This resource will be deployed with multiple subject lines and preheaders

Subject Line: Learn about a new treatment with flexible administration options
Preheader: See administration details below.

Subject Line: What do you know about this new treatment with flexible administration options?
Preheader: See interactive content below.

Subject Line: Did you know about this new product with a flexible administration option?
Preheader: Scroll below to learn more.

Subject Line: NOW APPROVED: Find out more about this new treatment option
Preheader: See administration information for this new treatment option.

Note Text

From: MerckConnect <MerckConnect@merck.com>
To: MerckHCP <MerckHCP@merck.com>
Subject: Learn about a new treatment with flexible administration options

NOW APPROVED

KEYTRUDA QLEX®
pembrolizumab + vibo[illegible]ase dil[illegible]

KEYTRUDA QLEX is approved for use in adult patients across most tumor types, including NSCLC, HNSCC, cervical, gastrointestinal, urothelial, and others, as a monotherapy or in combination with other therapies

One such indication is as the adjuvant treatment of adult patients with stage IIB and stage IIC melanoma who have undergone complete resection of lymph node involvement or metastatic lesions, and resection of metastatic lesions.

Selected Safety Information

Contraindications

- KEYTRUDA QLEX is contraindicated in patients with known hypersensitivity to pembrolizumab, 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 immunotherapy drugs. By programmed death receptor-1 (PD-1) blockade, they can cause T-cell (PD-1), blocking the PD-1 ligand, and PD-L2 ligand, covalently bound to antibodies, enhance immune 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. Immune-mediated adverse reactions can occur at any time after starting treatment or after discontinuation of treatment. Important immune-mediated adverse reactions listed here are not all-inclusive of possible severe and fatal immune-mediated adverse reactions.

Expand to See Selected Safety Information

Selected Safety Information continued below

KEYTRUDA QLEX can be administered in as little as 1 minute

SCM	IV
Single administration	**Single administration**
Subcutaneous injection in abdomen or thigh	Intravenous infusion over 30 minutes
"Fixed" administration	**"Fixed" administration**
2.4 mL injection volume	4.8 mL injection volume

Dose not around for all dosages of KEYTRUDA and KEYTRUDA QLEX

KEYTRUDA QLEX may be administered by trained healthcare providers

1 / 3

Tap arrows to see more.

For the adjuvant treatment of patients with melanoma, KEYTRUDA QLEX should continue until disease recurrence, unacceptable toxicity, or up to 12 months.

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

For certain patients, treatment with KEYTRUDA QLEX offers flexibility of the site of care 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

- Severe patients should for symptoms and signs that may be consistent with an immune-mediated adverse reaction. Early identification and prompt treatment of suspected cases are crucial for adequate monitoring and evaluation of suspected immune-mediated adverse reactions. Withholding or permanently discontinue administration of KEYTRUDA QLEX or KEYTRUDA depending on severity. Administer corticosteroids and, if clinically indicated, other immunosuppressants in patients without contraindications to corticosteroids.

Immune-Mediated Pneumonitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated pneumonitis. The incidence is higher in patients with extensive thoracic radiation. Immune-mediated pneumonitis occurred in 3.6% (206/5748) of patients receiving KEYTRUDA, including Grade 5 (0.1%), Grade 4 (<0.1%), Grade 3 (1.1%), and Grade 2 (2.1%). Of patients with thoracic radiation, Grade 3 or higher pneumonitis occurred in 5.6% (14/250). Pneumonitis led to permanent discontinuation of KEYTRUDA in 1.6% (94), withheld in 0.9% (51) of patients receiving KEYTRUDA, and was resolved in 62% (32/52) of patients with resolution information available. Of patients who resolved, 19% (6/32) had recurrent pneumonitis. Pneumonitis resolved in 90% (26/29) of patients with complete or partial corticosteroid administration, including 69% (20/29) with corticosteroid administration for at least 1 month.

Immune-Mediated Colitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated colitis, which may be severe or fatal. Colitis occurred in 2.4% (138/5748) of patients receiving KEYTRUDA, including Grade 5 (<0.1%), Grade 4 (<1%), and Grade 3 (1.4%). Of patients with thoracic radiation, Grade 3 or higher colitis occurred in 2.8% (7/249), additional patients had Grade 2 immune-mediated colitis. Colitis led to permanent discontinuation of KEYTRUDA in 0.9% (51) and withholding in 0.3% (15) of patients receiving KEYTRUDA, and resolved 60/77 (78%) patients with available information. Of these, 37% (22/60) had recurrent colitis. Colitis resolved in 75% (21/28) of patients with complete or partial corticosteroid administration, including 54% (15/28) with corticosteroid administration for at least 1 month.

Immune-Mediated Hepatitis and Immune-Mediated Hepatitis with Cholestasis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated hepatitis with cholestasis, which may be severe or fatal. Hepatitis occurred in 0.7% (40/5748) of patients receiving KEYTRUDA, including Grade 5 (0.2%), and Grade 3 (0.7%). Hepatitis led to permanent discontinuation of KEYTRUDA in 0.3% (17) of patients, withheld in 0.3% (17) of patients, and resolved in 71% of patients. Hepatitis with cholestasis occurred in 0.2% (12/5748) of patients receiving KEYTRUDA, including Grade 3 (0.2%) adverse reactions. Hepatitis with cholestasis led to permanent discontinuation of KEYTRUDA in 0.1% (4) and withheld in 0.1% (4) of patients receiving KEYTRUDA, and resolved in 75% (9/12) of patients. Systemic corticosteroids were required in 71% (8/11) of patients with evaluable resolution information. Hepatitis with cholestasis led to permanent discontinuation of KEYTRUDA in 1% (3) of patients with PSC, withheld in 1% (2) of patients with pre-existing liver cirrhosis, and resolved in 1 patient.

Immune-Mediated Nephritis with Renal Dysfunction

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated nephritis with renal dysfunction, which may be severe or fatal. Nephritis with renal dysfunction occurred in 0.9% (49/5748) of patients receiving KEYTRUDA, including Grade 5 (<0.1%), Grade 4 (<0.1%), and Grade 3 (0.3%). Nephritis led to permanent discontinuation of KEYTRUDA in 0.3% (16) of patients, withheld in 0.2% (12) of patients, and resolved in 39% (7/18) of patients with available information. Of patients who resolved, 43% (3/7) had recurrent nephritis. Nephritis with renal dysfunction resolved in 50% (3/6) of patients with complete or partial corticosteroid administration, including 33% (2/6) with corticosteroid administration for at least 1 month.

Immune-Mediated Endocrinopathies

Adrenal Insufficiency

- KEYTRUDA and KEYTRUDA QLEX can cause adrenal insufficiency, which may be severe or fatal. Adrenal insufficiency occurred in 0.8% (45/5748) of patients receiving KEYTRUDA, including Grade 4 (<0.1%), Grade 3 (0.4%), and Grade 2 (0.3%). Adrenal insufficiency led to permanent discontinuation of KEYTRUDA in 0.2% (12) of patients, withheld in 0.2% (12) of patients receiving KEYTRUDA, and resolved in 43% (13/30) of patients with available information. Of patients who resolved, 23% (3/13) had recurrent adrenal insufficiency. Adrenal insufficiency resolved in 3% (1/29) of patients with complete or partial corticosteroid administration, including 0% (0/29) with corticosteroid administration for at least 1 month.

Hypophysitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated hypophysitis, which may be severe or fatal. Hypophysitis occurred in 0.4% (21/5748) of patients receiving KEYTRUDA, including Grade 4 (<0.1%), Grade 3 (0.2%), and Grade 2 (0.1%). Hypophysitis led to permanent discontinuation of KEYTRUDA in 0.1% (4) of patients, withheld in 0.1% (4) of patients receiving KEYTRUDA, and resolved in 67% (8/12) of patients with available information. Of patients who resolved, 25% (2/8) had recurrent hypophysitis. Hypophysitis resolved in 50% (1/2) of patients with complete or partial corticosteroid administration, including 50% (1/2) with corticosteroid administration for at least 1 month.

Thyroid Disorders

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated thyroid disorders. Thyroiditis can be preceded by hypothyroidism or hyperthyroidism and follow a biphasic course. Hypothyroidism can follow resolution of thyroiditis or hypothyroidism or hypothyroidism in patients without thyroiditis. Thyroiditis occurred in 0.2% (12/5748) of patients receiving KEYTRUDA, including Grade 2 (0.1%) and Grade 1 (0.1%). Thyroiditis led to permanent discontinuation of KEYTRUDA in 0.1% (3) of patients, withheld in 0.1% (3) of patients receiving KEYTRUDA, and resolved in 50% (6/12) of patients with available information. Hypothyroidism can follow resolution of thyroiditis or hypothyroidism or hypothyroidism in patients without thyroiditis. Hypothyroidism occurred in 10% (573/5748) of patients receiving KEYTRUDA, including Grade 3 (0.1%) and Grade 2 (9.4%). Hypothyroidism led to permanent discontinuation of KEYTRUDA in 0.1% (3) of patients, withheld in 0.3% (16) of patients receiving KEYTRUDA, and resolved in 21% (120/573) of patients with available information. Of patients who resolved, 6% (7/120) had recurrent hypothyroidism. Hypothyroidism resolved in 3% (1/29) of patients with complete or partial corticosteroid administration, including 0% (0/29) with corticosteroid administration for at least 1 month. Hypothyroidism can be managed with hormone replacement. Hyperthyroidism can follow resolution of thyroiditis or hyperthyroidism or hyperthyroidism in patients without thyroiditis. Hyperthyroidism occurred in 2% (117/5748) of patients receiving KEYTRUDA, including Grade 3 (0.1%) and Grade 2 (1.9%). Hyperthyroidism led to permanent discontinuation of KEYTRUDA in <0.1% (2) of patients, withheld in 0.3% (17) of patients receiving KEYTRUDA, and resolved in 71% (83/117) of patients with available information. Of patients who resolved, 9% (7/83) had recurrent hyperthyroidism. Type 1 DM can be a consequence of thyroiditis leading KEYTRUDA QLEX or KEYTRUDA to be discontinued.

