/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with pemetrexed and platinum chemotherapy, including Grade 3 (0.2%) and Grade 5 (0.1%) adrenal insufficiency.

Immune-Mediated Hyperthyroidism and Hypothyroidism

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated hypothyroidism, defined as immune-mediated adverse reactions presenting as hypothyroidism, Graves' hypothyroidism, Graves' hypothyroidism with pituitary hormone deficiency, or hypopituitarism. Hypothyroidism occurred in 9.1% (91/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX monotherapy, including Grade 3 (0.1%) and Grade 5 (0.1%) hypothyroidism. Hypothyroidism occurred in 12.1% (121/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with axitinib, including Grade 3 (0.2%) and Grade 5 (0.1%) hypothyroidism. Hypothyroidism occurred in 12.1% (121/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with lenvatinib, including Grade 3 (0.2%) and Grade 5 (0.1%) hypothyroidism. Hypothyroidism occurred in 10.1% (101/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with pemetrexed and platinum chemotherapy, including Grade 3 (0.1%) and Grade 5 (0.1%) hypothyroidism.

- Hyperthyroidism occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX monotherapy, including Grade 3 (0.1%) and Grade 5 (0.1%) hyperthyroidism. Hyperthyroidism occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with axitinib, including Grade 3 (0.1%) and Grade 5 (0.1%) hyperthyroidism. Hyperthyroidism occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with lenvatinib, including Grade 3 (0.1%) and Grade 5 (0.1%) hyperthyroidism. Hyperthyroidism occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with pemetrexed and platinum chemotherapy, including Grade 3 (0.1%) and Grade 5 (0.1%) hyperthyroidism.

Immune-Mediated Diabetes Mellitus

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated diabetes mellitus. Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Initiate insulin and resume at clinically appropriate time. Withhold KEYTRUDA or KEYTRUDA QLEX depending on severity. Immune-mediated diabetes mellitus occurred in 0.2% (2/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX monotherapy, including Grade 3 (0.1%) and Grade 5 (0.1%) diabetes mellitus. Immune-mediated diabetes mellitus occurred in 0.2% (2/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with axitinib, including Grade 3 (0.1%) and Grade 5 (0.1%) diabetes mellitus. Immune-mediated diabetes mellitus occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with lenvatinib, including Grade 3 (0.1%) diabetes mellitus. Immune-mediated diabetes mellitus occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with pemetrexed and platinum chemotherapy, including Grade 5 (0.1%) diabetes mellitus.

Other Immune-Mediated Adverse Reactions

- The following clinically significant immune-mediated adverse reactions occurred at the indicated rate in patients receiving KEYTRUDA or KEYTRUDA QLEX monotherapy or KEYTRUDA QLEX in cases reported with KEYTRUDA or KEYTRUDA QLEX in combination with chemotherapy, axitinib, lenvatinib, or pemetrexed and platinum chemotherapy: Guillain-Barré syndrome, myasthenic syndrome/myasthenia gravis, myelitis, vasculitis, uveitis, pancreatitis, nephritis with renal dysfunction, myocarditis, myositis/polymyositis, rhabdomyolysis, Guillain-Barré syndrome, myasthenic syndrome/myasthenia gravis, myelitis, vasculitis, uveitis, pancreatitis, nephritis with renal dysfunction, myocarditis, myositis/polymyositis, rhabdomyolysis, and sarcoidosis.

Infusion-Related and Cutaneous Immune-Mediated Adverse Reactions

- KEYTRUDA and KEYTRUDA QLEX can cause infusion-related reactions. Severe infusion-related reactions have been observed in patients receiving KEYTRUDA or KEYTRUDA QLEX. Stop KEYTRUDA or KEYTRUDA QLEX for severe or life-threatening infusion-related reactions. Withhold or stop KEYTRUDA or KEYTRUDA QLEX for other infusion-related reactions. Immune-mediated dermatitis, defined as immune-mediated adverse reactions presenting as rash, exfoliative rash, or dermatitis, occurred in 0.7% (7/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX monotherapy, including Grade 3 (0.1%) and Grade 5 (0.1%) dermatitis. Immune-mediated dermatitis occurred in 0.3% (3/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with axitinib, including Grade 3 (0.1%) and Grade 5 (0.1%) dermatitis. Immune-mediated dermatitis occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with lenvatinib, including Grade 3 (0.1%) dermatitis. Immune-mediated dermatitis occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with pemetrexed and platinum chemotherapy, including Grade 3 (0.1%) dermatitis.

