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 flex ible 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.

US-PDX-0000-20250417-PDF-Email-Email-Email

Render View Inspector

From: Merck Connect <MerckConnect@DeliverEx.com>
Tap: Merck PDL <MerckPDL@tap.com>
Subject: Learn about a new treatment with fixed-dose administration options

NOW APPROVED

KEYTRUDA QLEX
pembrolizumab and hyaluronidase-ziahyal
subcutaneous injection

KEYTRUDA QLEX is approved for use in adult patients across most cancers, including those treated with KEYTRUDA® (pembrolizumab) injection 100 mg/whether alone or in combination with chemotherapy

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

Selected Safety Information

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

Severe and Fatal Immune-Mediated Adverse Reactions

- KEYTRUDA and KEYTRUDA QLEX monotherapy administered to patients with a class of drugs that bind to either PD-1 or PD-L1 may cause immune-mediated adverse reactions. The PD-1/PD-L1 pathway, thereby removing immune cell vascular adhesion properties, thereby potential immune-mediated inflammation and immune-mediated adverse reactions. Immune-mediated adverse reactions may be severe or fatal, can occur in any organ system or tissue, can affect more than one organ system at a time, and can occur at any time after starting treatment or after discontinuation of treatment. Immune-mediated adverse reactions commonly manifest during treatment with PD-1/PD-L1 blockade with use of anti-PD-1/PD-L1 monoclonal antibodies, including, but not limited to, pneumonitis, colitis, hepatitis, endocrinopathies, and Thyroid disorders, and renal dysfunction. Immune-mediated adverse reactions may also occur with other immune-mediated adverse reactions. Early recognition and prompt management of suspected immune-mediated adverse reactions are critical to ensure safety use of anti-PD-1/PD-L1 monoclonal antibodies. Ensure adequate evaluation to confirm etiology of adverse reactions. Initiate appropriate workup and exclusion of infectious causes including infection, metabolic disorder, disease progression, and other causes, as specially consultation as appropriate.
- Immune-mediated adverse reactions in KEYTRUDA and KEYTRUDA QLEX monotherapy administered to patients with a class of drugs that bind to either PD-1 or PD-L1 may be severe or life-threatening and can include: Pneumonitis, Hepatitis, Colitis, Endocrinopathies, Nephritis and renal dysfunction, Pancreatitis, Myocarditis, Myositis, Myasthenia gravis, Neuropathies, Hypophysitis, Adrenal insufficiency, Hypothyroidism, Hyperthyroidism, Type 1 diabetes mellitus, Ophthalmic inflammatory events, Hemolytic anemia, Aplastic anemia, Hemolytic uremic syndrome, Thrombocytopenia, Immune thrombocytopenia purpura, Hemolytic anemia, Hemophagocytic lymphohistiocytosis, Histiocytic necrosis of lymph node, Sarcoidosis, Immune-mediated dermatitis, Immune-mediated skin disorders, Stevens-Johnson syndrome, Toxic epidermal necrosis, Drug rash with eosinophilia and systemic symptoms, Vasculitis, Immune-mediated ocular disorders, Uveitis, Iritis and other ocular inflammatory events, Diabetes, Diabetic ketoacidosis, Immune-mediated myocarditis, Myocarditis, Myositis, Myasthenia gravis, Immune-mediated peripheral neuropathy, Guillain-Barre syndrome, Immune-mediated encephalitis, Cerebral ischemia, Cerebral infarction, Cerebral edema, Cerebral vasculitis, Cerebral hemorrhage, Immune-mediated hypophysitis, Hypopituitarism, Immune-mediated adrenal insufficiency, Adrenal crisis, Immune-mediated hypothyroidism, Hypothyroidism, Immune-mediated hyperthyroidism, Thyrotoxicosis, Immune-mediated Type 1 diabetes mellitus, Diabetes mellitus, Diabetic ketoacidosis, Immune-mediated ocular disorders, Immune-mediated orbitopathy, Immune-mediated hemolytic anemia, Hemolysis, Immune-mediated aplastic anemia, Aplastic anemia, Immune-mediated hemolytic uremic syndrome, Hemolytic uremic syndrome, Immune-mediated thrombocytopenia, Thrombocytopenia, Immune-mediated Stevens-Johnson syndrome, Toxic epidermal necrosis, Immune-mediated vasculitis, Vasculitis, Immune-mediated sarcoidosis, Sarcoidosis, Immune-mediated nephritis, Nephritis, Immune-mediated renal dysfunction, Renal dysfunction, Immune-mediated hepatitis, Hepatitis, Immune-mediated myocarditis, Myocarditis, Immune-mediated myositis, Myositis, Immune-mediated myasthenia gravis, Myasthenia gravis, Immune-mediated neuropathy, Neuropathy, Immune-mediated Guillain-Barre syndrome, Guillain-Barre syndrome, Immune-mediated encephalitis, Encephalitis, Immune-mediated cerebrovascular events, Cerebrovascular events, Immune-mediated hypophysitis, Hypophysitis, Immune-mediated hypopituitarism, Hypopituitarism, Immune-mediated adrenal insufficiency, Adrenal insufficiency, Immune-mediated hypothyroidism, Hypothyroidism, Immune-mediated hyperthyroidism, Hyperthyroidism, Immune-mediated Type 1 diabetes mellitus, Type 1 diabetes mellitus, Immune-mediated ocular disorders, Ocular disorders, Immune-mediated orbitopathy, Orbitopathy, Immune-mediated hemolytic anemia, Hemolytic anemia, Immune-mediated aplastic anemia, Aplastic anemia, Immune-mediated hemolytic uremic syndrome, Hemolytic uremic syndrome, Immune-mediated thrombocytopenia, Thrombocytopenia, Immune-mediated Stevens-Johnson syndrome, Stevens-Johnson syndrome, Immune-mediated Toxic epidermal necrosis

US-PDA-180000-1-EN-V1.0-JUL2018-Referencing_Dosing_Dosage_Email_Mailer_Letter

Notes from Tasks

From: MerckConnect <MerckConnect@Merck.com>

To: HCP<STE_FIRSTNAME>@HCP.COM

Subject: Learn about a new treatment with flexible administration options

NOW APPROVED

KEYTRUDA Qlex
pembrolizumab and hyaluronidase-pmph
injection, 165 mg/2,400 U

KEYTRUDA QLEX is approved for use in adult patients across most solid tumor indications for which KEYTRUDA intravenous formulation 200 mg is administered alone or in combination with other therapies

One such indication is the adjuvant treatment of adult patients with melanoma (N012) at intermediate-high or high risk of recurrence after complete resection, or following neoadjuvant systemic therapy and resection.

Selected Safety Information

Contraindications

KEYTRUDA QLEX is contraindicated in patients with severe hypersensitivity to pembrolizumab or hyaluronidase or excipients of KEYTRUDA QLEX.