Immune-Mediated Diarrhea With Or Without Colitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated diarrhea. Immune-mediated diarrhea occurred in 0.7% (39/5748) of patients receiving KEYTRUDA, including Grade 4 (<0.1%), Grade 3 (0.2%), and Grade 2 (0.3%). Immune-mediated diarrhea led to permanent discontinuation of KEYTRUDA in 0.1% (4) of patients, withheld in 0.1% (4) of patients receiving KEYTRUDA, and resolved in 87% (34/39) of patients with available information. Of patients who resolved, 6% (2/34) had recurrent diarrhea. Immune-mediated diarrhea resolved in 100% (1/1) of patients with complete or partial corticosteroid administration, including 100% (1/1) with corticosteroid administration for at least 1 month.

Immune-Mediated Dermatologic Adverse Reactions

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated rash or dermatitis. Exfoliative dermatitis, including Stevens-Johnson syndrome, has occurred with pembrolizumab and systemic kaposiform lymphangiomatosis (KLA) has occurred with anti-PD-1/PD-L1 monoclonal antibodies. Withholding or permanently discontinuing KEYTRUDA or KEYTRUDA QLEX depending on severity.

- Immune-mediated dermatologic adverse reactions listed here are not all-inclusive of possible severe dermatologic adverse reactions. Systemic corticosteroids were required in 0.7% (40/5748) of patients receiving KEYTRUDA, including Grade 5 (<0.1%), Grade 4 (<0.1%), and Grade 3 (0.3%). Rash or dermatitis led to permanent discontinuation of KEYTRUDA in 0.3% (16) of patients, withheld in 0.4% (21) of patients receiving KEYTRUDA, and resolved in 73% (29/40) of patients with available information. Of patients who resolved, 14% (4/29) had recurrent rash or dermatitis. Rash or dermatitis resolved in 75% (21/28) of patients with complete or partial corticosteroid administration, including 61% (17/28) with corticosteroid administration for at least 1 month.

- The following clinically significant immune-mediated adverse reactions have been reported in patients who received KEYTRUDA or patients who received KEYTRUDA QLEX in the KEYTRUDA QLEX clinical trial: Myocarditis, Myositis/polymyositis, Rhabdomyolysis (and associated sequelae, including renal failure), Hypophysitis, Uveitis/iritis and pathologic inflammation of the eye, including vitreoretinal lymphoid tissue, Hemolytic anemia, Hemolytic uremic syndrome (thrombotic thrombocytopenic purpura), Myasthenia gravis (including exacerbation), Guillain-Barré syndrome, Leukoencephalopathy, Myelitis and demyelination, Pancreatitis, including Type 1 diabetes mellitus, Hypophysitis, Hypothyroidism, Hyperthyroidism, Thyroiditis, Adrenal insufficiency, Type 1 diabetes mellitus, Gastritis, Duodenitis, Sialadenitis, Cholangitis, Cholecystitis, Sphincter of Oddi syndrome, Pancreatitis, Gastritis, Hepatitis, including autoimmune hepatitis, Nephritis, Renal dysfunction, Myocarditis, Pericarditis, Vasculitis, Pericardial disease, Gastrointestinal Pneumatosis, Vitiligo, Alopecia, Hypopigmentation, Pemphigoid, Erythema multiforme, Psoriasis, Dermatitis herpetiformis, Exfoliative dermatitis, Stevens-Johnson syndrome, Drug rash with eosinophilia and systemic symptoms, Lichenoid keratosis, Lichen planus, Hypophysitis, Uveitis, Arthritis, Polymyalgia rheumatica, Sjögren's syndrome, Hemolytic anemia, Aplastic anemia, Hemoglobinuria, Systemic inflammatory response syndrome, Histiocytic necrotizing lymphadenitis, Sarcoidosis, Immune thrombocytopenia, Purpura, Autoimmune myocarditis, Myocarditis, Myositis, Myasthenia gravis, Vasculitis, Autoimmune hepatitis, Colitis, Adrenal insufficiency, Hypophysitis, Nephritis, Renal failure

Refer Now - Expanded

From: Merck Connect <MerckConnect@merck.com>
To: Mon 07/29 <Mon@fake.com>
Subject: Learn about a new treatment with Keytruda combination options

NOW APPROVED

KEYTRUDA QLEX™
pembrolizumab and hyaluronidase-ziahyal
50 mg/5 mL 1,000 mg/15 mL

KEYTRUDA QLEX is approved for adult patients with locally advanced or metastatic solid tumors for whom a PD-1/PD-L1 inhibitor injection 100 mg/ml is either alone or in combination with other therapies

One such indication is the adjuvant treatment of adult patients with locally advanced or metastatic solid tumors for whom a PD-1/PD-L1 inhibitor injection 100 mg/ml is either monotherapy or following neoadjuvant and resection of resectable tumors.

Indications

Selected Safety Information

Contraindications

KEYTRUDA QLEX is contraindicated in patients with known severe hypersensitivity to pembrolizumab, hyaluronidase or any excipient in KEYTRUDA QLEX.

Severe and Fatal Immune-Mediated Adverse Reactions

Immune-mediated adverse reactions which may be severe or life-threatening can occur in patients treated with KEYTRUDA QLEX. These reactions are primarily a result of enhanced immune-mediated activity against normal tissues, but other mechanisms may also be involved. Immune-mediated adverse reactions may be severe or life-threatening and can occur after any organ system or tissue can affected by immune-mediated adverse reactions, simultaneously, and can occur at any time after initiation of treatment. Immune-mediated adverse reactions listed below may not include all possible severe and life-threatening 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 KEYTRUDA QLEX. Evaluate liver enzymes, creatinine, and function of endocrine and exocrine glands at baseline and periodically during treatment. Based on severity of adverse reaction, withhold or permanently discontinue KEYTRUDA QLEX, administer corticosteroids, and, if applicable, initiate hormone replacement therapy. In severe or life-threatening cases, consider systemic corticosteroid therapy. Upon improvement to baseline, initiate corticosteroid tapering and continue to taper over at least 1 month. Consider the benefit versus the risk of rechallenging after resolution of other adverse reactions. Immune-mediated adverse reactions will not be managed with corticosteroid therapy.

Colitis

Selected Safety Information continued below

KEYTRUDA QLEX can be administered every 3 weeks or every 6 weeks

3 WEEK	6 WEEK
2 mL injection every 3 weeks	4 mL injection every 6 weeks
2 mL injection every 3 weeks	4 mL injection every 6 weeks
2 mL injection every 3 weeks	4 mL injection every 6 weeks
2 mL injection every 3 weeks	4 mL injection every 6 weeks

These are known for all aspects of pembrolizumab and hyaluronidase

KEYTRUDA QLEX may be administered by a healthcare provider

Tap arrows to see more.

For the adjuvant treatment of adult patients with KEYTRUDA QLEX should continue until disease recurrence, unacceptable toxicity, or up to 12 months.

Patients may be able to switch from KEYTRUDA to KEYTRUDA QLEX. Ask your healthcare provider if this can be considered for you.

For certain patients, treatment with KEYTRUDA QLEX offers a shorter time in the clinic 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 KEYTRUDA QLEX. Evaluate liver enzymes, creatinine, and function of endocrine and exocrine glands at baseline and periodically during treatment. In severe or life-threatening cases, consider systemic corticosteroid therapy. Upon improvement to baseline, initiate corticosteroid tapering and continue to taper over at least 1 month. Consider the benefit versus the risk of rechallenging after resolution of other adverse reactions. Immune-mediated adverse reactions will not be managed with corticosteroid therapy.

Colitis

- KEYTRUDA QLEX administered as a single agent for 2 years in adjuvant melanoma patients (N=1019) caused colitis including severe (Grade 3) in 0.6% (6), including life-threatening (Grade 4) in 0.1% (1), and fatal (Grade 5) in 0.1% (1) patients. Colitis led to permanent discontinuation of KEYTRUDA in 0.3% (3) patients, and to withholding in 0.3% (3) of patients. Colitis resolved in 2 patients who permanently discontinued KEYTRUDA and in 3 patients who withheld KEYTRUDA after a median duration of 3 weeks (range: 1 to 4 weeks). Colitis resolved in 2 of 3 patients who resumed KEYTRUDA after a median duration of 2 weeks (range: 1 to 3 weeks). Colitis resolved in 3 of 6 patients who received corticosteroids. Colitis resolved in 3 of 3 patients who permanently discontinued KEYTRUDA and in 3 of 3 patients who withheld KEYTRUDA after a median duration of 2 weeks (range: 1 to 3 weeks). Colitis resolved in 3 of 3 patients who received corticosteroids.
- KEYTRUDA as a single agent for 2 years in adjuvant melanoma patients (N=1019) caused colitis including severe (Grade 3) in 0.6% (6), including life-threatening (Grade 4) in 0.1% (1), and fatal (Grade 5) in 0.1% (1) patients. Colitis led to permanent discontinuation of KEYTRUDA in 0.3% (3) patients, and to withholding in 0.3% (3) of patients. Colitis resolved in 2 patients who permanently discontinued KEYTRUDA and in 3 patients who withheld KEYTRUDA after a median duration of 3 weeks (range: 1 to 4 weeks). Colitis resolved in 2 of 3 patients who resumed KEYTRUDA after a median duration of 2 weeks (range: 1 to 3 weeks). Colitis resolved in 3 of 6 patients who received corticosteroids. Colitis resolved in 3 of 3 patients who permanently discontinued KEYTRUDA and in 3 of 3 patients who withheld KEYTRUDA after a median duration of 2 weeks (range: 1 to 3 weeks).

