US-PDS-00024 ADT HCP QLEX Pan Tumor Launch Now Approved Dosing HQ Kinetic Email\_v11

9/18/2025

**Subject Line Options**

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

**Preheader Options**

1. See administration details below.
2. See administration information for this new treatment option.
3. Scroll below to learn more.
4. See interactive content below.

------------------

[headline]

NOW APPROVED

[KEYTRUDA QLEX logo]

[subhead]

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

[Do NOT anchor above statement to QLEX Draft PI because it is not currently anchorable. However, it likely will be anchorable to a future version, so keep copy as is.

Until you can anchor it, include Note to Reviewers along these lines:

“This claim has not been anchored due to the lack of inclusion of KN-689 in the QLEX label. To reduce churn, we are keeping this claim worded as is in the event that future QLEX labels include the 689 and other Keytruda indication updates. Post approval, this claim will align to the label.”]

[Don’t include KEYTRUDA anchors either until QLEX PI is anchorable.]

[KEYTRUDA QLEX Draft PI FPI-14321 (v6.0): 1.1A, 1.1B, 1.2A, 1.2B, 1.2C, 1.2D, 1.2E, 1.2F, 1.3A, 1.4A, 1.4B, 1.4C, 1.5A (p. 4), 1.5B, 1.5C, 1.6A, 1.7A, 1.8A, 1.8B, 1.8C, 1.9A, 1.10A, 1.10B (p. 5), 1.10C, 1.11A, 1.12A, 1.13A, 1.14A, 1.14B, 1.14C, 1.15A, 1.15B, 1.15C, 1.16A, 1.16B, 1.16C (p. 6), 1.17A, 1.18A, 1.18B (p. 7)]

[KEYTRUDA PI r091 FPI-14997: 1.1A, 1.1B, 1.2A, 1.2B, 1.2C, 1.2D, 1.2E, 1.2F, 1.3A, 1.4A, 1.4B, 1.4C (p. 4), 1.4D, 1.5A, 1.5B, 1.6A, 1.7A, 1.7B, 1.7C, 1.8A, 1.9A, 1.10A, 1.10B, 1.11A (p. 5); 1.11A, 1.12A, 1.12B, 1.12C, 1.13A, 1.14A, 1.15A, 1.16A, 1.16B, 1.16C, 1.17A, 1.17B, 1.17C (p. 6); 1.18A, 1.19A, 1.20A, 1.20B (p. 7)]

[body copy]

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

[KEYTRUDA PI r091 FPI-14997 1.16C; KEYTRUDA QLEX Draft PI Draft PI FPI-14321 (v6.0) 1.14C]

[expandable SSI. Contraindications and first bullet of SSI body are visible in initial view.]

[subhead]

Selected Safety Information

**Contraindications**

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

[SSI 1]

**Severe and Fatal Immune-Mediated Adverse Reactions**

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

Monitor patients closely for symptoms and signs that may be clinical manifestations of underlying immune-mediated adverse reactions. Early identification and management are essential to ensure safe use of anti–PD-1/PD-L1 treatments. Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. In cases of suspected immune-mediated adverse reactions, initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate.

Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity of the immune-mediated adverse reaction. In general, if KEYTRUDA and KEYTRUDA QLEX require interruption or discontinuation, administer systemic corticosteroid therapy (1 to 2 mg/kg/day prednisone or equivalent) until improvement to Grade 1 or less. Upon improvement to Grade 1 or less, initiate corticosteroid taper and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants in patients whose adverse reactions are not controlled with corticosteroid therapy.