Other Immune-Mediated Adverse Reactions

- The following clinically significant immune-mediated adverse reactions occurred at the indicated rate in patients receiving KEYTRUDA or KEYTRUDA QLEX monotherapy or KEYTRUDA QLEX in cases reported with KEYTRUDA or KEYTRUDA QLEX in combination with chemotherapy, axitinib, lenvatinib, or pemetrexed and platinum chemotherapy: Guillain-Barré syndrome, myasthenic syndrome/myasthenia gravis, myelitis, vasculitis, uveitis, pancreatitis, nephritis with renal dysfunction, myocarditis, myositis/polymyositis, rhabdomyolysis, and sarcoidosis. Guillain-Barré syndrome, myasthenic syndrome/myasthenia gravis, myelitis, vasculitis, uveitis, pancreatitis, nephritis with renal dysfunction, myocarditis, myositis/polymyositis, rhabdomyolysis, and sarcoidosis occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX monotherapy, including Grade 3 (0.1%) myocarditis. Myocarditis occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with axitinib, including Grade 3 (0.1%) myocarditis. Myocarditis occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with lenvatinib, including Grade 3 (0.1%) myocarditis. Myocarditis occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with pemetrexed and platinum chemotherapy, including Grade 3 (0.1%) myocarditis.

Immune-Mediated Encephalitis, Immune-Mediated Meningitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated meningitis, defined as immune-mediated adverse reactions presenting as meningitis, aseptic meningitis, or meningitis with cerebrospinal fluid pleocytosis. Fatal cases have occurred. Immune-mediated encephalitis, defined as immune-mediated adverse reactions presenting as encephalitis, encephalitis with cerebrospinal fluid pleocytosis, or encephalitis with cerebrospinal fluid pleocytosis and meningitis. Immune-mediated meningitis occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX monotherapy, including Grade 3 (0.1%) and Grade 5 (0.1%) meningitis. Immune-mediated meningitis occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with axitinib, including Grade 3 (0.1%) and Grade 5 (0.1%) meningitis. Immune-mediated meningitis occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with lenvatinib, including Grade 3 (0.1%) and Grade 5 (0.1%) meningitis. Immune-mediated meningitis occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with pemetrexed and platinum chemotherapy, including Grade 3 (0.1%) and Grade 5 (0.1%) meningitis.

Immune-Mediated Myocarditis, Immune-Mediated Myositis/Polymyositis, Immune-Mediated Rhabdomyolysis (or Myoglobinuria)

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated myocarditis, defined as immune-mediated adverse reactions presenting as myocarditis, myocarditis with cardiomyopathy, or myocarditis with cardiomyopathy and cardiac arrest. Fatal cases have occurred. Immune-mediated myositis/polymyositis, defined as immune-mediated adverse reactions presenting as myositis, polymyositis, or myositis with elevated creatine phosphokinase (CPK). Immune-mediated rhabdomyolysis (or myoglobinuria), defined as immune-mediated adverse reactions presenting as rhabdomyolysis (or myoglobinuria) with elevated CPK. Immune-mediated myocarditis occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX monotherapy, including Grade 3 (0.1%) and Grade 5 (0.1%) myocarditis. Immune-mediated myocarditis occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with axitinib, including Grade 3 (0.1%) and Grade 5 (0.1%) myocarditis. Immune-mediated myocarditis occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with lenvatinib, including Grade 3 (0.1%) and Grade 5 (0.1%) myocarditis. Immune-mediated myocarditis occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with pemetrexed and platinum chemotherapy, including Grade 3 (0.1%) and Grade 5 (0.1%) myocarditis.

Immune-Mediated Nephritis with Renal Dysfunction

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated nephritis with renal dysfunction, defined as immune-mediated adverse reactions presenting as nephritis, nephritis with renal dysfunction, renal failure, renal impairment, renal tubular disorder, or renal tubular necrosis. Systemic corticosteroids were used in 0.3% (3/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX monotherapy, including Grade 3 (0.1%) and Grade 5 (0.1%) nephritis. Of patients who were treated with systemic corticosteroids, 0.3% (3/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX monotherapy, including Grade 3 (0.1%) and Grade 5 (0.1%) nephritis.

Immune-Mediated Dermatologic Adverse Reactions

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated rash or immune-mediated dermatitis, including Stevens-Johnson syndrome, drug rash with eosinophilia and systemic symptoms, toxic epidermal necrosis, and SJS/TEN/DRESS syndrome. Topical emollients and/or topical corticosteroids have been used to maintain cutaneous integrity in patients who developed immune-mediated rash.

- Immune-mediated dermatitis, defined as immune-mediated adverse reactions presenting as dermatitis, exfoliative dermatitis, or ulcerative dermatitis, occurred in 0.4% (4/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX monotherapy, including Grade 3 (0.1%) and Grade 5 (0.1%) dermatitis. Of patients who were treated with systemic corticosteroids were used in 0.3% (3/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX monotherapy, including Grade 3 (0.1%) and Grade 5 (0.1%) dermatitis. Of patients who were treated with systemic corticosteroids, 0.3% (3/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX monotherapy, including Grade 3 (0.1%) and Grade 5 (0.1%) dermatitis.