Immune-Mediated Pneumonitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated pneumonitis. The clinical presentation of pneumonitis can be variable and may resemble disease progression. Patients with pneumonitis presenting with dyspnea, cough, and chest pain have been reported in patients with pneumonitis after initiation of KEYTRUDA. Pneumonitis has been fatal in 1 of 1 patients in clinical studies.
- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated pneumonitis, defined as requiring corticosteroids, and infectious pneumonitis have been reported in patients with hematologic malignancies who received allogeneic hematopoietic stem cell transplantation prior to and/or after treatment with a PD-1/PD-L1 blockade antibody. Consider infectious etiologies in patients with pneumonitis presenting with signs and symptoms of pneumonitis.
- Pneumonitis occurred in 1.8% (27/1494) of patients receiving KEYTRUDA, including Grade 3 (0.7%), Grade 4 (<0.1%), and Grade 5 (<0.1%) pneumonitis. Systemic corticosteroids were required in 19 of these 27 patients, and were maintained for a median duration of 4 months (range: 1 to 9 months). Pneumonitis resolved in 17/27 patients. Of these, the majority (12/17) resolved within 3 months of the onset of pneumonitis. Pneumonitis led to permanent discontinuation of KEYTRUDA in 9/27 patients, and to withholding in 12/27 patients. Pneumonitis resolved in 7 of 9 patients who permanently discontinued KEYTRUDA and in 5 of 12 patients who withheld KEYTRUDA after a median duration of 2 months (range: 1 to 5 months). Pneumonitis recurred in 2 patients who resumed KEYTRUDA. Pneumonitis resolved in 5 of 5 patients who received corticosteroids.
- Pneumonitis occurred in 1.8% (27/1494) of patients receiving KEYTRUDA, including Grade 3 (0.7%), Grade 4 (<0.1%), and Grade 5 (<0.1%) pneumonitis. Systemic corticosteroids were required in 19 of these 27 patients, and were maintained for a median duration of 4 months (range: 1 to 9 months). Pneumonitis resolved in 17/27 patients. Of these, the majority (12/17) resolved within 3 months of the onset of pneumonitis. Pneumonitis led to permanent discontinuation of KEYTRUDA in 9/27 patients, and to withholding in 12/27 patients. Pneumonitis resolved in 7 of 9 patients who permanently discontinued KEYTRUDA and in 5 of 12 patients who withheld KEYTRUDA after a median duration of 2 months (range: 1 to 5 months). Pneumonitis recurred in 2 patients who resumed KEYTRUDA. Pneumonitis resolved in 5 of 5 patients who received corticosteroids.

Immune-Mediated Hepatitis and Immune-Mediated Hepatitis with Jaundice/Cholestasis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated hepatitis and immune-mediated hepatitis with jaundice/cholestasis. Immune-mediated hepatitis with normal liver tests or transaminase elevations followed by hepatitis with total bilirubin elevation or other signs of liver dysfunction has been observed in patients treated with other anti-PD-1/PD-L1 and anti-PD-L2 containing antibodies. Hepatitis with or without jaundice has been fatal in 1 of 1 patients in clinical studies.
- Immune-mediated hepatitis occurred in 0.4% (7/1494) of patients receiving KEYTRUDA, including Grade 3 (0.2%), Grade 4 (<0.1%), and Grade 5 (<0.1%) hepatitis. Systemic corticosteroids were required in all 7 patients, and were maintained for a median duration of 1 month (range: 1 to 1 month). Hepatitis resolved in 2/7 patients. Of these, the majority (2/2) resolved within 3 months of the onset of hepatitis. Hepatitis led to permanent discontinuation of KEYTRUDA in 5/7 patients, and to withholding in 2/7 patients. Hepatitis resolved in 2 of 5 patients who permanently discontinued KEYTRUDA and in 2 of 2 patients who withheld KEYTRUDA after a median duration of 1 month (range: 1 to 1 month). Hepatitis recurred in 2 patients who resumed KEYTRUDA. Hepatitis resolved in 5 of 5 patients who received corticosteroids.
- Immune-mediated hepatitis occurred in 0.4% (7/1494) of patients receiving KEYTRUDA, including Grade 3 (0.2%), Grade 4 (<0.1%), and Grade 5 (<0.1%) hepatitis. Systemic corticosteroids were required in all 7 patients, and were maintained for a median duration of 1 month (range: 1 to 1 month). Hepatitis resolved in 2/7 patients. Of these, the majority (2/2) resolved within 3 months of the onset of hepatitis. Hepatitis led to permanent discontinuation of KEYTRUDA in 5/7 patients, and to withholding in 2/7 patients. Hepatitis resolved in 2 of 5 patients who permanently discontinued KEYTRUDA and in 2 of 2 patients who withheld KEYTRUDA after a median duration of 1 month (range: 1 to 1 month). Hepatitis recurred in 2 patients who resumed KEYTRUDA. Hepatitis resolved in 5 of 5 patients who received corticosteroids.

Immune-Mediated Nephritis with Renal Dysfunction

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated nephritis with renal dysfunction. Immune-mediated nephritis with renal dysfunction has been observed in patients treated with other anti-PD-1/PD-L1 and anti-PD-L2 containing antibodies. Immune-mediated nephritis with renal dysfunction has been fatal in 1 of 1 patients in clinical studies.
- Immune-mediated nephritis occurred in 0.4% (7/1494) of patients receiving KEYTRUDA, including Grade 3 (0.2%), Grade 4 (<0.1%), and Grade 5 (<0.1%) nephritis. Systemic corticosteroids were required in all 7 patients, and were maintained for a median duration of 1 month (range: 1 to 1 month). Nephritis resolved in 2/7 patients. Of these, the majority (2/2) resolved within 3 months of the onset of nephritis. Nephritis led to permanent discontinuation of KEYTRUDA in 5/7 patients, and to withholding in 2/7 patients. Nephritis resolved in 2 of 5 patients who permanently discontinued KEYTRUDA and in 2 of 2 patients who withheld KEYTRUDA after a median duration of 1 month (range: 1 to 1 month). Nephritis recurred in 2 patients who resumed KEYTRUDA.
- Immune-mediated nephritis occurred in 0.4% (7/1494) of patients receiving KEYTRUDA, including Grade 3 (0.2%), Grade 4 (<0.1%), and Grade 5 (<0.1%) nephritis. Systemic corticosteroids were required in all 7 patients, and were maintained for a median duration of 1 month (range: 1 to 1 month). Nephritis resolved in 2/7 patients. Of these, the majority (2/2) resolved within 3 months of the onset of nephritis. Nephritis led to permanent discontinuation of KEYTRUDA in 5/7 patients, and to withholding in 2/7 patients. Nephritis resolved in 2 of 5 patients who permanently discontinued KEYTRUDA and in 2 of 2 patients who withheld KEYTRUDA after a median duration of 1 month (range: 1 to 1 month). Nephritis recurred in 2 patients who resumed KEYTRUDA.

Immune-Mediated Dermatologic Adverse Reactions

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated rash or dermatitis. Exfoliative dermatitis, including Stevens-Johnson syndrome, drug-induced rash with eosinophilia and systemic symptoms, has been observed in patients treated with other anti-PD-1/PD-L1 and anti-PD-L2 containing antibodies. Topical corticosteroids and/or antihistamines for the prophylaxis of rash in nivolumab monotherapy clinical trials in patients treated with other anti-PD-1/PD-L1 and anti-PD-L2 containing antibodies.
- Immune-mediated dermatologic adverse reactions occurred in 0.7% (11/1494) of patients receiving KEYTRUDA, including Grade 3 (0.3%) and Grade 4 (<0.1%) reactions. Systemic corticosteroids were required in 5 of these 11 patients, and were maintained for a median duration of 1 month (range: 1 to 1 month). Rash resolved in 5/11 patients. Of these, the majority (3/5) resolved within 3 months of the onset of rash. Rash led to permanent discontinuation of KEYTRUDA in 3/11 patients, and to withholding in 5/11 patients. Rash resolved in 2 of 3 patients who permanently discontinued KEYTRUDA and in 3 of 5 patients who withheld KEYTRUDA after a median duration of 1 month (range: 1 to 1 month). Rash recurred in 3 patients who resumed KEYTRUDA. Rash resolved in 3 of 3 patients who received corticosteroids.

Other Severe Or Life-Threatening Reactions

- The following clinically significant immune-mediated adverse reactions have been observed in fewer than 1% of cases (Grade 3 or 4) in patients treated with other anti-PD-1/PD-L1 and anti-PD-L2 containing antibodies: Guillain-Barre syndrome, Myasthenic syndrome, Sarcoid, Hemolytic anemia, Autoimmune hemolysis, Immune thrombocytopenia, Cerebral flare-up, Myasthenia gravis, Autoimmune myocarditis, Myocarditis, Cardiomyopathy, Vasculitis, Uveitis, Iridocyclitis, Myositis/polymyositis, Rhabdomyolysis (and sequelae), Pancreatitis, Islet cell hyperglycemia, Endocrinopathy, Adrenal insufficiency, Hypophysitis, Thyroiditis, Thyroid disorders, Autoimmune thyroid disorders, Type 1 diabetes mellitus, Ulcerative colitis, Inflammatory bowel disease, Local inflammatory reactions, Vitiligo, Psoriasis, Gastritis, Duodenitis, Uveitis (or iridocyclitis), Pancreatitis, Nephritis, Renal failure, Autoimmune nephritis, Autoimmune renal disorder, Interstitial lung disease, Sarcoidosis, Eosinophilic pneumonia, Autoimmune pneumonitis, Pneumonitis, Myelitis, Myelitis transverse, Autoimmune encephalitis, Encephalitis, Myasthenic syndrome, Autoimmune neuropathy, Peripheral neuropathy, Guillain-Barre syndrome, Myasthenia gravis, Autoimmune hypophysitis, Hypophysitis, Autoimmune thyroid disorder, Hypothyroidism, Hyperthyroidism, Autoimmune adrenal insufficiency, Primary adrenal insufficiency, Autoimmune hepatitis, Autoimmune pancreatitis, Type 1 diabetes mellitus, Autoimmune myocarditis, Myocarditis, Autoimmune dermatitis, Exfoliative dermatitis, Toxic epidermal necrosis of Lyell syndrome, Stevens-Johnson syndrome, Autoimmune myositis, Polymyositis, Autoimmune rhabdomyolysis, autoimmune hemolytic anemia, Autoimmune hemolysis, Hemolytic transfusion reaction/hemolysis, Hemolytic uremic syndrome (thrombotic thrombocytopenic purpura), Autoimmune thrombocytopenia, Myocardial infarction, Autoimmune vasculitis, Vasculitis, Autoimmune uveitis, Uveitis, Autoimmune keratitis, Keratitis, Keratoconjunctivitis sicca, Vitiligo

Reply Reply Reply

From: Merck Patient Affairs(noreply@merck.com)

To: [redacted]

Sent: [redacted]

Subject: Learn about a new treatment with flexible administration options

NOW APPROVED

KEYTRUDA QLEX®

pembrolizumab and hyaluronidase-pmph

KEYTRUDA QLEX is approved for use in adult patients across most solid tumor indications for KEYTRUDA intravenous formulation, regardless of PD-L1 status, whether alone or in combination with other therapies

KEYTRUDA QLEX is a prescription medicine for treatment of adult patients with solid tumor cancer (KEYTRUDA intravenous formulation is approved for treatment of adult patients with lymphoma and leukemia). It is administered by injection under the skin.