Severe and Fatal Immune-Mediated Adverse Reactions

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated adverse reactions which may involve any organ system or tissue. Immune-mediated adverse reactions usually manifest after tumor inflammation signs and symptoms are observed. Immune-mediated adverse reactions may also occur with other systemic immune-stimulating cancer therapeutics (e.g., chemotherapy, targeted therapy) or after stopping treatment. Immune-mediated adverse reactions may mimic other disease processes and may be severe or fatal. Evaluate liver enzymes, creatinine, and other chemistries at baseline and periodically during treatment. Immune-mediated hypophysitis, immune-mediated adrenal insufficiency, and immune-mediated diabetes can lead to acute alternative etiologies, including diabetic ketoacidosis and hypovolemia, complicating diagnosis. Early diagnosis and management are critical.
- Withhold or permanently discontinue KEYTRUDA or KEYTRUDA QLEX depending on severity of the immune-mediated adverse reaction. In clinical trials, KEYTRUDA and KEYTRUDA QLEX were withheld or discontinued in patients who received Intravenous Immunoglobulin, Tumor Necrosis Factor (TNF) blocking agent, or high dose corticosteroid.
- In general, if KEYTRUDA or KEYTRUDA QLEX is withheld or permanently discontinued, administer high dose corticosteroid therapy (1-2 mg/kg/day prednisone or prednisone equivalent) until improvement to Grade 1 or less. Upon improvement, initiate corticosteroid taper and continue to taper over at least 1 month. Based on the severity of the immune-mediated adverse reaction, administer other immunosuppressants in addition to corticosteroids.
- Monitor patients closely for symptoms and signs that may be clinical manifestations of underlying immune-mediated adverse reactions. Early identification and management are critical to minimize irreversible adverse reactions. Evaluate liver enzymes, creatinine, and other chemistries at baseline and periodically during treatment. Immune-mediated nephritis and renal dysfunction can lead to acute alternative etiologies, including renal cancer progression, nephrotoxic chemotherapy, nephrotoxic antibiotics, and infectious etiologies.
- Withhold or permanently discontinue KEYTRUDA or KEYTRUDA QLEX depending on severity of the immune-mediated adverse reaction in patients with sarcoidosis. KEYTRUDA and KEYTRUDA QLEX may exacerbate underlying sarcoidosis and immune-mediated adverse reactions resembling sarcoidosis were observed in patients receiving KEYTRUDA and other anti-PD-1/PD-L1 antibodies. Consider the benefit versus risk of treatment with KEYTRUDA or KEYTRUDA QLEX in patients with active sarcoidosis.

Selected Safety Information continues below

KEYTRUDA QLEX can be administered in as little as 1 minute

Time to process for all aspects of administration was 3 minutes.

KEYTRUDA QLEX must be administered by a healthcare provider.

Selected Safety Information (continued)

Immune-Mediated Pneumonitis

- KEYTRUDA and KEYTRUDA QLEX can cause fatal immune-mediated pneumonitis. In patients treated with PD-1 blockade, pneumonitis occurred more frequently in patients with lung cancer than in patients with other tumors. Pneumonitis occurred in patients with and without underlying chronic obstructive pulmonary disease. Pneumonitis occurred in patients receiving radiation therapy. Pneumonitis occurred in patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with chemotherapy, including Grade 5 cases in clinical trial 2 patients with NSCLC. Pneumonitis occurred in 3% (21/1567) of patients receiving KEYTRUDA or KEYTRUDA QLEX alone, including Grade 5 (0.1%), Grade 4 (0.1%), Grade 3 (1.1%), and Grade 2 (1.7%). Pneumonitis occurred in 5% (8/158) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with chemotherapy, including Grade 3 (1.9%) and Grade 2 (1.9%) pneumonitis.

Selected Safety Information continues below

Give your patients a choice of where you administer their treatment

Two subcutaneous injection options:

Abdomen or thigh, avoiding the 5 cm area surrounding the navel

Important Dosage and Administration Information

- KEYTRUDA QLEX has different dosage and administration recommendations than KEYTRUDA.
- Administer KEYTRUDA QLEX as a single injection in the thigh or abdomen, avoiding the 5 cm area surrounding the navel.
- Inject one healthy skin and scar site per dose. Do not inject into a vein, muscle, or bruise.
- Do not dilute or shake KEYTRUDA QLEX. Do not freeze. Do not use if KEYTRUDA QLEX has been frozen.
- Do not administer KEYTRUDA QLEX concomitantly with other medications for subcutaneous use or at the same injection site.
- Do not administer KEYTRUDA QLEX intravenously.

For the adjuvant treatment of NSCLC patients, KEYTRUDA QLEX would partnership with disease monitoring, chemotherapy, or follow-up in 18 months.

Patients have the option to switch from KEYTRUDA to KEYTRUDA QLEX after 18 mo. of KEYTRUDA treatment ...or first visit scheduled time

For certain patients, treatment with KEYTRUDA QLEX offers flexibility in dosing, including 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 colitis or diarrhea. Immune-mediated colitis was observed with diarrhea. Cytomegalovirus infection/reactivation has been reported in patients with corticosteroid-refractory immune-mediated colitis. In cases of corticosteroid-refractory immune-mediated colitis, consider testing to exclude alternative etiologies.
- Immune-mediated colitis occurred in 2% (29/1567) of patients receiving KEYTRUDA or KEYTRUDA QLEX alone, including Grade 3 (1.7%), and Grade 2 (0.5%). Immune-mediated colitis occurred in 0% (0/158) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with chemotherapy, including Grade 3 (0.6%) and Grade 2 (0.6%) immune-mediated colitis. Immune-mediated colitis occurred in 1.5% (23/1511) of patients receiving KEYTRUDA or KEYTRUDA QLEX after systemic chemotherapy, including Grade 3 (1.1%) and Grade 2 (0.3%) immune-mediated colitis. Immune-mediated colitis occurred in 1.3% (12/1000) of patients receiving KEYTRUDA or KEYTRUDA QLEX after radiation therapy, including Grade 3 (0.8%) and Grade 2 (0.3%) immune-mediated colitis.

Hepatotoxicity/Immune-Mediated Hepatitis

- KEYTRUDA and KEYTRUDA QLEX can cause severe/life-threatened hepatitis, including autoimmune hepatitis. Hepatitis occurred in patients receiving KEYTRUDA or KEYTRUDA QLEX alone, including Grade 5 (0.1%), and Grade 4 (0.7%) immune-mediated hepatitis. Immune-mediated hepatitis occurred in patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with chemotherapy, including Grade 4 (1.3%) immune-mediated hepatitis. Immune-mediated hepatitis occurred in 1.1% (17/1511) of patients receiving KEYTRUDA or KEYTRUDA QLEX after systemic chemotherapy, including Grade 4 (0.7%) immune-mediated hepatitis. Immune-mediated hepatitis occurred in 0.8% (8/1000) of patients receiving KEYTRUDA or KEYTRUDA QLEX after radiation therapy, including Grade 4 (0.3%) immune-mediated hepatitis.