Immune-Mediated Ocular Adverse Reactions

- Immune-mediated keratitis, defined as immune-mediated adverse reactions presenting as keratitis, ulcerative keratitis, or keratitis with corneal ulcer, occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX monotherapy, including Grade 3 (0.1%) and Grade 5 (0.1%) keratitis. Systemic corticosteroids were used in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX monotherapy, including Grade 3 (0.1%) and Grade 5 (0.1%) keratitis. Of patients who were treated with systemic corticosteroids, 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX monotherapy, including Grade 3 (0.1%) and Grade 5 (0.1%) keratitis. Immune-mediated uveitis, defined as immune-mediated adverse reactions presenting as uveitis, iridocyclitis, or choroiditis, occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX monotherapy, including Grade 3 (0.1%) and Grade 5 (0.1%) uveitis. Of patients who were treated with systemic corticosteroids, 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX monotherapy, including Grade 3 (0.1%) and Grade 5 (0.1%) uveitis. Immune-mediated ocular myasthenia occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX monotherapy, including Grade 3 (0.1%) and Grade 5 (0.1%) ocular myasthenia. Immune-mediated ocular myasthenia occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX monotherapy, including Grade 3 (0.1%) and Grade 5 (0.1%) ocular myasthenia.

Immune-Mediated Endocrinopathies, Immune-Mediated Adrenal Insufficiency, Immune-Mediated Hypophysitis, Immune-Mediated Diabetes Mellitus, Immune-Mediated Thyroid Disorders

- For the immune-mediated endocrinopathies, KEYTRUDA or KEYTRUDA QLEX may be withheld or stopped and hormonal replacement therapy or corticosteroids may be sufficient for patients who develop immune-mediated endocrinopathies. Based on the severity of the immune-mediated endocrinopathy, KEYTRUDA or KEYTRUDA QLEX may be withheld or stopped, and systemic corticosteroids should be administered. Upon improvement to a lower severity, initiate corticosteroid replacement therapy and resume KEYTRUDA or KEYTRUDA QLEX at a reduced dose. Permanently discontinue KEYTRUDA or KEYTRUDA QLEX for any immune-mediated endocrinopathy that recurs in severe form. In most cases, KEYTRUDA or KEYTRUDA QLEX should be withheld or permanently discontinued if a diagnosis of immune-mediated endocrinopathy is confirmed. Depending on severity of the immune-mediated endocrinopathy, KEYTRUDA or KEYTRUDA QLEX may be resumed after resolution of the adverse reaction. Refer to the Prescribing Information for KEYTRUDA or KEYTRUDA QLEX for additional information on immune-mediated endocrinopathies.

Immune-Mediated Adrenal Insufficiency

- Immune-mediated adrenal insufficiency, defined as immune-mediated adverse reactions presenting as adrenal insufficiency, adrenal crisis, or hypophysitis with secondary adrenal insufficiency, occurred in 0.2% (2/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX monotherapy, including Grade 3 (0.1%) and Grade 5 (0.1%) adrenal insufficiency. Immune-mediated adrenal insufficiency occurred in 0.2% (2/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with axitinib, including Grade 3 (0.1%) and Grade 5 (0.1%) adrenal insufficiency. Immune-mediated adrenal insufficiency occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with lenvatinib, including Grade 3 (0.1%) adrenal insufficiency. Immune-mediated adrenal insufficiency occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with pemetrexed and platinum chemotherapy, including Grade 5 (0.1%) adrenal insufficiency.

Hypophysitis and Secondary Adrenal Insufficiency, Other Endocrine Administration-Related Reactions

- Hypophysitis, defined as immune-mediated adverse reactions presenting as hypophysitis, hypophysitis with pituitary hormone deficiency, or hypopituitarism. Hypophysitis occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX monotherapy, including Grade 3 (0.1%) and Grade 5 (0.1%) hypophysitis. Hypophysitis occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with axitinib, including Grade 3 (0.1%) and Grade 5 (0.1%) hypophysitis. Hypophysitis occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with lenvatinib, including Grade 3 (0.1%) and Grade 5 (0.1%) hypophysitis. Hypophysitis occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with pemetrexed and platinum chemotherapy, including Grade 3 (0.1%) and Grade 5 (0.1%) hypophysitis.

Immune-Mediated Hypophysitis, Immune-Mediated Adrenal Insufficiency, Other Endocrine Administration-Related Reactions

- Immune-mediated hypophysitis, defined as immune-mediated adverse reactions presenting as hypophysitis, hypophysitis with pituitary hormone deficiency, or hypopituitarism. Hypophysitis occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX monotherapy, including Grade 3 (0.1%) and Grade 5 (0.1%) hypophysitis. Hypophysitis occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with axitinib, including Grade 3 (0.1%) and Grade 5 (0.1%) hypophysitis. Hypophysitis occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with lenvatinib, including Grade 3 (0.1%) and Grade 5 (0.1%) hypophysitis. Hypophysitis occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with pemetrexed and platinum chemotherapy, including Grade 3 (0.1%) and Grade 5 (0.1%) hypophysitis.