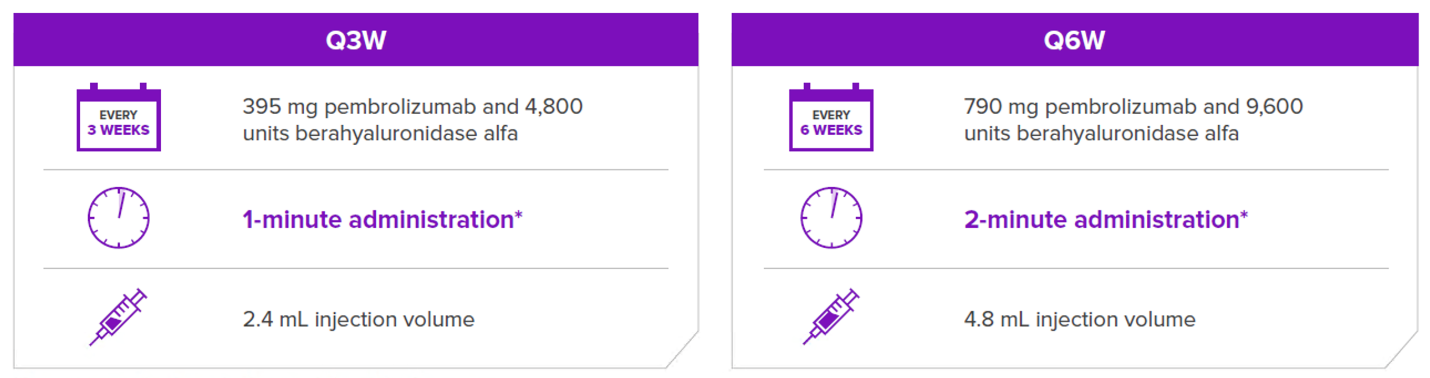
[SSI 2]

*Selected Safety Information continues below.*

[carousel card 1]

KEYTRUDA QLEX can be administered in as little as 1 minute

[KEYTRUDA QLEX Draft PI PI FPI-14321 (v6.0) 2.2A (p. 8), 2.3A (p. 8), 2.3A (p. 9), 2.3A (p. 10), 2.3A (p. 11)]



[KEYTRUDA QLEX Draft PI FPI-14321 (v6.0) 2.2A (p. 8), 2.3A (p. 8), 2.3A (p. 9), 2.3A (p. 10), 2.3A (p. 11)]

Q3W

[EVERY 3 WEEKS icon] pembrolizumab 395 mg and berahyaluronidase alfa 4,800 units

[clock icon] Administered over 1 minute\*

[syringe with lower dose icon] 2.4 mL injection volume

Q6W

[EVERY 6 WEEKS icon] pembrolizumab 790 mg and berahyaluronidase alfa 9,600 units

[clock icon] Administered over 2 minutes\*

[syringe with higher dose icon] 4.8 mL injection volume

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

Tap arrows to see more.

[carousel card 2]

[based on page 13 of Parent PDF dated 8/11]

Give your patients a choice of where you administer their treatment

Two subcutaneous injection-site options: abdomen or thigh

KEYTRUDA QLEX can only be administered by a healthcare provider.

[KEYTRUDA QLEX Draft PI FPI-14321 (v6.0) 2.2A (p. 8)] – Covers preceding 2 sentences.

A diagram of a person's body

AI-generated content may be incorrect.

[KEYTRUDA QLEX Draft PI FPI-14321 (v6.0) 2.2A (p. 8)]

Tap arrows to see more.

[carousel card 3]

Important Dosage and Administration Information

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

[KEYTRUDA QLEX Draft PI FPI-14321 (v6.0) 2.2A (p. 8)]

Tap arrows to see more.

[**Jason**: Delete this static box]

~~[static]~~

~~For the adjuvant treatment of RCC:~~

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

[KEYTRUDA QLEX Draft PI FPI-14321 (v6.0) 2.3A (p. 8), 2.3A (p. 9), 2.3A (p. 10), 2.3A (p. 11)]

[new static element above CTA box]

[based on page 8 of 7/7 PDF]

[**Jason**: Replace icon below with syringe and IV bag icon]



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

[KEYTRUDA QLEX Draft PI FPI-14321 (v6.0) 2.2A (p. 8)]

[static box]