Immune-Mediated Endocrinopathies

Adrenal Insufficiency

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated adrenal insufficiency, including adrenal crisis. Immune-mediated adrenal insufficiency occurred in patients receiving KEYTRUDA or KEYTRUDA QLEX alone, including Grade 3 (0.1%), and Grade 2 (0.7%) immune-mediated adrenal insufficiency. Immune-mediated adrenal insufficiency occurred in patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with chemotherapy, including Grade 2 (1.3%) immune-mediated adrenal insufficiency. Immune-mediated adrenal insufficiency occurred in 0.7% (11/1511) of patients receiving KEYTRUDA or KEYTRUDA QLEX after systemic chemotherapy, including Grade 2 (0.6%) immune-mediated adrenal insufficiency. Immune-mediated adrenal insufficiency occurred in 0.2% (2/1000) of patients receiving KEYTRUDA or KEYTRUDA QLEX after radiation therapy, including Grade 2 (0.2%) immune-mediated adrenal insufficiency.

Hypophysitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated hypophysitis. Hypophysitis occurred with PD-1 blockade, including hypophysitis with onset of hypopituitarism and/or exacerbation of pituitary gland function. Hypophysitis can also cause other hormonal deficiencies and/or exacerbation of other hormonal deficiencies. Hypophysitis can also cause headache and/or visual disturbances. Hypophysitis can also manifest with signs and symptoms of pituitary mass effect, including headache and visual disturbances, or with signs and symptoms of other hormonal deficiencies. Hypophysitis can also be diagnosed with or without imaging abnormalities. Hypophysitis occurred in patients receiving KEYTRUDA or KEYTRUDA QLEX depending on severity, including Grade 3 (0.1%), Grade 2 (0.4%) of patients receiving KEYTRUDA or KEYTRUDA QLEX alone, including Grade 2 (0.7%). Grade 2 hypophysitis occurred in patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with chemotherapy, including Grade 2 (0.6%). Hypophysitis occurred in 0.4% (6/1511) of patients receiving KEYTRUDA or KEYTRUDA QLEX after systemic chemotherapy, including Grade 2 (0.2%). Hypophysitis occurred in 0.1% (1/1000) of patients receiving KEYTRUDA or KEYTRUDA QLEX after radiation therapy, including Grade 2 (0.1%).

Type 1 Diabetes Mellitus (DM), Which Can Manifest as Diabetic Ketoacidosis

- Monitor patients for hyperglycemia or other signs and symptoms of diabetes mellitus and perform timely glucose monitoring to initiate insulin therapy and medical management of diabetes mellitus. Type 1 DM occurred in 0.4% (6/1567) of patients receiving KEYTRUDA or KEYTRUDA QLEX alone, including Grade 4 (0.1%) and Grade 3 (0.1%). Type 1 DM occurred in 0.6% (1/158) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with chemotherapy, including Grade 3 (0.6%). Type 1 DM occurred in 0.4% (6/1511) of patients receiving KEYTRUDA or KEYTRUDA QLEX after systemic chemotherapy, including Grade 4 (0.2%), Grade 3 (0.1%), and Grade 2 (0.1%). Type 1 DM occurred in 0.1% (1/1000) of patients receiving KEYTRUDA or KEYTRUDA QLEX after radiation therapy, including Grade 2 (0.1%). Monitor patients for hyperglycemia or other signs and symptoms of diabetes mellitus and perform timely glucose monitoring to initiate insulin therapy and medical management of diabetes mellitus. Type 1 DM occurred in 0.4% (6/1567) of patients receiving KEYTRUDA or KEYTRUDA QLEX alone, including Grade 4 (0.1%) and Grade 3 (0.1%). Type 1 DM occurred in 0.6% (1/158) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with chemotherapy, including Grade 3 (0.6%). Type 1 DM occurred in 0.4% (6/1511) of patients receiving KEYTRUDA or KEYTRUDA QLEX after systemic chemotherapy, including Grade 4 (0.2%), Grade 3 (0.1%), and Grade 2 (0.1%). Type 1 DM occurred in 0.1% (1/1000) of patients receiving KEYTRUDA or KEYTRUDA QLEX after radiation therapy, including Grade 2 (0.1%).

Immune-Mediated Nephritis with Renal Dysfunction

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated nephritis. Immune-mediated nephritis occurred in 0.3% (5/1567) of patients receiving KEYTRUDA or KEYTRUDA QLEX alone, including Grade 3 (0.1%) and Grade 2 (0.2%). Immune-mediated nephritis occurred in 0.6% (1/158) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with chemotherapy, including Grade 2 (0.6%). Immune-mediated nephritis occurred in 0.3% (4/1511) of patients receiving KEYTRUDA or KEYTRUDA QLEX after systemic chemotherapy, including Grade 3 (0.1%) and Grade 2 (0.1%). Immune-mediated nephritis occurred in 0.1% (1/1000) of patients receiving KEYTRUDA or KEYTRUDA QLEX after radiation therapy, including Grade 2 (0.1%).

Immune-Mediated Dermatologic Adverse Reactions

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated rash or dermatitis. Exfoliative dermatitis, including Stevens-Johnson syndrome, has occurred in patients receiving single agent PD-1 and PD-L1 blockers. Immune-mediated rash with PD-1/PD-L1 blockers may also be associated with other immune-mediated dermatologic adverse reactions. Withhold or permanently discontinue KEYTRUDA or KEYTRUDA QLEX depending on severity. Immune-mediated rash or dermatitis occurred in 0.6% (9/1567) of patients receiving KEYTRUDA or KEYTRUDA QLEX alone, including Grade 3 (0.1%), Grade 2 (0.3%). Immune-mediated rash or dermatitis occurred in 0.6% (1/158) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with chemotherapy, including Grade 2 (0.6%). Immune-mediated rash or dermatitis occurred in 0.6% (9/1511) of patients receiving KEYTRUDA or KEYTRUDA QLEX after systemic chemotherapy, including Grade 3 (0.1%), Grade 2 (0.3%). Immune-mediated rash or dermatitis occurred in 0.1% (1/1000) of patients receiving KEYTRUDA or KEYTRUDA QLEX after radiation therapy, including Grade 2 (0.1%).

Other Immune-Mediated Adverse Reactions

- The following immune-mediated adverse reactions have been reported with PD-1 and PD-L1 blockers: Myocarditis, including fatal cases, has occurred in patients receiving single agent PD-1 and PD-L1 blockers. Second or third cardiac transplants in patients who had undergone transplantation for myocarditis secondary to PD-1 blockade have been reported. Immune-mediated myocarditis, myositis/polymyositis, myasthenia gravis (including exacerbation), Guillain-Barré syndrome, hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis, systemic inflammatory response syndrome, similar to graft-versus-host disease, sarcoidosis, uveitis, and other ocular inflammatory events have also been reported with or associated with other immune-mediated adverse reactions. Immune-mediated myocarditis, myositis/polymyositis, myasthenia gravis (including exacerbation), Guillain-Barré syndrome, and hemolytic anemia have been reported in patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with other immune-mediated adverse reactions. Withhold or permanently discontinue KEYTRUDA or KEYTRUDA QLEX depending on severity of the immune-mediated adverse reaction. In general, if KEYTRUDA or KEYTRUDA QLEX is withheld or permanently discontinued, administer high dose corticosteroid therapy (1-2 mg/kg/day prednisone or prednisone equivalent) until improvement to Grade 1 or less. Upon improvement, initiate corticosteroid taper and continue to taper over at least 1 month. Based on the severity of the immune-mediated adverse reaction, administer other immunosuppressants in addition to corticosteroids.