Immune-Mediated Adrenal Insufficiency, Other Endocrine Administration-Related Reactions

- Immune-mediated adrenal insufficiency, defined as immune-mediated adverse reactions presenting as adrenal insufficiency, adrenal crisis, or hypophysitis with secondary adrenal insufficiency, occurred in 0.2% (2/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX monotherapy, including Grade 3 (0.1%) and Grade 5 (0.1%) adrenal insufficiency. Immune-mediated adrenal insufficiency occurred in 0.2% (2/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with axitinib, including Grade 3 (0.1%) and Grade 5 (0.1%) adrenal insufficiency. Immune-mediated adrenal insufficiency occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with lenvatinib, including Grade 3 (0.1%) adrenal insufficiency. Immune-mediated adrenal insufficiency occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with pemetrexed and platinum chemotherapy, including Grade 5 (0.1%) adrenal insufficiency.

Immune-Mediated Hyperthyroidism and Hypothyroidism, Other Endocrine Administration-Related Reactions

- Immune-mediated hypothyroidism, defined as immune-mediated adverse reactions presenting as hypothyroidism, Graves' hypothyroidism, Graves' hypothyroidism with pituitary hormone deficiency, or hypopituitarism. Hypothyroidism occurred in 9.1% (91/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX monotherapy, including Grade 3 (0.1%) and Grade 5 (0.1%) hypothyroidism. Hypothyroidism occurred in 12.1% (121/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with axitinib, including Grade 3 (0.2%) and Grade 5 (0.1%) hypothyroidism. Hypothyroidism occurred in 12.1% (121/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with lenvatinib, including Grade 3 (0.2%) and Grade 5 (0.1%) hypothyroidism. Hypothyroidism occurred in 10.1% (101/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with pemetrexed and platinum chemotherapy, including Grade 3 (0.1%) and Grade 5 (0.1%) hypothyroidism.

- Hyperthyroidism occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX monotherapy, including Grade 3 (0.1%) and Grade 5 (0.1%) hyperthyroidism. Hyperthyroidism occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with axitinib, including Grade 3 (0.1%) and Grade 5 (0.1%) hyperthyroidism. Hyperthyroidism occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with lenvatinib, including Grade 3 (0.1%) and Grade 5 (0.1%) hyperthyroidism. Hyperthyroidism occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with pemetrexed and platinum chemotherapy, including Grade 3 (0.1%) and Grade 5 (0.1%) hyperthyroidism.

Immune-Mediated Hyperglycemia

- Immune-mediated hyperglycemia, defined as immune-mediated adverse reactions presenting as hyperglycemia, diabetes mellitus, or diabetes mellitus with ketoacidosis. Fatal cases have occurred. Immune-mediated hyperglycemia occurred in 0.2% (2/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX monotherapy, including Grade 3 (0.1%) and Grade 5 (0.1%) hyperglycemia. Immune-mediated hyperglycemia occurred in 0.2% (2/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with axitinib, including Grade 3 (0.1%) and Grade 5 (0.1%) hyperglycemia. Immune-mediated hyperglycemia occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with lenvatinib, including Grade 3 (0.1%) hyperglycemia. Immune-mediated hyperglycemia occurred in 0.1% (1/1,000) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with pemetrexed and platinum chemotherapy, including Grade 5 (0.1%) hyperglycemia.

**Immune-Mediated Hyperglycemia, Other Endocrine Administration-Related Reactions

Desktop View

NOW APPROVED

KEYTRUDA Qlex®
pembrolizumab + berahyaluronidase alfa-pmph
Intravenous Injection | 50 mg – 200 mg/4 mL

KEYTRUDA QLEX is approved for use in adult patients across all 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
EVERY 3 WEEKS	EVERY 6 WEEKS
395 mg pembrolizumab and 4,800 units berahyaluronidase alfa	790 mg pembrolizumab and 8,000 units berahyaluronidase alfa
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 administration sites.

1 / 2

Give your patients a choice of where you administer their treatment

Two injection-site options: abdomen or upper thigh

KEYTRUDA QLEX can only be administered by a health care professional.

Tap arrows to see dosing options.

2 / 2

For the adjuvant treatment of RCC:

Treatment with KEYTRUDA QLEX should continue until disease recurrence, unacceptable toxicity, or up to 12 months

Patients receiving KEYTRUDA can switch to KEYTRUDA QLEX at their next scheduled dose.*

Patients receiving KEYTRUDA QLEX can switch to KEYTRUDA at their next scheduled dose.*

**KEYTRUDA QLEX is administered under the skin as a subcutaneous injection. Do not administer intravenously.*

For certain patients, treatment with KEYTRUDA QLEX offers more 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. In general, if KEYTRUDA or KEYTRUDA QLEX is withheld or KEYTRUDA or KEYTRUDA QLEX require interruption or discontinuation, administer systemic corticosteroid therapy (1 to 2 mg/kg/day prednisone or equivalent) until improvement to Grade 1 or less. Upon improvement to Grade 1 or less, initiate corticosteroid taper and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants in patients whose adverse reactions are not controlled with corticosteroid therapy.