Selected Safety Information

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

Severe and Fatal Immune-Mediated Adverse Reactions

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated adverse reactions, which may be severe or life-threatening, affecting any organ or tissue. These adverse reactions may involve any organ system, including the following: pneumonitis, colitis, hepatitis, nephritis, endocrinopathies, myocarditis, myositis, neuropathies, and hematologic adverse reactions. Immune-mediated adverse reactions may occur after the initiation of treatment, with variable onset and frequency, and may affect more than one body system.
- Immune-mediated adverse reactions of any grade have been reported in patients treated with KEYTRUDA or other PD-1/PD-L1 blockade treatments. Immune-mediated adverse reactions may not include those observed in other immune-mediated or autoimmune disorders.
- Monitor patients closely for signs/symptoms of immune-mediated adverse reactions. Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically thereafter, and monitor patients for signs and symptoms of pneumonitis, colitis, hepatitis, endocrinopathies, nephritis, and myocarditis during treatment. In cases of suspected immune-mediated adverse reactions, initiate appropriate workup to exclude infectious causes and monitoring effection. Institute hormone-replacement therapy for endocrinopathies as appropriate.
- Based on the severity of adverse reaction, KEYTRUDA and KEYTRUDA QLEX may require interruption or discontinuation of treatment. Administer corticosteroids and, if not contraindicated, KEYTRUDA QLEX requires interruption or discontinuation of immune-mediated adverse reactions. Resume KEYTRUDA and KEYTRUDA QLEX in patients with improvement to Grade 1 or 2 adverse reactions within 12 weeks. In severe (Grade 3) or life-threatening (Grade 4) adverse reactions, consider permanently discontinuing KEYTRUDA and KEYTRUDA QLEX. Permanently discontinue KEYTRUDA and KEYTRUDA QLEX for any immune-mediated adverse reaction in patients with severe or life-threatening adverse reactions when corticosteroids are contraindicated.
- Monitor patients closely for symptoms and signs of myocarditis and myositis (including myopathy) and myasthenia gravis. Immune-mediated myocarditis, myositis, and myasthenia gravis have been reported in patients treated with KEYTRUDA and other immune-mediated adverse reactions, sometimes with delayed onset after initiation of treatment, in cases of suspected myocarditis, myositis, or myasthenia gravis, initiate appropriate workup to exclude infectious causes and monitoring effection. Institute hormone-replacement therapy for endocrinopathies as appropriate.

KEYTRUDA QLEX can cause serious side effects. For more information, contact your doctor or visit www.KEYTRUDAQLEX.com.

Selected Safety Information (continued) below

KEYTRUDA QLEX can be administered in as little as 1 minute

Does not provide the full amount of pembrolizumab in a single dose

KEYTRUDA QLEX dose can be administered by a healthcare provider

Selected Safety Information (continued)

Immune-Mediated Pneumonitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated pneumonitis, defined as cases requiring corticosteroids. Pneumonitis occurred in patients treated with other PD-1/PD-L1 blockade treatments. In patients treated with KEYTRUDA monotherapy, pneumonitis occurred in 2.9% (61/2117) of patients starting treatment with KEYTRUDA, including 0.7% (15) Grade 3, 0.2% (4) Grade 4, and 0.3% (7) Grade 5 pneumonitis. Median time to onset was 5.4 months (range: 0.2 to 27.7 months). In patients treated with KEYTRUDA QLEX monotherapy, pneumonitis occurred in 2.6% (22/847) of patients starting treatment with KEYTRUDA QLEX, including 0.7% (6) Grade 3, 0.1% (1) Grade 4, and 0.1% (1) Grade 5 pneumonitis. Median time to onset was 4.7 months (range: 0.2 to 17.1 months). In patients treated with KEYTRUDA and chemotherapy, pneumonitis occurred in 1.6% (12/755) of patients starting treatment with KEYTRUDA, including 0.4% (3) Grade 3 and 0.1% (1) Grade 5 pneumonitis. Median time to onset was 1.4 months (range: 0.2 to 4.2 months). In patients treated with KEYTRUDA after surgery and chemotherapy, Grade 3 or higher pneumonitis occurred in 1.1% (2/177) of patients treated with KEYTRUDA, including 0.6% (1) Grade 3 pneumonitis. Median time to onset was 1.2 months (range: 0.9 to 1.4 months).

Hepatitis and Immune-Mediated Hepatitis

- KEYTRUDA and KEYTRUDA QLEX can cause serious mediated hepatitis, defined as cases requiring corticosteroids. In patients treated with other PD-1/PD-L1 blockade treatments, hepatitis occurred in Grade 3 (0.4%), and Grade 4 (0.1%) hepatitis. In patients treated with KEYTRUDA monotherapy, hepatitis occurred in 1.1% (23/2117) of patients starting treatment with KEYTRUDA, including 0.5% (10) Grade 3, 0.2% (4) Grade 4, and 0.2% (4) Grade 5 hepatitis. Median time to onset was 4.2 months (range: 0.2 to 20.7 months). In patients treated with KEYTRUDA QLEX monotherapy, hepatitis occurred in 1.1% (9/847) of patients starting treatment with KEYTRUDA QLEX, including 0.5% (4) Grade 3 and 0.1% (1) Grade 4 hepatitis. Median time to onset was 4.1 months (range: 0.2 to 8.3 months). In patients treated with KEYTRUDA and chemotherapy, hepatitis occurred in 1.5% (12/755) of patients starting treatment with KEYTRUDA, including 0.4% (3) Grade 3 and Grade 5 hepatitis. Median time to onset was 1.4 months (range: 0.3 to 4.2 months).

Immune-Mediated Enterocolitis/Colitis

- KEYTRUDA and KEYTRUDA QLEX can cause serious mediated hypertrophic cardiomyopathy, defined as cases requiring corticosteroids. Hypothyroidism can follow hyperthyroidism. Manage hypothyroidism with hormone replacement therapy. Manage hyperthyroidism with medical therapy. In patients treating KEYTRUDA, hypothyroidism occurred in 10% (217/2117) of patients starting KEYTRUDA, including Grade 3 (0.1%) and Grade 4 (0.1%) hypothyroidism. Median time to onset was 3.4 months (range: 0.2 to 29.4 months). In patients treated with KEYTRUDA QLEX monotherapy, hypothyroidism occurred in 9.7% (82/847) of patients starting KEYTRUDA QLEX, including Grade 3 (0.1%) hypothyroidism. Median time to onset was 3.4 months (range: 0.2 to 8.3 months). In patients treated with KEYTRUDA and chemotherapy, hypothyroidism occurred in 11% (83/755) of patients starting KEYTRUDA, including Grade 3 (0.1%) and Grade 5 (0.1%) hypothyroidism. Median time to onset was 2.8 months (range: 0.3 to 8.3 months).

Immune-Mediated Endocrinopathies: Adrenal Insufficiency

- KEYTRUDA and KEYTRUDA QLEX can cause serious mediated hypophysitis, defined as cases requiring corticosteroids. Hypophysitis can cause hypopituitarism. Manage hypopituitarism with hormone replacement therapy. In patients treating KEYTRUDA, hypophysitis occurred in 0.2% (4/2117) of patients starting KEYTRUDA, including Grade 3 (0.1%) hypophysitis. Median time to onset was 6.1 months (range: 2.1 to 9.3 months). In patients treated with KEYTRUDA QLEX monotherapy, hypophysitis occurred in 0.2% (2/847) of patients starting KEYTRUDA QLEX, including Grade 3 (0.1%) hypophysitis. Median time to onset was 4.2 months (range: 2.1 to 6.3 months). In patients treated with KEYTRUDA and chemotherapy, hypophysitis occurred in 0.1% (1/755) of patients starting KEYTRUDA, including Grade 3 (0.1%) hypophysitis. Median time to onset was 2.1 months (range: 2.1 to 2.1 months).

Immune-Mediated Endocrinopathies: Adrenal Insufficiency

- KEYTRUDA and KEYTRUDA QLEX can cause serious mediated primary and secondary adrenal insufficiency, defined as cases requiring corticosteroids. Manage adrenal insufficiency with hormone replacement therapy. In patients treating KEYTRUDA, primary adrenal insufficiency occurred in 0.1% (2/1777) of patients starting KEYTRUDA, including Grade 3 (0.1%) primary adrenal insufficiency. Median time to onset was 2.8 months (range: 2.8 to 2.8 months). In patients treated with KEYTRUDA QLEX monotherapy, primary adrenal insufficiency occurred in 0.1% (1/847) of patients starting KEYTRUDA QLEX, including Grade 3 (0.1%) primary adrenal insufficiency. Median time to onset was 2.8 months (range: 2.8 to 2.8 months). In patients treated with KEYTRUDA and chemotherapy, primary adrenal insufficiency occurred in 0.1% (1/755) of patients starting KEYTRUDA, including Grade 3 (0.1%) primary adrenal insufficiency. Median time to onset was 2.1 months (range: 2.1 to 2.1 months). In patients treated with KEYTRUDA after surgery and chemotherapy, primary adrenal insufficiency occurred in 0.6% (1/177) of patients treated with KEYTRUDA, including Grade 3 (0.6%) primary adrenal insufficiency. Median time to onset was 1.2 months (range: 1.2 to 1.2 months).

Immune-Mediated Endocrinopathies: Hypophysitis

- KEYTRUDA and KEYTRUDA QLEX can cause serious mediated hypophysitis, defined as cases requiring corticosteroids. Hypophysitis can cause hypopituitarism. Manage hypopituitarism with hormone replacement therapy. In patients treating KEYTRUDA, hypophysitis occurred in 0.2% (4/2117) of patients starting KEYTRUDA, including Grade 3 (0.1%) hypophysitis. Median time to onset was 6.1 months (range: 2.1 to 9.3 months). In patients treated with KEYTRUDA QLEX monotherapy, hypophysitis occurred in 0.2% (2/847) of patients starting KEYTRUDA QLEX, including Grade 3 (0.1%) hypophysitis. Median time to onset was 4.2 months (range: 2.1 to 6.3 months). In patients treated with KEYTRUDA and chemotherapy, hypophysitis occurred in 0.1% (1/755) of patients starting KEYTRUDA, including Grade 3 (0.1%) hypophysitis. Median time to onset was 2.1 months (range: 2.1 to 2.1 months).