Hypersensitivity and Infusion or Injection Site Reactions

- KEYTRUDA and KEYTRUDA QLEX can cause severe or life-threatening hypersensitivity reactions, including anaphylaxis and anaphylaxis. Withhold or permanently discontinue KEYTRUDA or KEYTRUDA QLEX depending on severity. Hypersensitivity reactions, including anaphylaxis, flushing, rigors, rash, pruritus, dyspnea, wheezing, hypotension, hypoxemia and fever, occurred with administration of other intravenous therapeutic proteins and small molecule drugs. Hypersensitivity reactions occurred in 0.5% (8/1567) of patients receiving KEYTRUDA or KEYTRUDA QLEX alone, including Grade 3 (0.1%) and Grade 2 (0.3%). Hypersensitivity reactions occurred in 0% (0/158) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with chemotherapy. Hypersensitivity reactions occurred in 0.4% (6/1511) of patients receiving KEYTRUDA or KEYTRUDA QLEX after systemic chemotherapy, including Grade 3 (0.2%), Grade 2 (0.1%). Hypersensitivity reactions occurred in 0.1% (1/1000) of patients receiving KEYTRUDA or KEYTRUDA QLEX after radiation therapy, including Grade 2 (0.1%).

Infusion-Related Reactions

- Monitor patients for signs and symptoms of infusion-related reactions. Interrupt or slow the rate of administration of KEYTRUDA or KEYTRUDA QLEX depending on severity. Infusion-related reactions occurred in patients receiving KEYTRUDA or KEYTRUDA QLEX alone, including Grade 3 (0.1%), Grade 2 (0.3%). Infusion-related reactions occurred in 0% (0/158) of patients receiving KEYTRUDA or KEYTRUDA QLEX in combination with chemotherapy, including Grade 2 (0.6%). Infusion-related reactions occurred in 0.3% (4/1511) of patients receiving KEYTRUDA or KEYTRUDA QLEX after systemic chemotherapy, including Grade 3 (0.1%), Grade 2 (0.1%). Infusion-related reactions occurred in 0.1% (1/1000) of patients receiving KEYTRUDA or KEYTRUDA QLEX after radiation therapy, including Grade 2 (0.1%).

Complications of Allogeneic Hematopoietic Stem Cell Transplantation (HSCT)

- Fatal and other serious complications can occur in patients who receive allogeneic HSCT before or after anti-PD-1/PD-L1 treatment. Transplant-related complications include hyperacute graft-versus-host-disease (GVHD), acute GVHD, chronic GVHD, hepatic veno-occlusive disease after non-myeloablative conditioning, and steroid-requiring febrile pneumonitis/pulmonary infiltrates without infectious cause. These complications may occur despite intervening therapy between anti-PD-1/PD-L1 blockade and allogeneic HSCT. Monitor patients for signs and symptoms of these complications and intervene as clinically appropriate. Consider the benefit versus risk of treatment with KEYTRUDA or KEYTRUDA QLEX prior to or after allogeneic HSCT.

Increased Mortality in Patients With Multiple Myeloma

- In three customer-sponsored randomized trials in patients with multiple myeloma, PD-1 blockade in combination with a thalidomide analog plus dexamethasone has shown a detrimental effect on survival. The use of PD-1 blockade in combination with thalidomide analogs plus dexamethasone is not recommended outside of controlled trials.

Embryofetal Toxicity

- Based on their mechanism of action and data from animal models of PD-1 and PD-L1 blockade, KEYTRUDA and KEYTRUDA QLEX can cause fetal harm when administered to a pregnant woman. Administer two effective contraceptives during treatment and for 4 months after the last dose of KEYTRUDA or KEYTRUDA QLEX.

Adverse Reactions

- In 1 clinical trial (N012) in 1019 patients with stage IIB/C/IIIA resected melanoma who received adjuvant KEYTRUDA, serious adverse reactions occurred in 14% of patients receiving KEYTRUDA. Serious adverse reactions in 2% of patients were pneumonitis, colitis, adrenal insufficiency, hypophysitis, infusion reaction, and renal failure (acute renal failure, decreased glomerular filtration rate, and creatinine increase). Fatal adverse reactions occurred in 0.4% (4/1019) of patients receiving KEYTRUDA. Fatal adverse reactions in 0.3% (3/1019) of patients were pneumonitis, hepatitis, and renal failure. Adverse reactions leading to withdrawal of KEYTRUDA occurred in 14% of patients receiving KEYTRUDA. Adverse reactions leading to interruption of KEYTRUDA occurred in 24% of patients receiving KEYTRUDA. The most common adverse reactions (≥ 1%) in patients receiving KEYTRUDA were diarrhea (6%), rash (6%), and hypothyroidism (5%).
- In KEYNOTE-054, after KEYTRUDA was discontinued for disease recurrence, delayed resection of one lymph node was performed in 1 patient who had complete response of a pleural recurrence 10 months after last dose of KEYTRUDA. Adverse reactions in patients who received KEYTRUDA were similar to those in patients who received placebo except for cardiac disorders, including pericarditis (1.1% vs 0), cardiomyopathy (1% vs 0), heart failure (0.8% vs 0.2%), and atrial fibrillation (0.8% vs 0.2%). Fatal adverse reactions occurred in 0.4% (2/499) of patients receiving KEYTRUDA. Fatal adverse reactions in 0.2% (1/499) of patients were cardiomyopathy and sudden death. Adverse reactions leading to withdrawal of KEYTRUDA occurred in 14% of patients receiving KEYTRUDA. Adverse reactions leading to interruption of KEYTRUDA occurred in 19% of patients receiving KEYTRUDA. The most common adverse reactions (≥ 1%) in patients receiving KEYTRUDA were diarrhea (5%), rash (5%), and hypothyroidism (5%).

Lactation

- There are no data on the presence of immune-mediated adverse reactions in breastfed children. Because of the potential for serious adverse reactions in breastfed children, advise women not to nurse while they are receiving KEYTRUDA.

Before administering KEYTRUDA or KEYTRUDA QLEX, please review the complete prescribing information for KEYTRUDA and KEYTRUDA QLEX. Also review the KEYTRUDA and KEYTRUDA QLEX Dosing Guide.