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% (962/799) of patients receiving KEYTRUDA, including fatal (0.1%), Grade 4 (0.3%), Grade 3 (0.9%), and Grade 2 (1.2%) reactions. Systemic corticosteroids were required in 67% (639/94) of patients. Pneumonitis led to permanent discontinuation of KEYTRUDA in 1.3% (36) and withholding in 0.9% (26) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement; of these, 23% had recurrence. Pneumonitis resolved in 59% of the 94 patients. Immune-mediated pneumonitis occurred in 5% (13/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including fatal (0.4%), Grade 3 (2%), and Grade 2 (1.2%) adverse reactions.

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% (46/2799) of patients receiving KEYTRUDA, including Grade 4 (<0.1%), Grade 3 (1.1%), and Grade 2 (0.4%) reactions. Systemic corticosteroids were required in 69% (33/48); additional immunosuppressant therapy was required in 4.2% of patients. Colitis led to permanent discontinuation of KEYTRUDA in 0.5% (15) and withholding in 0.5% (13) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement; of these, 23% had recurrence. Colitis resolved in 85% of the 48 patients. Immune-mediated colitis occurred in 1.2% (3/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 3 (0.8%) and Grade 2 (0.4%) adverse reactions.

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 47% of the 19 patients. Immune-mediated hepatitis occurred in 0.4% (1/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 2 (0.4%) adverse reactions.

Immune-Mediated Endocrinopathies

Adrenal Insufficiency

- KEYTRUDA and KEYTRUDA QLEX can cause primary or secondary adrenal insufficiency. For Grade 2 or higher, initiate symptomatic treatment, including hormone replacement as clinically indicated. Withhold KEYTRUDA and KEYTRUDA QLEX depending on severity. Adrenal insufficiency occurred in 0.8% (22/2799) of patients receiving KEYTRUDA, including Grade 4 (<0.1%), Grade 3 (0.3%), and Grade 2 (0.3%) reactions. Systemic corticosteroids were required in 77% (17/22) of patients; of these, the majority remained on systemic corticosteroids. Adrenal insufficiency led to permanent discontinuation of KEYTRUDA in 0.1% (2) 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 defects, hypopituitarism, or pituitary hormone hypersecretion. 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 (0.3%) 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. The majority of patients with hypothyroidism required long-term thyroid hormone replacement.
- Hypophysitis occurred in 0.4% (1/251) 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 2 (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 in 0.2% (5) 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 0.6% (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, KEYTRUDA QLEX, or KEYTRUDA in combination with chemotherapy in KEYNOTE-189 unless otherwise noted. Severe or fatal cases have been reported for some of these adverse reactions. *Cardiac/ Vascular:* Myocarditis, pericarditis, vasculitis; *Nervous System:* Meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia gravis (including exacerbation), Guillain-Barré syndrome, nerve paresis, autoimmune neuropathy; *Ocular:* Uveitis, iritis and other ocular inflammatory toxicities can occur. Some cases can be associated with retinal detachment. Various grades of visual impairment, including blindness, can occur. If uveitis occurs in combination with other immune-mediated adverse reactions, consider a Vogt-Koyanagi-Harada-like syndrome, as this may require treatment with systemic steroids to reduce the risk of permanent vision loss. *Gastrointestinal:* Pancreatitis, to include increases in serum amylase and lipase levels, gastritis, duodenitis, and sclerosing cholangitis, gastrointestinal perforation, pancreatic polyneuropathy, rhabdomyolysis (and associated sequelae, including renal failure), arthritis (1.5%), polymyalgia rheumatica; *Endocrine:* Hypoparathyroidism; *Hematological/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-related reactions including rigors, chills, wheezing, pruritus, flushing, rash, hypotension, hypoxemia and fever. Infusion-related reactions have been reported in 0.2% of 2799 patients receiving KEYTRUDA. Interrupt or slow the rate of infusion for Grade 1 or Grade 2 reactions. For Grade 3 or Grade 4 reactions, stop infusion and permanently discontinue KEYTRUDA. Hypersensitivity and administration-related systemic reactions occurred in 3.2% (8/251) of patients receiving KEYTRUDA QLEX in combination with platinum doublet chemotherapy, including Grade 2 (2.8%). Stop injection (if not already fully administered) and continue 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 undergo HSCT after anti-PD-1/PD-L1 treatments for immune-mediated adverse reactions. 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-3475-017, 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 (2.8%), febrile neutropenia (1.2%), respiratory failure (1.2%), neutropenic sepsis (0.4%), septic shock (0.4%), pentitis (0.4%), pneumonitis (0.4%), pneumothorax (0.4%), pulmonary embolism (0.4%), neutropenic colitis (0.4%), and seizure (0.4%). KEYTRUDA QLEX was permanently discontinued due to adverse reactions in 21% of patients, adverse reactions leading to permanent discontinuation of KEYTRUDA QLEX in 12% of patients included pneumonia (3.2%) and pneumonitis (2.4%). 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 27% 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 1 case of pneumonia. Discontinuation of KEYTRUDA due to adverse reactions occurred in 21% of 489 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 Guide for KEYTRUDA and KEYTRUDA QLEX also is available.