Immune-Mediated Endocrinopathies: Thyroid Disorders

- KEYTRUDA and KEYTRUDA QLEX can cause serious mediated thyroid disorders, defined as cases requiring endocrine therapy. Thyroiditis can cause hyperthyroidism followed by hypothyroidism. Manage hypothyroidism with hormone replacement therapy. Manage hyperthyroidism with medical therapy. In patients treating KEYTRUDA, hypothyroidism occurred in 10% (217/2117) of patients starting KEYTRUDA, including Grade 3 (0.1%) and Grade 4 (0.1%) hypothyroidism. Median time to onset was 3.4 months (range: 0.2 to 29.4 months). In patients treated with KEYTRUDA QLEX monotherapy, hypothyroidism occurred in 9.7% (82/847) of patients starting KEYTRUDA QLEX, including Grade 3 (0.1%) hypothyroidism. Median time to onset was 3.4 months (range: 0.2 to 8.3 months). In patients treated with KEYTRUDA and chemotherapy, hypothyroidism occurred in 11% (83/755) of patients starting KEYTRUDA, including Grade 3 (0.1%) and Grade 5 (0.1%) hypothyroidism. Median time to onset was 2.8 months (range: 0.3 to 8.3 months).

Immune-Mediated Nephritis and Renal Dysfunction

- KEYTRUDA and KEYTRUDA QLEX can cause serious mediated nephritis, defined as cases requiring corticosteroids. Nephritis can cause renal dysfunction. Manage renal dysfunction with medical therapy. In patients treating KEYTRUDA, nephritis occurred in 0.2% (4/2117) of patients starting KEYTRUDA, including Grade 3 (0.1%) nephritis. Median time to onset was 4.1 months (range: 2.1 to 6.1 months). In patients treated with KEYTRUDA QLEX monotherapy, nephritis occurred in 0.1% (1/847) of patients starting KEYTRUDA QLEX, including Grade 3 (0.1%) nephritis. Median time to onset was 2.1 months (range: 2.1 to 2.1 months). In patients treated with KEYTRUDA and chemotherapy, nephritis occurred in 0.1% (1/755) of patients starting KEYTRUDA, including Grade 3 (0.1%) nephritis. Median time to onset was 2.1 months (range: 2.1 to 2.1 months).

Immune-Mediated Dermatologic Adverse Reactions

- KEYTRUDA and KEYTRUDA QLEX can cause serious mediated rash, defined as cases requiring systemic corticosteroids. Severe skin reactions occurred in patients treating other PD-1/PD-L1 blockade treatments. In patients treating KEYTRUDA, rash occurred in 1.4% (30/2117) of patients starting KEYTRUDA, including Grade 3 (0.1%) and Grade 4 (0.1%) rash. Median time to onset was 2.8 months (range: 0.1 to 29.7 months). In patients treating KEYTRUDA QLEX monotherapy, rash occurred in 1.2% (10/847) of patients starting KEYTRUDA QLEX, including Grade 3 (0.1%) rash. Median time to onset was 2.8 months (range: 0.1 to 8.3 months). In patients treated with KEYTRUDA and chemotherapy, rash occurred in 1.3% (10/755) of patients starting KEYTRUDA, including Grade 3 (0.1%) and Grade 5 (0.1%) rash. Median time to onset was 1.4 months (range: 0.3 to 4.2 months).

Immune-Mediated Adverse Reactions in Patients with Renal Impairment

- KEYTRUDA and KEYTRUDA QLEX can cause serious mediated hypophysitis, defined as cases requiring corticosteroids. Hypophysitis can cause hypopituitarism. Manage hypopituitarism with hormone replacement therapy. In patients treating KEYTRUDA, hypophysitis occurred in 0.2% (4/2117) of patients starting KEYTRUDA, including Grade 3 (0.1%) hypophysitis. Median time to onset was 6.1 months (range: 2.1 to 9.3 months). In patients treated with KEYTRUDA QLEX monotherapy, hypophysitis occurred in 0.2% (2/847) of patients starting KEYTRUDA QLEX, including Grade 3 (0.1%) hypophysitis. Median time to onset was 4.2 months (range: 2.1 to 6.3 months). In patients treated with KEYTRUDA and chemotherapy, hypophysitis occurred in 0.1% (1/755) of patients starting KEYTRUDA, including Grade 3 (0.1%) hypophysitis. Median time to onset was 2.1 months (range: 2.1 to 2.1 months).

Other Immune-Mediated Adverse Reactions

- The following clinically significant immune-mediated adverse reactions occurred at incidences of 1% or less (previous cohort) in patients treating KEYTRUDA or other PD-1/PD-L1 blockade treatments: Guillain-Barre syndrome, myasthenic syndrome, myasthenia gravis, myelitis, vasculitis, sarcoidosis, uveitis, and ophthalmic inflammatory disorders, Vogt-Koyanagi-Harada syndrome, hemolytic anemia, aplastic anemia, hemolytic uremic syndrome, thrombotic thrombocytopenic purpura, immune thrombocytopenia, pancreatitis, including fulminant pancreatitis, hypophysitis, uveitis, iridocyclitis, gastritis, duodenitis, sialadenitis, colitis, diverticulitis, large intestine perforation, pancreatitis, gastritis, duodenitis, sialadenitis, colitis, diverticulitis, large intestine perforation, inflammatory bowel disease, inflammatory bowel disease, vitiligo, alopecia, psoriasis, dermatitis, including exfoliative dermatitis, erythema multiforme, urticaria, dermatitis bullous, and other immune-mediated adverse reactions. Immune-mediated adverse reactions, including those listed above, may occur after discontinuation of KEYTRUDA or KEYTRUDA QLEX. Depending on the severity of the adverse reaction, consider interruption of treatment with KEYTRUDA or KEYTRUDA QLEX, administer corticosteroids, and, if not contraindicated, administer immunosuppressant therapy. Immune-Mediated and Connective Tissue Disorders: Sarcoidosis, including cases with neurosarcoidosis, including cases with central nervous system hepatitis, Sjogren's syndrome, including cases with hepatitis, autoimmune myositis, including polymyositis, dermatomyositis, and polymyalgia rheumatica, systemic lupus erythematosus, including cases with nephritis, rheumatoid arthritis, including cases with hepatitis, Stevens-Johnson syndrome, including cases with hepatitis, and toxic epidermal necrolysis, including cases with hepatitis.

Immune-Mediated Adverse Reactions in Patients with Renal Impairment

- KEYTRUDA and KEYTRUDA QLEX can cause serious mediated hepatitis.

Immune-Mediated Adverse Reactions in Patients with Renal Impairment

- In 2,117 patients treating KEYTRUDA monotherapy, hepatitis occurred in 1.1% (23/2117) of patients starting KEYTRUDA, including Grade 3 (0.5%), and Grade 4 (0.2%) hepatitis. Median time to onset was 4.2 months (range: 0.2 to 20.7 months). In patients treating KEYTRUDA QLEX monotherapy, hepatitis occurred in 1.1% (9/847) of patients starting KEYTRUDA QLEX, including Grade 3 (0.5%) and Grade 4 (0.1%) hepatitis. Median time to onset was 4.1 months (range: 0.2 to 8.3 months). In patients treated with KEYTRUDA and chemotherapy, hepatitis occurred in 1.5% (12/755) of patients starting KEYTRUDA, including Grade 3 (0.4%) and Grade 5 (0.1%) hepatitis. Median time to onset was 1.4 months (range: 0.3 to 4.2 months).

Immune-Mediated Adverse Reactions in Patients with Renal Impairment

- In 2,117 patients treating KEYTRUDA monotherapy, hypothyroidism occurred in 10% (217/2117) of patients starting KEYTRUDA, including Grade 3 (0.1%) and Grade 4 (0.1%) hypothyroidism. Median time to onset was 3.4 months (range: 0.2 to 29.4 months). In patients treating KEYTRUDA QLEX monotherapy, hypothyroidism occurred in 9.7% (82/847) of patients starting KEYTRUDA QLEX, including Grade 3 (0.1%) hypothyroidism. Median time to onset was 3.4 months (range: 0.2 to 8.3 months). In patients treated with KEYTRUDA and chemotherapy, hypothyroidism occurred in 11% (83/755) of patients starting KEYTRUDA, including Grade 3 (0.1%) and Grade 5 (0.1%) hypothyroidism. Median time to onset was 2.8 months (range: 0.3 to 8.3 months).

Immune-Mediated Adverse Reactions in Patients with Renal Impairment

- In 2,117 patients treating KEYTRUDA monotherapy, hypophysitis occurred in 0.2% (4/2117) of patients starting KEYTRUDA, including Grade 3 (0.1%) hypophysitis. Median time to onset was 6.1 months (range: 2.1 to 9.3 months). In patients treating KEYTRUDA QLEX monotherapy, hypophysitis occurred in 0.2% (2/847) of patients starting KEYTRUDA QLEX, including Grade 3 (0.1%) hypophysitis. Median time to onset was 4.2 months (range: 2.1 to 6.3 months). In patients treated with KEYTRUDA and chemotherapy, hypophysitis occurred in 0.1% (1/755) of patients starting KEYTRUDA, including Grade 3 (0.1%) hypophysitis. Median time to onset was 2.1 months (range: 2.1 to 2.1 months).

Immune-Mediated Adverse Reactions in Patients with Renal Impairment

- In 2,117 patients treating KEYTRUDA monotherapy, nephritis occurred in 0.2% (4/2117) of patients starting KEYTRUDA, including Grade 3 (0.1%) nephritis. Median time to onset was 4.1 months (range: 2.1 to 6.1 months). In patients treating KEYTRUDA QLEX monotherapy, nephritis occurred in 0.1% (1/847) of patients starting KEYTRUDA QLEX, including Grade 3 (0.1%) nephritis. Median time to onset was 2.1 months (range: 2.1 to 2.1 months). In patients treated with KEYTRUDA and chemotherapy, nephritis occurred in 0.1% (1/755) of patients starting KEYTRUDA, including Grade 3 (0.1%) nephritis. Median time to onset was 2.1 months (range: 2.1 to 2.1 months).