Visit KeytrudaHCP.com/Qlex

Call 1-877-MSD-HELP

Learn About Patient Support Options

Learn About Medical Information Requests

Learn About Medical Information Requests

Fast alternative: click here for EMA-required pharmacovigilance.

Note: This message was delivered from an email account used only for sending messages. Do not reply to this email address.

Copyright © 2018 Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA. All rights reserved.

Merck Sharp & Dohme Corp.
Attn: Medical Information
2000 Galloping Hill Road
Kenilworth, NJ 07033-0530, USA

To learn more about Merck's commitment to privacy, see our Privacy Statement.

Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA

US-PDA-180000-1-EN-V1.0-JUL2018-Referencing_Dosing_Dosage_Email_Mailer_Letter

Desktop View

From: MerckConnect <MerckConnect@2merck.com>

To: MerckZSt <Merckt@zs.com>

Subject: Learn about a new treatment with flexible administration options

NOW APPROVED

KEYTRUDA Qlex™
pembrolizumab + berahyaluronidase alfa-pmph
Subcutaneous injection | IV for CSR-which

KEYTRUDA QLEX is approved for use in adult patients across most solid tumor indications for KEYTRUDA.[1] (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 the initiation of therapy 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
2-VIAL 1-MINUTE	2-VIAL 2-MINUTE
pembrolizumab 395 mg and berahyaluronidase alfa 4,000 units	pembrolizumab 790 mg and berahyaluronidase alfa 4,000 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.

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 (1to 2 mg/kg/day prednisone or equivalent) until improvement to ≤ Grade 1. Upon improvement to ≤ Grade 1, initiate corticosteroid tapering and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants in patients whose adverse reactions are not controlled with corticosteroid therapy.

Immune-Mediated Pneumonitis

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

Immune-Mediated Colitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated colitis, which may present with diarrhea. Cytomegalovirus infection/reactivation has been reported in patients with corticosteroid-refractory immune-mediated colitis. In cases of corticosteroid-refractory colitis, consider repeating infectious workup to exclude alternative etiologies.
- Immune-mediated colitis occurred in 1.7% (46/2799) of patients receiving KEYTRUDA, including Grade 4 (<0.1%), Grade 3 (1.1%), and Grade 2 (0.4%) reactions. Systemic corticosteroids were required in 69% (33/46); additional immunosuppressant therapy was required in 4.2% of patients. Colitis led to permanent discontinuation of KEYTRUDA in 0.5% (15) and withholding in 0.5% (13) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement; of these, 23% had recurrence. Colitis resolved in 72% of the 46 patients. Immune-mediated colitis occurred in 1.2% (3/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 3 (0.8%) and Grade 2 (0.4%) adverse reactions.

Hepatotoxicity and Immune-Mediated Hepatitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated hepatitis. Immune-mediated hepatitis occurred in 0.7% (19/2799) of patients receiving KEYTRUDA, including Grade 4 (<0.1%), Grade 3 (0.4%), and Grade 2 (0.1%) reactions. Systemic corticosteroids were required in 95% (13/19) of patients; additional immunosuppressant therapy was required in 8% of patients. Hepatitis led to permanent discontinuation of KEYTRUDA in 0.2% (6) and withholding in 0.3% (9) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement; of these, none had recurrence. Hepatitis resolved in 79% of the 19 patients. Immune-mediated hepatitis occurred in 0.4% (1/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 2 (0.4%) adverse reactions.

Immune-Mediated Endocrinopathies

Adrenal Insufficiency

- KEYTRUDA and KEYTRUDA QLEX can cause primary or secondary adrenal insufficiency. For Grade 3 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, photophobia, or visual field defects. Hypophysitis can cause hypopituitarism. Initiate hormone replacement as indicated. Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity.
- Hypophysitis occurred in 0.8% (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 (0.9%). 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 (7.1%). It led to permanent discontinuation of KEYTRUDA in <0.1% (1) and withholding in 0.5% (14) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. The majority of patients with hypothyroidism required long-term thyroid hormone replacement.
- Thyroiditis occurred in 0.4% (1/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 2 (0.4%). Hyperthyroidism occurred in 8% (20/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 3 (3.2%). Hypothyroidism occurred in 14% (35/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 2 (11%).

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

- Monitor patients for hyperglycaemia 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% (2) and withholding in 0.1% (3) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement; of these, none had recurrence. Nephritis resolved in 56% of the 9 patients.

Immune-Mediated Dermatologic Adverse Reactions

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

Other Immune-Mediated Adverse Reactions

- The following clinically significant immune-mediated adverse reactions occurred at an incidence of <1% (unless otherwise noted) in patients who received KEYTRUDA, KEYTRUDA QLEX, or were reported with the use of other anti-PD-1/PD-L1 treatments. Severe or fatal cases have been reported for some of these adverse reactions. *Cardiac/Vascular:* Myocarditis, pericarditis, vasculitis; *Nervous System:* Meningitis, encephalitis, myelitis and demyelination, myasthenic syndrome/myasthenia gravis (including exacerbation), Guillain-Barré syndrome, nerve paresis, autoimmune neuropathy; *Ocular:* Uveitis, iridocyclitis, choroiditis, ophthalmopathy, myositis of extraocular muscles, transient blindness, and ocular inflammatory toxicity (defined as uveitis, iridocyclitis, episcleritis, 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, hemolytic uremic syndrome, thrombocytopenia, systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenic purpura, solid organ transplant rejection, other transplant (including corneal graft) rejection.

Hypersensitivity and Infusion- or Administration-Related Reactions

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

Complications of Allogeneic Hematopoietic Stem Cell Transplantation (HSCT)

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

Increased Mortality in Patients With Multiple Myeloma

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

Embryofetal Toxicity

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

Adverse Reactions

- In study MK-3475A-D77, when KEYTRUDA QLEX was administered with chemotherapy in metastatic non-small cell lung cancer (NSCLC), serious adverse reactions occurred in 39% of patients. Serious adverse reactions in ≥1% of patients who received KEYTRUDA QLEX were pneumonia (10%), thrombocytopenia (4%), febrile neutropenia (4%), neutropenia (2.8%), musculoskeletal pain (2%), pneumonitis (2%), diarrhea (1.6%), rash (1.2%), respiratory failure (1.2%), and anemia (1.2%). Fatal adverse reactions occurred in 10% of patients including pneumonia (3.2%), neutropenia sepsis (2%), death not otherwise specified (1.6%), respiratory failure (1.2%), pneumonitis (0.4%), pneumonitis with COVID-19 infection (0.4%), cardiopulmonary arrest (0.4%), and cardiac arrest (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 45% of patients. Adverse reactions which required dosage interruption in ≥2% of patients included neutropenia, anemia, thrombocytopenia, pneumonia, rash, and increased aspartate aminotransferase. The most common adverse reactions (≥20%) were nausea (25%), fatigue (25%), and musculoskeletal pain (21%).
- In KEYNOTE-564, when KEYTRUDA was administered as a single agent for the adjuvant treatment of renal cell carcinoma, serious adverse reactions occurred in 20% of patients receiving KEYTRUDA; the serious adverse reactions (≥1%) were acute kidney injury, adrenal insufficiency, pneumonia, colitis, and diabetic ketoacidosis (1% each). Fatal adverse reactions occurred in 0.4% of patients due to cardiac arrest. Permanent discontinuation of KEYTRUDA due to adverse reactions occurred in 21% of 498 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.

keytrudahcp.com/qlex

Ask Merck

Learn About

The Merck Access Program >

Learn About Merck Oncology Patient Support >

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

Note: This message was distributed from an email account used for sending messages only. Please do not reply to this message.