For prescribers: please click here for state-required price disclosures.

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KEYTRUDA QLEX®
pembrolizumab + berahyaluronidase alfa-pmph
Intravenous bolus | 10 mL | 200 mg/mL

KEYTRUDA QLEX is approved for use in adult patients across all 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/PDL1 pathway, thereby removing inhibition of the immune response, potentially breaking peripheral tolerance in humans. 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.
- Monitor patients closely for symptoms and signs that may be clinical manifestations of underlying immune-mediated adverse reactions. Early identification and management are essential to ensure safe use of anti-PD-1/PD-L1 treatments. Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. In cases of suspected immune-mediated adverse reactions, initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate.
- Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity of the immune-mediated adverse reaction. In general, if KEYTRUDA and KEYTRUDA QLEX require interruption or discontinuation, administer systemic corticosteroid therapy (1 to 2 mg/kg/day prednisone or equivalent) until improvement to Grade 1 or less. Upon improvement to Grade 1 or less, initiate corticosteroid taper and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants in patients whose adverse reactions are not controlled with corticosteroid therapy.

Collapse

Selected Safety Information continues below.

KEYTRUDA QLEX can be administered in as little as 1 minute

Q3W	Q6W
395 mg pembrolizumab and 4,800 units berahyaluronidase alfa	790 mg pembrolizumab and 9,600 units berahyaluronidase alfa
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 administration sites.

1 / 2

For the adjuvant treatment of RCC:

Treatment with KEYTRUDA QLEX should continue until disease recurrence, unacceptable toxicity, or up to 12 months.

Patients receiving **KEYTRUDA** can switch to **KEYTRUDA QLEX at their next scheduled dose.***

Patients receiving **KEYTRUDA QLEX** can switch to **KEYTRUDA at their next scheduled dose.***

**KEYTRUDA QLEX is administered under the skin as a subcutaneous injection. Do not administer intravenously.*

For certain patients, treatment with KEYTRUDA QLEX offers more 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 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 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% (362/799) of patients receiving KEYTRUDA, including Grade 4 (<0.1%), Grade 3 (0.7%), Grade 2 (1.6%) adverse reactions. Systemic corticosteroids were required in 67% (63/94) of patients. Pneumonitis led to permanent discontinuation of KEYTRUDA in 1.3% (8) and withholding in 0.9% (8) 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 3% (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 68% (33/48); additional immunosuppressant therapy was required in 4.2% of patients. Colitis led to permanent discontinuation of KEYTRUDA in 0.6% (3) and withholding in 0.8% (6) 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% (192/799) 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% (3) and withholding in 0.3% (5) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement; of these, none had recurrence. Hepatitis resolved in 47% of the 19 patients. Immune-mediated hepatitis occurred in 0.4% (1/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 2 (0.4%) adverse reactions.

Immune-Mediated Endocrinopathies

Adrenal Insufficiency

- KEYTRUDA and KEYTRUDA QLEX can cause primary or secondary adrenal insufficiency. For Grade 2 or higher, initiate symptomatic treatment, including hormone replacement as clinically indicated. Withhold KEYTRUDA and KEYTRUDA QLEX depending on severity. Adrenal insufficiency occurred in 0.8% (6/799) 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 defects. Hypophysitis can cause hypopituitarism. Initiate hormone replacement as indicated. Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity.
- Hypophysitis occurred in 0.4% (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 82% (14/17) of patients; additional hormone replacement was required in 71% of patients. Hypophysitis led to permanent discontinuation of KEYTRUDA in 0.1% (4) and withholding in 0.3% (7) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement.

Thyroid Disorders

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated thyroid disorders. Thyroiditis can present with or without endocrinopathy. Hypothyroidism can follow hyperthyroidism. Initiate hormone replacement for hypothyroidism or institute medical management of hyperthyroidism as clinically indicated. Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity.
- Thyroiditis occurred in 0.6% (16/799) 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% (962/799) 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% (237/2789) 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 0.3% (14) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. A 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 2 (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% (12/251) 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% (9/2789) of patients receiving KEYTRUDA, including Grade 4 (<0.1%), Grade 3 (0.1%), and Grade 2 (0.1%) reactions. Systemic corticosteroids were required in 89% (8/9) of patients. Nephritis led to permanent discontinuation of KEYTRUDA in 0.1% (3) and withholding in 0.1% (3) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement; of these, none had recurrence. Nephritis resolved in 56% of the 9 patients.