Immune-Mediated Adverse Reactions in Patients with Renal Impairment

- Fatal and other serious complications can occur in allogeneic hematopoietic stem cell transplant (allo-HSCT) after treatment with a PD-1/PD-L1 blocking antibody. Transplant-related complications include hyperacute graft-versus-host-disease (GVHD), acute GVHD, chronic GVHD, hepatic veno-occlusive disease after reduced intensity conditioning, and steroid-requiring febrile syndrome, among others, all occurring post-transplant. These complications may occur despite intervening therapies between PD-1/PD-L1 treatment and allogeneic HSCT. Monitor patients for signs and symptoms of these complications and intervene as appropriate. Consider the benefit of PD-1/PD-L1 treatment prior to allogeneic HSCT after weighing the risk of these complications for individual patients.

Immune-Mediated Adverse Reactions in Patients with Renal Impairment

- In clinical trials of solid tumor malignancies, immune-mediated adverse reactions occurred in patients who had undergone solid organ transplant. Treatment of these patients with PD-1/PD-L1 blockers may increase the risk of graft rejection, organ failure, and death.

Embryofetal Toxicity

- Based on its mechanism of action and data from animal models of PD-1/PD-L1 pathway blockade, KEYTRUDA and KEYTRUDA QLEX can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise women of reproductive potential to use effective contraception during treatment with KEYTRUDA and KEYTRUDA QLEX and for at least four months after the last dose.

Adverse Reactions

- In patients treating KEYTRUDA monotherapy, adverse reactions occurred in 77% (1,631/2,117) of patients starting KEYTRUDA, including serious (SAE) (52%), serious pneumonitis (2.9%), Grade 3 (0.7%), Grade 4 (0.2%), and Grade 5 (0.3%) pneumonitis, serious hepatitis (1.1%), serious colitis (0.9%), serious hypothyroidism (10%), serious hyperthyroidism (1.2%), serious hypophysitis (0.2%), serious nephritis (0.2%), serious adrenal insufficiency (0.1%), serious diabetes (0.5%), serious hypophysitis (0.2%), serious nephritis (0.2%), serious adrenal insufficiency (0.1%), serious diabetes (0.5%). Fatal adverse reactions occurred in patients with pneumonitis (0.3%), hepatitis (0.2%), hypophysitis (0.2%), Stevens-Johnson syndrome (0.1%), toxic epidermal necrolysis (0.1%), myocarditis (0.1%), myositis (0.1%), and myasthenia gravis (0.1%).
- In patients treating KEYTRUDA QLEX monotherapy, adverse reactions occurred in 77% (655/847) of patients starting KEYTRUDA QLEX, including serious (SAE) (50%), serious pneumonitis (2.6%), Grade 3 (0.7%), Grade 4 (0.1%), and Grade 5 (0.1%) pneumonitis, serious hepatitis (1.1%), serious colitis (0.5%), serious hypothyroidism (9.7%), serious hyperthyroidism (1.2%), serious hypophysitis (0.2%), serious nephritis (0.1%), serious adrenal insufficiency (0.1%), serious diabetes (0.4%). Fatal adverse reactions occurred in patients with pneumonitis (0.4%), hepatitis (0.2%), hypophysitis (0.2%), Stevens-Johnson syndrome (0.1%), and myasthenia gravis (0.1%).
- In patients treating KEYTRUDA and chemotherapy, adverse reactions occurred in 77% (581/755) of patients starting KEYTRUDA, including serious (SAE) (52%), serious pneumonitis (1.6%), Grade 3 (0.4%), and Grade 5 (0.1%) pneumonitis, serious hepatitis (1.5%), serious colitis (0.8%), serious hypothyroidism (11%), serious hyperthyroidism (1.1%), serious nephritis (0.1%), serious adrenal insufficiency (0.1%), serious diabetes (0.4%). Fatal adverse reactions occurred in patients with pneumonitis (0.1%), hepatitis (0.2%), and hypothyroidism (0.1%).

Lactation

- Because of the potential for serious adverse reactions in nursing infants, advise women not to breastfeed during treatment with KEYTRUDA and KEYTRUDA QLEX.

Before prescribing KEYTRUDA or KEYTRUDA QLEX, please read the full Prescribing Information for KEYTRUDA or KEYTRUDA QLEX. For information about KEYTRUDA, call 1-855-699-7378. For information about KEYTRUDA QLEX, call 1-855-699-7379.

Instructions complete

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Desktop View

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To: MerckZSt <Merckt@rs.com>

Subject: Learn about a new treatment with flexible administration options

NOW APPROVED

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

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

One such indication 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

KETRUDA 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 programmed death ligand-1 (PD-L1), blocking the PD-1/PD-L1 pathway. Therefore, immunostimulatory antibodies can cause immune-mediated disrupting 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
pembrolizumab 200 mg and berahyaluronidase alfa 5,000 units	pembrolizumab 400 mg and berahyaluronidase alfa 5,000 units
1-minute administration*	**2-minute administration***
2.4 mL injection volume	4.8 mL injection volume

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

KEYTRUDA QLEX must be administered by a healthcare provider.

1 / 3

Tap arrows to see more.

For the adjuvant treatment of RCC: Treatment with KEYTRUDA QLEX should continue until disease recurrence, unacceptable toxicity, or up to 12 months.

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

For certain patients, treatment with KEYTRUDA QLEX offers flexibility of the site of care 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 detection 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% (38/2799) of patients receiving KEYTRUDA, including fatal (0.1%), Grade 4 (0.3%), Grade 3 (0.8%), and Grade 2 (1.3%) reactions. Systemic corticosteroids were required in 67% (8/34) 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 1.3% (36/2799) 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% (25/48); additional immunosuppressant therapy was required in 17% of patients. Colitis led to permanent discontinuation of KEYTRUDA in 0.5% (13) and withholding in 0.5% (13) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement; of these, 23% had recurrence. Colitis resolved in 85% of the 48 patients. Immune-mediated colitis occurred in 1.2% (3/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 3 (0.8%) and Grade 2 (0.4%) adverse reactions.

Hepatotoxicity and Immune-Mediated Hepatitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated hepatitis. Immune-mediated hepatitis occurred in 0.7% (19/2799) of patients receiving KEYTRUDA, including Grade 4 (<0.1%), Grade 3 (0.4%), and Grade 2 (0.3%) 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 resolved in 74% of the 19 patients. Immune-mediated hepatitis occurred in 0.4% (1/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 2 (0.4%) adverse reactions.

Immune-Mediated Endocrinopathies

Adrenal Insufficiency

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

Hypophysitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated hypophysitis. Hypophysitis can present with acute symptoms associated with mass effect such as headache, phlebophobia, 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 0.8% (17/2799) of patients receiving KEYTRUDA, including Grade 3 (0.4%) and Grade 2 (0.4%) reactions. Systemic corticosteroids were required in 94% (16/17) of patients; of these, the majority remained on systemic corticosteroids. Hypophysitis led to permanent discontinuation of KEYTRUDA in 0.1% (4) and withholding in 0.3% (7) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement.

Thyroid Disorders

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated thyroid disorders. Thyroiditis can present with or without endocrinopathy. Hypothyroidism can follow hyperthyroidism. Initiate hormone replacement for hypothyroidism or institute medical management of hyperthyroidism as clinically indicated. Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity.
- Thyroiditis occurred in 0.6% (16/2799) of patients receiving KEYTRUDA, including Grade 2 (0.3%). None discontinued, but KEYTRUDA was withheld in <0.1% (1) of patients.
- Hyperthyroidism occurred in 3.4% (96/2799) of patients receiving KEYTRUDA, including Grade 3 (0.1%) and Grade 2 (0.8%). It led to permanent discontinuation of KEYTRUDA in <0.1% (2) and withholding in 0.3% (7) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. Hypothyroidism occurred in 8% (237/2799) of patients receiving KEYTRUDA, including Grade 3 (0.1%) and Grade 2 (6.2%). It led to permanent discontinuation of KEYTRUDA in <0.1% (1) and withholding in 0.5% (16) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. The majority of patients with hypothyroidism required long-term hormone replacement therapy.
- Thyroiditis occurred in 0.4% (12/251) 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 3 (0.4%), and Grade 2 (6.8%) adverse reactions.

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

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

Immune-Mediated Nephritis With Renal Dysfunction

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

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 45% (15/36) of patients. These reactions led to permanent discontinuation in 0.1% (2) and withholding of KEYTRUDA in 0.6% (16) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement; of these, 6% had recurrence. The reactions resolved in 70% of the 38 patients. Immune-mediated dermatologic adverse reactions occurred in 1.6% (4/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 4 (0.8%) and Grade 3 (0.8%) adverse reactions.

Other Immune-Mediated Adverse Reactions

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

Hypersensitivity and Infusion- or Administration-Related Reactions

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

Complications of Allogeneic Hematopoietic Stem Cell Transplantation (HSCT)

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

Increased Mortality in Patients With Multiple Myeloma

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

Embryofetal Toxicity

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

Adverse Reactions

- In study MK-3475A-D77, when KEYTRUDA QLEX was administered with chemotherapy in metastatic non-small cell lung cancer (NSCLC), serious adverse reactions occurred in 39% of patients. Serious adverse reactions in 11% of patients who received KEYTRUDA QLEX in combination with platinum doublet chemotherapy were febrile neutropenia (2.3%), 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 pneumonitis (2.2%), neutropenic sepsis (2%), death not otherwise specified (1.6%), respiratory failure (1.2%), pancitis (0.4%), pneumonitis (0.4%), pneumothorax (0.4%), pulmonary embolism (0.4%), neutropenic colitis (0.4%), and seizure (0.4%). KEYTRUDA QLEX was permanently discontinued due to an adverse reaction in 2% of patients. Adverse reactions which resulted in permanent discontinuation of KEYTRUDA QLEX in ≥2% of patients included pneumonitis (0.2%) and pneumonitis (0.2%). Dosage interruption due to an adverse reaction occurred in 49% of patients. Adverse reactions which required dosage interruption in ≥2% of patients included neutropenia, anemia, thrombocytopenia, pneumonia, rash, and increased aspartate aminotransferase. The most common adverse reactions (≥20%) were nausea (25%), fatigue (25%), and musculoskeletal pain (21%).
- In KEYNOTE-564, when KEYTRUDA was administered as a single agent for the adjuvant treatment of renal cell carcinoma, serious adverse reactions occurred in 20% of patients receiving KEYTRUDA, the serious adverse reactions (≥1%) were acute kidney injury, adrenal insufficiency, pneumonia, colitis, and diabetic ketoacidosis (1% each). Fatal adverse reactions occurred in 0.4% of patients receiving KEYTRUDA. Permanently discontinue KEYTRUDA due to adverse reactions occurred in 21% of 488 patients; the most common (≥1%) were increased alanine aminotransferase (ALT) (1.6%), colitis (1%), and adrenal insufficiency (1%). The most common adverse reactions (≥20%) were musculoskeletal pain (41%), fatigue (40%), rash (30%), diarrhea (27%), pruritus (23%), and hypothyroidism (21%).