This email communication is from Merck Sharp & Dohme LLC. Please manage your email preferences or unsubscribe anytime by clicking here. If you have trouble accessing this link, please send an email to merck_privacy_office@merck.com with a subject line of Email Opt-Out Request – US-PDS-00062.

Copyright © 2025 Merck & Co., Inc., Rahway, NJ, USA and its affiliates. All rights reserved.

To learn more about Merck's commitment to privacy and your rights, please visit merck.com/privacy.

Merck Privacy Office, 351 N Sumneytown Pike, UG4B-24, North Wales, PA 19454, USA

US-PDS-00062 11/25

MERCK

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.

Desktop View - Expanded

From: MerckConnect <MerckConnect@merck.com>

To: MerckZSt <Merckt@zs.com>

Subject: Learn about a new treatment with flexible administration options

NOW APPROVED

KEYTRUDA Qlex™
pembrolizumab + berahyaluronidase alfa-pmph
Injection/injectable | 10 mL (200 mg/2 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

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 listed here may not include all those that may 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 prednisone equivalent) until improvement to one grade or baseline. Upon improvement to 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 prednisone equivalent) until improvement to one grade or baseline. Upon Grade 1 or less, initiate corticosteroid taper and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants in patients whose adverse reactions are not controlled with corticosteroid therapy.

Collapse

Selected Safety Information continues below.

KEYTRUDA QLEX can be administered in as little as 1 minute

Q3W	Q6W
every 3 weeks	every 6 weeks
pembrolizumab 393 mg and berahyaluronidase alfa 4,915 units	pembrolizumab 786 mg and berahyaluronidase alfa 9,830 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.

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 prednisone equivalent) until improvement to one grade or baseline. Upon improvement to 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.

Immune-Mediated Pneumonitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated pneumonitis. The incidence is higher in patients who have received prior thoracic radiation. Immune-mediated pneumonitis occurred in 3.4% (362/798) of patients receiving KEYTRUDA, including fatal (0.1%), Grade 4 (0.3%), Grade 3 (0.9%), and Grade 2 (1.3%) reactions. Systemic corticosteroids were required in 67% (93/94) of patients. Pneumonitis led to permanent discontinuation of KEYTRUDA in 1.3% (38) and withholding in 0.9% (28) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. Of these, 23% had recurrence. Pneumonitis resolved in 93% of the 94 patients. Immune-mediated pneumonitis occurred in 5% (132/51) 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% (492/799) of patients receiving KEYTRUDA, including Grade 4 (<0.1%), Grade 3 (1.1%), and Grade 2 (0.4%) reactions. Systemic corticosteroids were required in 69% (33/48); additional immunosuppressant therapy was required in 4.2% of patients. Colitis led to permanent discontinuation of KEYTRUDA in 0.5% (15) and withholding in 0.5% (13) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. Of these, 8% had recurrence. Colitis resolved in 85% of the 48 patients. Immune-mediated colitis occurred in 1.2% (32/31) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 3 (0.8%) and Grade 2 (0.4%) adverse reactions.

Hepatotoxicity and Immune-Mediated Hepatitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated hepatitis. Immune-mediated hepatitis occurred in 0.7% (192/799) of patients receiving KEYTRUDA, including Grade 4 (<0.1%), Grade 3 (0.4%), and Grade 2 (0.1%) reactions. Systemic corticosteroids were required in 68% (13/19) of patients; additional immunosuppressant therapy was required in 11% of patients. Hepatitis led to permanent discontinuation of KEYTRUDA in 0.2% (6) and withholding in 0.3% (9) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement; of these, none had recurrence. Hepatitis resolved in 79% of the 19 patients. Immune-mediated hepatitis occurred in 0.4% (12/51) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 2 (0.4%) adverse reactions.

Immune-Mediated Endocrinopathies

Adrenal Insufficiency

- KEYTRUDA and KEYTRUDA QLEX can cause primary or secondary adrenal insufficiency. For Grade 2 or higher, initiate symptomatic treatment, including hormone replacement as clinically indicated. Withhold KEYTRUDA and KEYTRUDA QLEX depending on severity. Adrenal insufficiency occurred in 0.8% (22/799) of patients receiving KEYTRUDA, including Grade 3 (0.4%) and Grade 2 (0.4%) reactions. Adrenal insufficiency led to permanent discontinuation of KEYTRUDA in 0.3% (2) and withholding in 0.3% (2) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. Adrenal insufficiency occurred in 2% (32/51) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 3 (0.4%) and Grade 2 (0.8%) adverse reactions.

Hypophysitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated hypophysitis. Hypophysitis can present with acute symptoms associated with mass effect such as headache, neuroophthalmic disorders, and hypopituitarism. Hypophysitis can cause hypopituitarism. Initiate hormone replacement as indicated. Withhold/permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity.
- Hypophysitis occurred in 0.8% (17/799) of patients receiving KEYTRUDA, including Grade 4 (<0.1%), Grade 3 (0.3%), and Grade 2 (0.2%) reactions. Systemic corticosteroids were required in 94% (16/17) of patients; of these, the majority remained on systemic corticosteroids. Hypophysitis led to permanent discontinuation of KEYTRUDA in 0.1% (4) and withholding in 0.3% (7) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement.

Thyroid Disorders

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated thyroid disorders. Thyroiditis can present with or without endocrinopathy. Hypothyroidism can follow hyperthyroidism. Initiate hormone replacement for hypothyroidism or institute medical management of hyperthyroidism as clinically indicated. Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity.
- Thyroiditis occurred in 0.6% (192/799) of patients receiving KEYTRUDA, including Grade 2 (0.3%). None discontinued, but KEYTRUDA was withheld in <0.1% (1) of patients.
- Hyperthyroidism occurred in 3.4% (862/799) of patients receiving KEYTRUDA, including Grade 3 (0.1%) and Grade 2 (0.8%). It led to permanent discontinuation of KEYTRUDA in <0.1% (2) and withholding in 0.3% (7) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. Hypothyroidism occurred in 8% (1/51) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 3 (0.2%), Grade 2 (5.1%), and Grade 1 (2.5%) reactions. Hypothyroidism led to permanent discontinuation of KEYTRUDA QLEX in 0.2% (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%). Hypothyroidism occurred in 8% (20/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 3 (0.4%), Grade 2 (5.1%), and Grade 1 (2.5%) reactions. Hypothyroidism led to permanent discontinuation of KEYTRUDA QLEX in 0.4% (1) and withholding in 0.3% (7) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement.