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% (38/2789) of patients receiving KEYTRUDA, including Grade 3 (1%) and Grade 2 (0.1%) reactions. Systemic corticosteroids were required in 45% (15/38) of patients. Dermatitis led to permanent discontinuation of KEYTRUDA in <0.1% (1) and withholding in <0.1% (1) 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, 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, autonomic neuropathy; Ocular: Uveitis, iritis and other ocular inflammatory toxicities can occur. Some cases can be associated with retinal detachment. Various grades of visual impairment, including blindness, can occur. If uveitis occurs in combination with other immune-mediated adverse reactions, consider a Vogt-Koyanagi-Harada-like syndrome, as this may require treatment with systemic steroids to reduce the risk of permanent vision loss. Gastrointestinal: Pancreatitis, to include increases in serum amylase and lipase levels, gastritis, duodenitis; General: Hypophysitis, uveitis, pericarditis, vasculitis, pancreatitis, hypothyroidism (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-related reactions including rigors, chills, wheezing, pruritus, flushing, rash, hypotension, hypoxemia and fever. Infusion-related reactions have been reported in 0.2% of 2789 patients receiving KEYTRUDA. For Grade 3 or Grade 4 reactions, stop infusion and permanently discontinue KEYTRUDA. 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%). Stop injection (if not already fully administered) and continue 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 therapies between PD-1/PD-L1 blockade 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 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-3475-177, when KEYTRUDA QLEX was administered with chemotherapy in neoadjuvant and adjuvant treatment of locally advanced head and neck cancer, 93% of patients. Serious adverse reactions in 31% of patients who received KEYTRUDA QLEX were pneumonia (15%), 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 (2.8%), febrile neutropenia (1.2%), respiratory failure (1.2%), neutropenic sepsis (0.4%), septic shock (0.4%), parotitis (0.4%), cardiac failure (0.4%), cerebral hemorrhage (0.4%), cerebrovascular accident (0.4%), enterocolitis (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 (3.2%) and pneumonitis (2.4%). 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 1 case of pneumonitis. Discontinuation of KEYTRUDA due to adverse reactions occurred in 14% of patients; adverse reactions (≥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 Guide for KEYTRUDA and KEYTRUDA QLEX also is available.

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KEYTRUDA QLEX® (pembrolizumab and hyaluronidase-pmph)
Subcutaneous injection | 50 mg – 1,500 units/mL

KEYTRUDA QLEX is approved for use in adult patients across all 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 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 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. Early diagnosis of suspected immune-mediated adverse reactions, initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate.
- Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity of the immune-mediated adverse reaction. In general, if KEYTRUDA and KEYTRUDA QLEX require interruption or discontinuation, administer systemic corticosteroid therapy (1 to 2 mg/kg/day prednisone or equivalent) until improvement to Grade 1 or less. Upon improvement to Grade 1 or less, initiate corticosteroid tapering 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

QSW	QBW
398 mg pembrolizumab and 4,800 units berahyaluronidase alfa	796 mg pembrolizumab and 9,600 units berahyaluronidase alfa
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 with non-small cell lung cancer (NSCLC). Immune-mediated pneumonitis occurred in 3.4% (94/2766) of patients receiving KEYTRUDA, including fatal (0.1%). Grade 4 (0.3%), Grade 3 (0.9%), and Grade 2 (1.3%) reactions. Systemic corticosteroids were required in 67% (63/94) of patients. Pneumonitis led to permanent discontinuation of KEYTRUDA in 1.2% (36) and withholding in 0.9% (25) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement, of these, 20% had recurrences. Pneumonitis resolved in 95% of the patients. Immune-mediated pneumonitis occurred in 1% (13/201) 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 injection-site options: abdomen or upper thigh

KEYTRUDA QLEX can only be administered by a health care professional.

For the adjuvant treatment of RCC:

Treatment with KEYTRUDA QLEX should continue until disease recurrence, unacceptable toxicity, or up to 12 months.

Patients receiving KEYTRUDA can switch to KEYTRUDA QLEX at their next scheduled dose.*

Patients receiving KEYTRUDA QLEX can switch to KEYTRUDA at their next scheduled dose.*

**KEYTRUDA QLEX is administered under the skin as a subcutaneous injection. Do not administer intravenously.*

For certain patients, treatment with KEYTRUDA QLEX offers more 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 1.6% (46/2766) of patients receiving KEYTRUDA, including Grade 4 (0.1%), Grade 3 (1.1%), and Grade 2 (0.4%) reactions. Systemic corticosteroids were required in 67% (31/46) of patients. Immunosuppressive 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 resulted in 85% of the 46 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% (19/2766) of patients receiving KEYTRUDA, including Grade 4 (<0.1%), Grade 3 (0.4%), and Grade 2 (0.1%) reactions. Systemic corticosteroids were required in 68% (13/19) of patients; additional immunosuppressant therapy was required in 11% of patients. Hepatitis led to permanent discontinuation of KEYTRUDA in 0.2% (6) and withholding in 0.3% (9) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. Immune-mediated hepatitis resulted 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.