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

[KEYTRUDA QLEX Draft PI FPI-14321 (v6.0) 2.2A (p. 8), 2.3A (p. 8), 2.3A (p. 9), 2.3A (p. 10), 2.3A (p. 11)]

[CTA box]

Learn more about clinical data for KEYTRUDA QLEX

[Links to KEYTRUDA QLEX website: US-PDS-00126]

Selected Safety Information *(continued)*

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

Monitor patients closely for symptoms and signs that may be clinical manifestations of underlying immune-mediated adverse reactions. Early identification and management are essential to ensure safe use of anti–PD-1/PD-L1 treatments. Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment. In cases of suspected immune-mediated adverse reactions, initiate appropriate workup to exclude alternative etiologies, including infection. Institute medical management promptly, including specialty consultation as appropriate.

Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity of the immune-mediated adverse reaction. In general, if KEYTRUDA and KEYTRUDA QLEX require interruption or discontinuation, administer systemic corticosteroid therapy (1 to 2 mg/kg/day prednisone or equivalent) until improvement to Grade 1 or less. Upon improvement to Grade 1 or less, initiate corticosteroid taper and continue to taper over at least 1 month. Consider administration of other systemic immunosuppressants in patients whose adverse reactions are not controlled with corticosteroid therapy.

[SSI 2]

Immune-Mediated Pneumonitis

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

[SSI 2a]

Immune-Mediated Colitis

KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated colitis, which may present with diarrhea. Cytomegalovirus infection/reactivation has been reported in patients with corticosteroid-refractory immune-mediated colitis. In cases of corticosteroid-refractory colitis, consider repeating infectious workup to exclude alternative etiologies.

Immune-mediated colitis occurred in 1.7% (48/2799) of patients receiving KEYTRUDA, including Grade 4 (<0.1%), Grade 3 (1.1%), and Grade 2 (0.4%) reactions. Systemic corticosteroids were required in 69% (33/48); additional immunosuppressant therapy was required in 4.2% of patients. Colitis led to permanent discontinuation of KEYTRUDA in 0.5% (15) and withholding in 0.5% (13) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement; of these, 23% had recurrence. Colitis resolved in 85% of the 48 patients. Immune-mediated colitis occurred in 1.2% (3/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 3 (0.8%) and Grade 2 (0.4%) adverse reactions.

[SSI 2b]

Hepatotoxicity and Immune-Mediated Hepatitis

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

[SSI 2c]

Immune-Mediated Endocrinopathies

*Adrenal Insufficiency*

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

[SSI 2e]

*Hypophysitis*

KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated hypophysitis. Hypophysitis can present with acute symptoms associated with mass effect such as headache, photophobia, or visual field defects. Hypophysitis can cause hypopituitarism. Initiate hormone replacement as indicated. Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity.

Hypophysitis occurred in 0.6% (17/2799) of patients receiving KEYTRUDA, including Grade 4 (<0.1%), Grade 3 (0.3%), and Grade 2 (0.2%) reactions. Systemic corticosteroids were required in 94% (16/17) of patients; of these, the majority remained on systemic corticosteroids. Hypophysitis led to permanent discontinuation of KEYTRUDA in 0.1% (4) and withholding in 0.3% (7) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement.

[SSI 2f]

*Thyroid Disorders*

KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated thyroid disorders. Thyroiditis can present with or without endocrinopathy. Hypothyroidism can follow hyperthyroidism. Initiate hormone replacement for hypothyroidism or institute medical management of hyperthyroidism as clinically indicated. Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity.

Thyroiditis occurred in 0.6% (16/2799) of patients receiving KEYTRUDA, including Grade 2 (0.3%). None discontinued, but KEYTRUDA was withheld in <0.1% (1) of patients.

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

Thyroiditis occurred in 0.4% (1/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 2 (0.4%). Hyperthyroidism occurred in 8% (20/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 2 (3.2%). Hypothyroidism occurred in 14% (35/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 2 (11%).

[SSI 2g]

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

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

[SSI 2h]

Immune-Mediated Nephritis With Renal Dysfunction

KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated nephritis.