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% (0/2799) of patients receiving KEYTRUDA. It led to permanent discontinuation in <0.1% (1) and withholding in 0.1% (2) 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 3 (0.1%), Grade 2 (0.1%), and Grade 1 (<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 40% (15/38) of patients. These reactions led to permanent discontinuation of KEYTRUDA in 0.3% (8) and withholding in 0.6% (16) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement; of these, 6% had recurrence. The reactions resolved in 79% of the 38 patients. Immune-mediated dermatologic adverse reactions occurred in 1.8% (4/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 4 (0.8%) and Grade 3 (0.8%) adverse reactions.

Other Immune-Mediated Adverse Reactions

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

Hypersensitivity and Infusion- or Administration-Related Reactions

- KEYTRUDA and KEYTRUDA QLEX can cause severe or life-threatening administration-related reactions, including hypersensitivity and anaphylaxis. With KEYTRUDA and KEYTRUDA QLEX, monitor for signs and symptoms of infusion- and administration-related reactions, including chills, tremor, flushing, rash, pruritus, dyspnea, hypotension, hypoxemia and fever. Infusion-related reactions have been reported in 0.2% of 2799 patients receiving KEYTRUDA. Interrupt or slow the rate of infusion for Grade 1 or Grade 2 reactions. For Grade 3 or Grade 4 reactions, stop infusion and permanently discontinue KEYTRUDA. Hypersensitivity and administration-related systemic reactions occurred in 3.2% (62/51) 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 GVHD, chronic GVHD, hepatic veno-occlusive disease after reduced intensity conditioning, and steroid-requiring febrile syndrome (without an identified infectious cause). These complications may occur despite intervening therapy between anti-PD-1/PD-L1 treatments and allogeneic HSCT. Follow patients closely for evidence of these complications and intervene promptly. Consider the benefit vs risks of using anti-PD-1/PD-L1 treatments prior to or after an allogeneic HSCT.

Increased Mortality in Patients With Multiple Myeloma

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

Embryofetal Toxicity

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

Adverse Reactions

- In study MK-3475A-D77, when KEYTRUDA QLEX was administered with chemotherapy in metastatic non-small cell lung cancer (NSCLC), serious adverse reactions occurred in 39% of patients. Serious adverse reactions in 1% of patients who received KEYTRUDA QLEX were pneumonia (10%), thrombocytopenia (4%), febrile neutropenia (4%), neutropenia (2.8%), musculoskeletal pain (2%), pneumonitis (2%), diarrhea (1.6%), rash (1.6%), and acute kidney injury (1%). Fatal adverse reactions occurred in 2% of patients and included infections (pneumonia (0.2%), neutropenic sepsis (2%), death with not otherwise specified (1.6%), respiratory failure (1.2%), pyrexia (0.4%), pneumonitis (0.4%), pneumothorax (0.4%), pulmonary embolism (0.4%), neutropenic colitis (0.4%), and seizure (0.4%). KEYTRUDA QLEX was permanently discontinued due to an adverse reaction in 16% of 251 patients. Adverse reactions which resulted in permanent discontinuation of KEYTRUDA QLEX in ≥2% of patients included pneumonia (3.2%) and musculoskeletal pain (2%). Dosage interruption due to an adverse reaction occurred in 43% of patients. Adverse reactions which required dosage interruption in ≥2% of patients included neutropenia, anemia, thrombocytopenia, pneumonia, rash, and increased aspartate aminotransferase (2%). 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 496 patients, the fatal adverse reaction was pneumonitis. KEYTRUDA due to adverse reactions occurred in 21% of 496 patients, the most common (21%) 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.

keytrudahcp.com/qlex

Ask Merck

Learn About

The Merck Access Program >

Learn About Merck Oncology Patient Support >

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

Note: This message was distributed from an email account used for sending messages only. Please do not reply to this message.

This email communication is from Merck Sharp & Dohme LLC. Please manage your email preferences or unsubscribe anytime by clicking here. If you have trouble accessing this link, please send an email to merck_privacy_office@merck.com with a subject line of Email Opt-Out Request - US-PDS-00062.

Copyright © 2025 Merck & Co., Inc., Rahway, NJ, USA and its affiliates. All rights reserved.

To learn more about Merck's commitment to privacy and your rights, please visit merck.com/privacy

Merck Privacy Office, 351 N Sumneytown Pike, UG06-20, North Wales, PA 19454, USA

US-PDS-00062 11/25

MERCK

US-PDS-00062 M7_HCP_QLEX_MSNewsline_Study_Design_Email_Desktop_Collapsed_Desktop_Static

Desktop View - Static

From: MerckConnect <MerckConnect@merck.com>

To: MerckZSI <Merck@zs.com>,

Subject: Learn about a new treatment with flexible administration options

NOW APPROVED

KEYTRUDA QLex®
pembrolizumab + berahyaluronidase alfa-pmph
subcutaneous | IV by qBreviro

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 high risk of recurrence after a complete resection of 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 programmed death ligand 1 (PD-L1), blocks 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 in most cases if left untreated, can persist beyond clinical 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 clinical chemistries including liver enzymes and creatinine 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.
- Depending on the immune-mediated adverse reaction and KEYTRUDA QLEX depending on severity of the immune-mediated adverse reaction. In general, if KEYTRUDA and KEYTRUDA QLEX require interruption or discontinuation, administer systemic corticosteroid therapy (1 to 2 mg/kg/day prednisone or equivalent) until improvement to Grade 1 or less. Upon improvement to Grade 1 or less, initiate corticosteroid tapering over at least 1 month. Resume after 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 200 + berahyaluronidase alfa 2,000 units/mL	pembrolizumab 400 + berahyaluronidase alfa 2,000 units/mL
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.

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% (94/2799) of patients receiving KEYTRUDA, including Grade 5 (0.1%), Grade 4 (0.1%), Grade 3 (1.0%), and Grade 2 (2.1%) reactions. Systemic corticosteroids were required in 67% (63/94) of patients. Pneumonitis led to permanent discontinuation of KEYTRUDA in 1.3% (36) and withholding in 0.9% (26) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement; of these, 23% had recurrence. Pneumonitis resolved in 59% of the 94 patients. Immune-mediated pneumonitis occurred in 1.2% (32/2611) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 5 (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, or colitis with abdominal pain and mucus or blood in stool. In patients with corticosteroid-refractory immune-mediated colitis, in cases of corticosteroid-refractory colitis, consider repeating infectious workup to exclude alternative etiologies.
- Immune-mediated colitis occurred in 1.7% (46/2799) of patients receiving KEYTRUDA, including Grade 4 (<0.1%), Grade 3 (1.1%), and Grade 2 (0.4%) reactions. Systemic corticosteroids were required in 59% (33/46) 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% (12) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement; of these, 23% had recurrence. Colitis resolved in 85% of the 46 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 68% (13/19) of patients; additional immunosuppressant therapy was required in 11% of patients. Hepatitis led to permanent discontinuation of KEYTRUDA in 0.2% (6) and withholding in 0.3% (9) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement; of these, none had recurrence. Hepatitis resolved in 79% of the 19 patients. Immune-mediated hepatitis occurred in 0.4% (12/51) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 2 (0.4%) adverse reactions.