Lactation

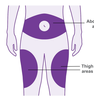
- Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment and for 4 months after the last dose.

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

Give your patients a choice of where you administer their treatment

Two subcutaneous injection-site options:

thigh or abdomen, avoiding the 5 cm area around the navel



Important Dosage and Administration Information

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

keytrudashop.com/qlex

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Subject: Learn about a new treatment with flexible administration options

NOW APPROVED

KEYTRUDA QLex®
pembrolizumab + berahyaluronidase alfa-pmph
subcutaneous injection | 395 mg | 20,000 U

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

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

Selected Safety Information

Contraindications

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

Severe and Fatal Immune-Mediated Adverse Reactions

- KEYTRUDA and KEYTRUDA QLEX are monoclonal antibodies that belong to a class of drugs that bind to either the programmed death receptor-1 (PD-1) or the programmed death ligand-1 (PDL1), blocking the PD-1/PD-L1 pathway, thereby removing inhibition of the immune response, potentially breaking peripheral tolerance induced by antibodies targeting the pathway. 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 a period of 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
every 3 WEEKS	every 6 WEEKS
pembrolizumab 395 mg and berahyaluronidase alfa 4,800 units	pembrolizumab 790 mg and berahyaluronidase alfa 9,600 units
1-minute administration*	2-minute administration*
2.4 mL injection volume	4.8 mL injection volume

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

KEYTRUDA QLEX must be administered by a healthcare provider.

1 / 3

Tap arrows to see more.

For the adjuvant treatment of RCC: Treatment with KEYTRUDA QLEX should continue until disease recurrence, unacceptable toxicity, or up to 12 months.

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

For certain patients, treatment with KEYTRUDA QLEX offers flexibility of the site of care 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 a period of 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% (94/3799) of patients receiving KEYTRUDA, including fatal (0.1%), Grade 4 (0.3%), Grade 3 (0.8%), 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% (26) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. Of these, 23% had recurrence. Pneumonitis resolved in 77% of the 94 patients. Immune-mediated pneumonitis occurred in 5% (132/2) 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% (66/2799) 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 0.7% (19) and withholding in 0.4% (11) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement; of these, 22% had recurrence. Colitis resolved in 85% of the 48 patients. Immune-mediated colitis occurred in 1.2% (32/51) 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 74% (14/19) of patients. Immune-mediated hepatitis led to permanent discontinuation of KEYTRUDA in 0.2% (6) and withholding in 0.2% (5) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement; of these, none had recurrence. Hepatitis resolved in 79% of the 19 patients. Immune-mediated hepatitis occurred in 0.4% (1/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 2 (0.4%) adverse reactions.

Immune-Mediated Endocrinopathies

Adrenal Insufficiency

- KEYTRUDA and KEYTRUDA QLEX can cause primary or secondary adrenal insufficiency. For Grade 2 or higher, initiate symptomatic treatment, including hormone replacement as clinically indicated. Withhold KEYTRUDA and KEYTRUDA QLEX depending on severity. Adrenal insufficiency occurred in 0.8% (22/2799) of patients receiving KEYTRUDA, including Grade 3 (0.4%) 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, cranial nerve palsies, and endocrinopathy. Hypophysitis can cause hypopituitarism. Initiate hormone replacement as indicated. Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity.
- Hypophysitis occurred in 0.6% (17/2799) of patients receiving KEYTRUDA, including Grade 4 (<0.1%), Grade 3 (0.3%), and Grade 2 (0.2%) reactions. Systemic corticosteroids were required in 94% (16/17) of patients; of these, the majority remained on systemic corticosteroids. Hypophysitis led to permanent discontinuation of KEYTRUDA in 0.1% (4) and withholding in 0.3% (7) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement.

Thyroid Disorders

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated thyroid disorders. Thyroiditis can present with or without endocrinopathy. Hypothyroidism can follow hyperthyroidism. Initiate hormone replacement for hypothyroidism or institute medical management of hyperthyroidism as clinically indicated. Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity.
- Thyroiditis occurred in 0.6% (16/2799) of patients receiving KEYTRUDA, including Grade 2 (0.3%). None discontinued, but KEYTRUDA was withheld in <0.1% (1) of patients.
- Hyperthyroidism occurred in 3.4% (96/2799) of patients receiving KEYTRUDA, including Grade 3 (0.1%) and Grade 2 (0.8%). It led to permanent discontinuation of KEYTRUDA in <0.1% (2) and withholding in 0.3% (7) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. Hypothyroidism occurred in 8% (227/2799) of patients receiving KEYTRUDA, including Grade 3 (0.1%) and Grade 2 (6.2%). It led to permanent discontinuation of KEYTRUDA in <0.1% (1) and withholding in 0.5% (14) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. The vast majority of patients with hypothyroidism required long-term thyroid hormone replacement.
- Thyroiditis occurred in 3.4% (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 in 0.5% (14) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. Type 1 DM occurred in 0.4% (1/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy.

Immune-Mediated Nephritis With Renal Dysfunction

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

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 39% (15/38) of patients. Rash led to permanent discontinuation in 0.1% (2) and withholding of KEYTRUDA in 0.9% (16) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement; of these, 6% had recurrence. The reactions resolved in 79% of the 38 patients. Immune-mediated dermatologic adverse reactions occurred in 1.6% (4/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 4 (0.8%) and Grade 3 (0.8%) adverse reactions.

Other Immune-Mediated Adverse Reactions

- The following clinically significant immune-mediated adverse reactions occurred at an incidence of <1% (unless otherwise noted) in patients who received KEYTRUDA, KEYTRUDA QLEX, or were reported with the use of other anti-PD-1/PD-L1 treatments: *Immune-mediated myocarditis, myositis/polymyositis, rhabdomyolysis (and associated sequelae, including renal failure), arthritis, polymyalgia rheumatica, 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 pigment epithelial tear or detachment, parenchymal keratitis, 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 (0.5%), polymyalgia rheumatica; *Endocrine* Hypophysitis, diabetes mellitus, including hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenic purpura, solid organ transplant rejection, other transplant (including corneal graft) rejection.

Hypersensitivity and Infusion- or Administration-Related Reactions

- KEYTRUDA and KEYTRUDA QLEX can cause severe or life-threatening administration-related reactions, including hypersensitivity and anaphylaxis. With KEYTRUDA and KEYTRUDA QLEX, monitor for signs and symptoms of infusion- and administration-related systemic reactions including rigors, chills, wheezing, pruritus, flushing, rash, hypotension, hypoxemia and fever. Infusion-related reactions have been reported in 0.2% (6/2799) of patients receiving KEYTRUDA, including Grade 3 (0.1%) and Grade 2 (0.1%) or Grade 2 reactions. For Grade 3 or Grade 4 reactions, stop infusion and permanently discontinue KEYTRUDA. Hypersensitivity and administration-related systemic reactions occurred in 3.2% (8/251) of patients receiving KEYTRUDA QLEX in combination with platinum doublet chemotherapy, including Grade 2 (2.8%). Interrupt injection (if not already in the chemotherapy infusion) if symptoms resolve for mild or moderate systemic reactions. For severe or life-threatening systemic reactions, stop injection and permanently discontinue KEYTRUDA QLEX.

Complications of Allogeneic Hematopoietic Stem Cell Transplantation (HSCT)

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

Increased Mortality in Patients With Multiple Myeloma

- In trials in patients with multiple myeloma, the addition of KEYTRUDA to a thalidomide analogue plus dexamethasone resulted in increased mortality. Treatment of these patients with 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 and KEYTRUDA QLEX, and advise them to use effective contraception during treatment and for 4 months after the last dose.

Adverse Reactions

- In study 6616A00-701, when KEYTRUDA QLEX was administered with chemotherapy in patients with 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 4.8% of patients, including cardiac arrest (0.8%), cardiopulmonary arrest (0.4%), otherwise specified (1.6%), respiratory failure (1.2%), pneumonitis (0.4%), pneumonia (0.4%), pulmonary embolism (0.4%), neutropenic colitis (0.4%), and seizure (0.4%). KEYTRUDA QLEX was permanently discontinued due to an adverse reaction in 16% of 251 patients. Adverse reactions which resulted in permanent discontinuation of KEYTRUDA QLEX in ≥2% of patients included pneumonia (3.2%) and pneumonitis (2.4%). Dosage interruptions of KEYTRUDA QLEX due to an adverse reaction occurred in 67% of patients. Adverse reactions which resulted in dosage interruption in 02% of patients included neutropenia, anemia, thrombocytopenia, pneumonia, rash, and increased aspartate aminotransferase. The most common adverse reactions (≥20%) were nausea (29%), 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, pneumonitis, hepatitis, and diabetes 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. The most common (21%) were increased alanine aminotransferase (ALT) (4%), colitis (1%), and adrenal insufficiency (1%). The most common adverse reactions (≥20%) were musculoskeletal pain (41%), fatigue (40%), rash (30%), diarrhea (27%), pruritus (23%), and hypothyroidism (21%).

Lactation

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

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

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NOW APPROVED

KEYTRUDA Qlex®
pembrolizumab + berahyaluronidase alpha
pembrolizumab 1 IV vial, 2 SC injections

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

One such indication 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.
- 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 thereafter and monitor for cases of suspected immune-mediated adverse reactions. Initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate.
- Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity of the immune-mediated adverse reaction. In general, if KEYTRUDA and KEYTRUDA QLEX require interruption or discontinuation, administer corticosteroids (prednisone 1 mg/kg/day or 10 mg methylprednisolone equivalent) until improvement to Grade 1 or less. Upon improvement to Grade 1 or less, initiate corticosteroid taper and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants in patients whose adverse reactions are not controlled with corticosteroid therapy.