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

[SSI 2i]

Immune-Mediated Dermatologic Adverse Reactions

KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated rash or dermatitis. Exfoliative dermatitis, including Stevens-Johnson syndrome, drug rash with eosinophilia and systemic symptoms, and toxic epidermal necrolysis, has occurred with anti–PD-1/PD-L1 treatments. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate nonexfoliative rashes. Withhold or permanently discontinue KEYTRUDA and KEYTRUDA QLEX depending on severity.

Immune-mediated dermatologic adverse reactions occurred in 1.4% (38/2799) of patients receiving KEYTRUDA, including Grade 3 (1%) and Grade 2 (0.1%) reactions. Systemic corticosteroids were required in 40% (15/38) of patients. These reactions led to permanent discontinuation in 0.1% (2) and withholding of KEYTRUDA in 0.6% (16) of patients. All patients who were withheld reinitiated KEYTRUDA after symptom improvement; of these, 6% had recurrence. The reactions resolved in 79% of the 38 patients. Immune-mediated dermatologic adverse reactions occurred in 1.6% (4/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 4 (0.8%) and Grade 3 (0.8%) adverse reactions.

[SSI 2j]

Other Immune-Mediated Adverse Reactions

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

[SSI 2k]

**Hypersensitivity and Infusion- or Administration-Related Reactions**

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

[SSI 3]

**Complications of Allogeneic Hematopoietic Stem Cell Transplantation (HSCT)**

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

[SSI 4]

**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.

[SSI 5]

**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.

[SSI 6]

**Adverse Reactions**

In study MK-347A-D77, when KEYTRUDA QLEX was administered with chemotherapy in metastatic non–small cell lung cancer (NSCLC), serious adverse reactions occurred in 39% of patients. Serious adverse reactions in ≥1% of patients who received KEYTRUDA QLEX were pneumonia (10%), thrombocytopenia (4%), febrile neutropenia (4%), neutropenia (2.8%), musculoskeletal pain (2%), pneumonitis (2%), diarrhea (1.6%), rash (1.2%), respiratory failure (1.2%), and anemia (1.2%). Fatal adverse reactions occurred in 10% of patients including pneumonia (3.2%), neutropenic sepsis (2%), death not otherwise specified (1.6%), ~~febrile neutropenia (1.2%),~~ respiratory failure (1.2%), ~~neutropenic sepsis (0.4%),~~ ~~septic shock (0.4%),~~ parotitis (0.4%), pneumonitis (0.4%), pneumothorax (0.4%), pulmonary embolism (0.4%), neutropenic colitis (0.4%), and seizure (0.4%). KEYTRUDA QLEX was permanently discontinued due to an adverse reaction in 16% of 251 patients. Adverse reactions which resulted in permanent discontinuation of KEYTRUDA QLEX in ≥2% of patients included pneumonia ~~(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%).

[SSI 7]

In KEYNOTE-564, when KEYTRUDA was administered as a single agent for the adjuvant treatment of renal cell carcinoma, serious adverse reactions occurred in 20% of patients receiving KEYTRUDA; the serious adverse reactions (≥1%) were acute kidney injury, adrenal insufficiency, pneumonia, colitis, and diabetic ketoacidosis (1% each). Fatal adverse reactions occurred in 0.2% including 1 case of pneumonia. Discontinuation of KEYTRUDA due to adverse reactions occurred in 21% of 488 patients; the most common (≥1%) were increased alanine aminotransferase (ALT) (1.6%), colitis (1%), and adrenal insufficiency (1%). The most common adverse reactions (≥20%) were musculoskeletal pain (41%), fatigue (40%), rash (30%), diarrhea (27%), pruritus (23%), and hypothyroidism (21%).

[SSI 39]

**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.

[SSI 50]

**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.**

[verbatim from US-KEY-09900, DRAFT KEYTRUDA & KEYTRUDA QLEX Combined SSI (v0.12)]

US-PDS-00024 09/25

[**Jason**: update month to 09]