Immune-Mediated Endocrinopathies

Adrenal Insufficiency

- KEYTRUDA and KEYTRUDA QLEX can cause primary or secondary adrenal insufficiency. For Grade 2 or higher, initiate symptomatic treatment, including hormone replacement as clinically indicated. Withhold KEYTRUDA and KEYTRUDA QLEX depending on severity. Adrenal insufficiency occurred in 0.8% (22/2799) of patients receiving KEYTRUDA, including Grade 4 (<0.1%), Grade 3 (0.3%), and Grade 2 (0.3%) reactions. Systemic corticosteroids were required in 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% (52/51) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 3 (0.4%) and Grade 2 (0.8%) adverse reactions.

Hypophysitis

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated hypophysitis. Hypophysitis can present with acute symptoms associated with mass effect such as headache, photophobia, or visual field defects. Hypophysitis can cause hypopituitarism. Initiate hormone replacement as indicated. Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity.
- Hypophysitis occurred in 0.6% (17/2799) of patients receiving KEYTRUDA, including Grade 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 symptoms of transient hyperthyroidism followed by hypothyroidism. 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.
- Hypothyroidism occurred in 3.4% (96/2799) of patients receiving KEYTRUDA, including Grade 3 (0.1%) and Grade 2 (3.3%). It led to permanent discontinuation of KEYTRUDA in <0.1% (2) and withholding in 0.3% (1) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. Hypothyroidism resolved in 6% (23/376) of patients receiving KEYTRUDA, including Grade 3 (0.7%) and Grade 2 (5.2%). It led to permanent discontinuation of KEYTRUDA in <0.1% (1) and withholding in 0.3% (14) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement. The majority of patients with hypothyroidism required long term hormone replacement.
- Thyroiditis occurred in 0.4% (12/51) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 2 (0.4%). Hypothyroidism occurred in 8% (20/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 3 (0.2%). 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 without other KEYTRUDA toxicities developed in 0.1% (2) of patients. 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% (12/51) 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 67% (6/9) of patients, of these, the majority remained on corticosteroids. Nephritis led to permanent discontinuation of KEYTRUDA in 0.1% (2) and withholding in 0.1% (3) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement; of these, none had recurrence. Nephritis resolved in 56% of the 9 patients.

Immune-Mediated Dermatologic Adverse Reactions

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated rash or dermatitis. Exfoliative dermatitis, including Stevens-Johnson syndrome, drug rash with eosinophilia and systemic symptoms, and toxic epidermal necrolysis, has occurred with anti-PD-1/PD-L1 treatments. Topical emollients and/or topical corticosteroids may be adequate to treat Grade 1 immune-mediated rash. Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity.
- Immune-mediated dermatologic adverse reactions occurred in 1.4% (39/2799) of patients receiving KEYTRUDA, including Grade 3 (1%) and Grade 2 (0.1%) reactions. Systemic corticosteroids were required in 40% (15/38) of patients. These reactions led to permanent discontinuation in 0.1% (2) and withholding of KEYTRUDA in 0.8% (19) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement; of these, 33% had recurrence. Rash resolved in 79% of the 38 patients. Immune-mediated dermatologic adverse reactions occurred in 1.6% (42/51) 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 anti-PD-1/PD-L1 treatments: Myocarditis, Myositis/polymyositis, Sarcoid, Hemolytic anemia, 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 hypotension, hypoxemia and flush. Infusion-related reactions have been reported in 0.2% of 2799 patients receiving KEYTRUDA. Interrupt or slow the rate of infusion for Grade 1 or Grade 2 reactions. For Grade 3 or Grade 4 reactions, stop infusion and permanently discontinue KEYTRUDA. Hypersensitivity and administration-related systemic reactions occurred in 0.4% (12/2611) of patients receiving KEYTRUDA QLEX in combination with platinum doublet chemotherapy, including Grade 2 (0.8%). 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 conditioning chemotherapy, and other complications of immunosuppression (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-077, when KEYTRUDA QLEX was administered with chemotherapy in metastatic non-squamous non-small cell lung cancer (NSCLC), serious adverse reactions occurred in 50% of patients. Serious adverse reactions in 1% of patients who received KEYTRUDA QLEX were febrile neutropenia (2.4%), pneumonitis (2.4%), anemia (1.6%), neutropenia (2.8%), musculoskeletal pain (2%), pneumonitis (2%), diarrhea (1.8%), rash (1.2%), respiratory failure (1.2%), and anemia (1.2%). Fatal adverse reactions occurred in 2.8% of patients including cardiac arrest (0.4%), pneumonitis (0.4%), sepsis (0.4%), otherwise specified (1.6%), respiratory failure (1.2%), pyrexia (0.8%), pneumonitis (0.4%), pneumothorax (0.4%), pulmonary embolism (0.4%), neutropenic colitis (0.4%), and seizure (0.4%). KEYTRUDA QLEX was permanently discontinued due to an adverse reaction in 16% of 251 patients. Adverse reactions which resulted in permanent discontinuation of KEYTRUDA QLEX in ≥2% of patients were musculoskeletal pain (4%), pneumonitis (2.4%). Dosage interruptions of KEYTRUDA QLEX due to an adverse reaction occurred in 45% of patients. Adverse reactions which required dosage interruption in ≥2% of patients included neutropenia, anemia, thrombocytopenia, pneumonitis, 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 RCC, serious adverse reactions occurred in approximately 26% 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 2.2% including 1 case of pneumonitis. Discontinuation of KEYTRUDA due to adverse reactions occurred in 21% of 488 patients; the most common adverse reactions resulting in discontinuation were AST increased (2%), 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 9 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.

keytrudahcp.com/qlex

Ask Merck

Learn About
The Merck Access Program >

Learn About Merck Oncology Patient Support >

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

Note: This message was distributed from an email account used for sending messages only. Please do not reply to this message.

This email communication is from Merck Sharp & Dohme LLC. Please manage your email preferences or unsubscribe by clicking here. If you have questions, please contact us by sending an email to merck_privacy_office@merck.com with a subject line of Email Opt-Out Request.—US-PDS-00062

Copyright © 2025 Merck & Co., Inc., Rahway, NJ, USA and its affiliates. All rights reserved.

To learn more about Merck's commitment to privacy and your rights, please visit merck.com/privacy.

Merck Privacy Office, 351 N Sumneytown Pike, UG4B-25, North Wales, PA 19454, USA

US-PDS-00062 11/25

MERCK