KEYTRUDA or KEYTRUDA QLEX With Axitinib

- KEYTRUDA and KEYTRUDA QLEX, when either is used in combination with axitinib, can cause hepatic toxicity. Monitor liver enzymes before initiation of and periodically throughout treatment. Consider monitoring more frequently as compared to when the drugs are administered as single agents. For elevated liver enzymes, interrupt axitinib, then after return to baseline KEYTRUDA QLEX and axitinib, and consider administering corticosteroids as needed.
- With the combination of KEYTRUDA and axitinib, Grades 3 and 4 increased alanine aminotransferase (ALT) (20%) and increased aspartate aminotransferase (AST) (13%) were seen at a higher frequency compared to KEYTRUDA alone. Fifty-nine percent of the patients with increased ALT received systemic corticosteroids. In patients with ALT 3 times upper limit of normal (ULN) (Grades 2-4, n=116), ALT resolved to Grades 0-1 in 79% (n=92) of patients after interruption of KEYTRUDA and axitinib. ALT 3 times ULN with axitinib (n=34) administered as a single agent or with both (n=65), recurrence of ALT 3 times ULN was observed in 1 patient receiving KEYTRUDA, 16 patients receiving axitinib, and 24 patients receiving both. All patients with a recurrence of ALT 3 times ULN subsequently recovered from the event.

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% (22/2766) of patients receiving KEYTRUDA, including Grade 3 (0.3%) and Grade 2 (0.4%) reactions. Systemic corticosteroids were required in 77% (17/22) of patients; of these, the majority remained on systemic corticosteroids. Adrenal insufficiency led to permanent discontinuation of KEYTRUDA in <0.1% (1) and withholding in 0.3% (8) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. Adrenal insufficiency occurred in 2% (5/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 3 (0.4%) and Grade 2 (0.8%) adverse reactions.

Hypophysitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated hypophysitis. Hypophysitis can present with acute symptoms associated with mass effect such as headache, photophobia, or visual field defects. Hypophysitis can cause hypopituitarism. Initiate hormone replacement as indicated. Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity.
- Hypophysitis occurred in 0.6% (17/2766) 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 0.6% (16/2766) 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% (96/2766) 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% (1) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. Hyperthyroidism resulted in 2% (2/129) of patients receiving KEYTRUDA, including Grade 3 (0.1%) and Grade 2 (0.2%). It led to permanent discontinuation of KEYTRUDA in <0.1% (1) and withholding in 0.3% (1) 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% (10/251) 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 3 (1%).

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% (6/2766) of patients receiving KEYTRUDA. It led to permanent discontinuation in <0.1% (1) and withholding of KEYTRUDA in 0.1% (2) 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% (9/2766) 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. 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% (38/2766) 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, 5% had recurrences. The reactions resulted 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, Guillain-Barré syndrome, myasthenic syndrome (or exacerbation), Guillain-Barré syndrome, nerve paresis, autoimmune neuropathy, Ocular: Uveitis, iritis and other ocular inflammatory toxicities can occur. Some cases can be associated with retinal detachment. Various grades of visual impairment, including blindness, can occur. If uveitis occurs in combination with other immune-mediated adverse reactions, consider a Vogt-Koyanagi-Harada like syndrome, as this may require treatment with systemic steroids to reduce the risk of permanent vision loss; Gastrointestinal: Pancreatitis, to include increases in serum amylase and lipase levels, gastritis (2.8%), duodenitis; Musculoskeletal and Connective Tissue: Myositis/ polymyositis, rhabdomyolysis (and associated sequelae, including renal failure), arthritis (1.1%), polymyalgia rheumatica; Endocrine: Hypoparathyroidism; Hematological/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 transplants (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-related reactions including chills, rash, flushing, and dyspnea. Stop KEYTRUDA or KEYTRUDA QLEX for infusion-related reactions have been reported in 0.2% of 2769 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 2.2% (55/51) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 3 (2.8%). Stop injection (if not already fully administered) and continue 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 undergo allogeneic HSCT for early and late toxicities to assess for treatment 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 38% of patients. Serious adverse reactions in ≥1% of patients who received KEYTRUDA QLEX in combination with chemotherapy were febrile neutropenia (2.8%), 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 (2.8%), febrile neutropenia (1.2%), respiratory failure (1.2%), neutropenic sepsis (0.4%), septic shock (0.4%), pancitrin (0.4%), cardiac arrest (0.4%), cardiopulmonary arrest (0.4%), cardiorespiratory arrest (0.4%), enterocolitis (0.4%), and secure (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 (3.2%) and pneumonitis (2.4%). The most common adverse reactions (≥20%) were nausea (29%), fatigue (27%), and hypothyroidism (21%).
- In KEYNOTE-564, when KEYTRUDA was administered as a single agent for the adjuvant treatment of patients with renal cell carcinoma at intermediate-high or high risk of recurrence, of the 392 patients receiving KEYTRUDA, the serious adverse reactions (31%) were acute kidney injury, adrenal insufficiency, pneumonia, colitis, and diabetic ketoacidosis (1% each). Fatal adverse reactions occurred in 0.2% including 1 case of pneumonia. Discontinuation of KEYTRUDA due to adverse reactions occurred in 21% of 488 patients; the most common adverse reactions were diarrhea (11.6%), colitis (1%), and adrenal insufficiency (1%). The most common adverse reactions (≥20%) were musculoskeletal pain (41%), fatigue (40%), rash (30%), diarrhea (27%), pruritus (22%), 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 Guide for KEYTRUDA and KEYTRUDA QLEX also is available.

keytrudaqlex.com

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