Selected Safety Information continues below.

KEYTRUDA QLEX can be administered in as little as 1 minute

Q3W	Q6W
every 3 WEEKS	every 6 WEEKS
pembrolizumab 395 mg and berahyaluronidase alfa 8,000 units	pembrolizumab 790 mg and berahyaluronidase alfa 8,000 units
1-minute administration[1]	2-minute administration[1]
2.4 mL injection volume	6.8 mL injection volume

[1]Does not account for all aspects of treatment. Actual clinic time may vary.

KEYTRUDA QLEX must be administered by a healthcare provider.

Selected Safety Information *(continued)*

Immune-Mediated Pneumonitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated pneumonitis. The incidence is higher in patients who have received prior thoracic radiation. Immune-mediated pneumonitis occurred in 3.4% (96/2799) of patients receiving KEYTRUDA, including fatal (0.1%), Grade 4 (0.3%), Grade 3 (0.9%), and Grade 2 (1.2%) reactions. Pneumonitis resulted in permanent discontinuation of KEYTRUDA in 1.1% (30) and in 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 resulted in 59% of the fatal patients. Immune-mediated pneumonitis occurred in 5% (133/51) of patients receiving KEYTRUDA in combination with chemotherapy, including fatal (0.4%), Grade 3 (2%), and Grade 2 (1.2%) adverse reactions.

Selected Safety Information continues below.

Give your patients a choice of where you administer their treatment

Two subcutaneous injection-site options:

thigh or abdomen, avoiding the 5 cm area around the navel

Important Dosage and Administration Information

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

For the adjuvant treatment of RCC: Treatment with KEYTRUDA QLEX should continue until disease recurrence, unacceptable toxicity, or up to 12 months.

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

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

Learn more about clinical data for KEYTRUDA QLEX

Selected Safety Information *(continued)*

Immune-Mediated Colitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated colitis, which may present with diarrhea. Cytomegalovirus infection/reactivation has been reported in patients with corticosteroid-refractory immune-mediated colitis. In cases of corticosteroid-refractory colitis, consider repeating infectious workup to exclude alternative etiologies.
- Immune-mediated colitis occurred in 1.7% (46/2799) of patients receiving KEYTRUDA, including Grade 3 (0.7%), Grade 2 (0.7%), and Grade 1 (0.3%). Systemic corticosteroids were required in 59% (33/46), additional immunosuppressant therapy was required in 4.2% of patients. Colitis led to permanent discontinuation of KEYTRUDA in 0.9% (15) and withholding in 0.5% (13) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement, of these, 23% had recurrence. Colitis resulted in 33% of the fatal immune-mediated adverse reactions. Colitis occurred in 1.2% (2/172) of patients receiving KEYTRUDA in combination with chemotherapy, including Grade 3 (0.8%) and Grade 2 (0.4%) adverse reactions.

Hepatitis 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 79% (15/19) of patients, of these, the majority tapered and maintained on systemic corticosteroids. Hepatitis led to permanent discontinuation of KEYTRUDA in 0.2% (6) and withholding in 0.3% (8) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. Hepatitis resulted in 79% of the 19 patients. Immune-mediated hepatitis occurred in 0.4% (1/251) of patients receiving KEYTRUDA in combination with chemotherapy, including Grade 2 (0.4%) adverse reaction.

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. Without 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 91% (20/22) 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 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 inflammatory manifestations including headache, pituitary apoplexy, or visual field deficits. Hypophysitis can cause hypopituitarism. Initiate hormone replacement as indicated. Without or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity.
- Hypophysitis occurred in 0.6% (17/2799) of patients receiving KEYTRUDA, including 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.

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. Without or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity.
- Thyroiditis occurred in 0.6% (16/2799) of patients receiving KEYTRUDA, including Grade 2 (0.3%). None discontinued, but KEYTRUDA was withheld in <0.1% (1) of patients.
- Hyperthyroidism occurred in 3.4% (96/2799) of patients receiving KEYTRUDA, including Grade 3 (0.1%) and Grade 2 (2.0%). It led to permanent discontinuation of KEYTRUDA in <0.1% (2) and withholding in 0.3% (7) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. Hypothyroidism occurred in 15% (2312/2799) of patients receiving KEYTRUDA, including Grade 3 (0.1%) and Grade 2 (8.2%). It led to permanent discontinuation of KEYTRUDA in <0.1% (1) and withholding in 0.5% (14) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. The majority of patients with hypothyroidism required long-term thyroid hormone replacement.
- Thyroiditis occurred in 0.4% (1/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 2 (0.4%) reaction. 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. Without KEYTRUDA and KEYTRUDA QLEX depending on severity. Type 1 DM occurred in 0.1% (2/1951) of patients receiving KEYTRUDA. It led to permanent discontinuation in <0.1% (1) and withholding of KEYTRUDA in <0.1% (1) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. Type 1 DM occurred in 0.4% (1/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy.

Immune-Mediated Nephritis With Renal Dysfunction

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated nephritis
- Immune-mediated nephritis occurred in 0.3% (9/2799) of patients receiving KEYTRUDA, including Grade 4 (<0.1%), Grade 3 (0.1%), and Grade 2 (0.1%) reactions. Systemic corticosteroids were required in 89% (8/9) of patients, of these, the majority tapered. It led to permanent discontinuation of KEYTRUDA in 0.1% (3) and withholding in 0.1% (2) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement, of these, none had recurrence. Nephritis resulted in 50% of the 6 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 uncomplicated rash. Without 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 of KEYTRUDA in 0.4% (10) and withholding in 0.7% (19) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement, of these, 6% had recurrence. 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: Phase I-III Studies of Pembrolizumab Monotherapy in Adult Patients with Solid Tumors. 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 palsies, autoimmune neuropathy; Ocular: Uveitis, iritis and other inflammatory ocular disorders, macular edema and uveitis 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; Hematologic/Immunologic: Hemolytic anemia, aplastic anemia, hemorrhagic diathesis, red blood cell (pure) aplasia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenic purpura, solid organ transplant rejection, other transplant (including corneal graft) rejection.

Hypersensitivity and Infusion- or Administration-Related Reactions

- KEYTRUDA and KEYTRUDA QLEX can cause severe or life-threatening administration-related reactions, including hypersensitivity and anaphylaxis. With KEYTRUDA and KEYTRUDA QLEX, monitor for signs and symptoms of infusion- and administration-related reactions. Interrupt or slow the rate of infusion for Grade 1 or Grade 2 reactions. Withhold or permanently discontinue KEYTRUDA. Hypersensitivity and administration-related systemic reactions, occurred in 3.2% (62/1951) of patients receiving KEYTRUDA. Interrupt or slow the rate of infusion for Grade 1 or Grade 2 reactions. Withhold or permanently discontinue KEYTRUDA depending on severity. Hypersensitivity and administration-related systemic reactions, occurred in 3.2% (62/1951) of patients receiving KEYTRUDA in combination with platinum doublet chemotherapy, including Grade 2 (2.8%). Interrupt injection (if not already fully administered) and resume if symptoms resolve for mild or moderate systemic reactions. Stop injection for severe anaphylactic reactions, stop injection and permanently discontinue for life-threatening 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 treatment. Hyperacute graft-versus-host-disease (GVHD), acute and chronic GVHD, hepatic veno-occlusive disease after reduced intensity conditioning, and steroid-requiring febrile pneumonitis (without an infectious cause) have been observed in patients who received despite intervening therapy between anti-PD-1/PD-L1 treatments and allogeneic HSCT. Follow patients who receive KEYTRUDA and KEYTRUDA QLEX for these complications. 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 and KEYTRUDA QLEX, and advise them to use effective contraception during treatment and for 4 months after the last dose.

Adverse Reactions

- In study MK-3475-407, 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 5% of patients who received KEYTRUDA QLEX were pneumonia (10%), thromboembolism (4%), febrile neutropenia (4%), pulmonary embolism (3%), pneumonitis (3%), acute kidney injury (3%), dyspnea (3%), rash (1.2%), respiratory failure (1.2%), and anemia (1.2%). Fatal adverse reactions occurred in 10% of patients including pneumonia (3.2%), neutropenic sepsis (2%), death not otherwise specified (1.6%), respiratory failure (1.2%), pneumonitis (0.4%), pneumonitis (0.4%), pulmonary embolism (0.4%), neutropenic colitis (0.4%), and sepsis (0.4%). KEYTRUDA QLEX was discontinued for pneumonitis or other adverse reaction in 10% of 231 patients. Adverse reactions which resulted in permanent discontinuation of KEYTRUDA QLEX in ≥2% of patients included pneumonitis (3.2%) and pneumonitis (2.4%). Dosage interruption of KEYTRUDA QLEX due to an adverse reaction occurred in 45% of patients. Adverse reactions which required dosage interruption in >2% of patients included pneumonitis, musculoskeletal pain, pneumonia, rash, and increased aspartate aminotransferase. The most common adverse reactions (≥20%) were nausea (25%), fatigue (25%), and musculoskeletal pain (21%).
- In KEYNOTE-564, when KEYTRUDA was administered as a single agent for the adjuvant treatment of renal cell carcinoma, serious adverse reactions occurred in 20% of patients receiving KEYTRUDA. The most common serious adverse reactions 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 (≥1%) were increased alanine aminotransferase (ALT) (1.8%), colitis (1%), and adrenal insufficiency (1%). Dosage interruption of KEYTRUDA due to adverse reactions occurred in 52% of patients. Adverse reactions which resulted in permanent discontinuation of KEYTRUDA in ≥2% of patients included pneumonitis (3.2%) and pneumonitis (2.4%). Dosage interruption of KEYTRUDA QLEX due to an adverse reaction occurred in 45% of patients. Adverse reactions which required dosage interruption in >2% of patients included musculoskeletal pain, pneumonitis, pneumonia, rash, and increased aspartate aminotransferase. The most common adverse reactions (≥20%) were nausea (25%), fatigue (25%), and musculoskeletal pain (21%).
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Lactation

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

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

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