HYPOTHETICAL PATIENT CASE:
Management of Immune-Mediated Hypothyroidism

KEYTRUDA and KEYTRUDA QLEX, as single agents, are each indicated for the treatment of adult patients with Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors who are ineligible for or have elected not to undergo cystectomy.

Donald[a]
76-Year-Old Male

Diagnosed with BCG-unresponsive, high-risk, NMIBC with CIS and papillary tumors; he was ineligible for cystectomy.



Hypothetical patient

Treatment was initiated with KEYTRUDA QLEX as monotherapy, 395 mg/4,800 units[b] Q3W.

Dosage and Administration for Adult Patients With High-Risk BCG-Unresponsive NMIBC:

- KEYTRUDA QLEX must be administered by a health care provider as a subcutaneous injection into the thigh or abdomen, avoiding the 5-cm area around the navel.
- Q3W dosing: Inject 2.4 mL (395 mg pembrolizumab/4,800 units berahyaluronidase alfa) over 1 minute.[c]
- Q6W dosing: Inject 4.8 mL (790 mg pembrolizumab/9,600 units berahyaluronidase alfa) over 2 minutes.[c]
- Treatment should continue until persistent or recurrent high-risk NMIBC, disease progression, unacceptable toxicity, or up to 24 months.

[a]This is a hypothetical patient case, and individual results may vary. [b]mg of pembrolizumab/units of berahyaluronidase alfa. [c]Does not account for all aspects of treatment. Actual clinic time may vary.

Q3W = every 3 weeks; Q6W = every 6 weeks.

SELECTED SAFETY INFORMATION

Contraindications

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

Severe and Fatal Immune-Mediated Adverse Reactions

- KEYTRUDA and KEYTRUDA QLEX are monoclonal antibodies that belong to a class of drugs that bind to either the programmed death receptor-1 (PD-1) or the programmed death ligand 1 (PD-L1), blocking the PD-1/PD-L1 pathway, thereby removing inhibition of the immune response, potentially breaking peripheral tolerance and inducing immune-mediated adverse reactions. Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue, can affect more than one body system simultaneously, and can occur at any time after starting treatment or after discontinuation of treatment. Important immune-mediated adverse reactions listed here may not include all possible severe and fatal immune-mediated adverse reactions.
- Monitor patients closely for symptoms and signs that may be clinical manifestations of underlying immune-mediated adverse reactions. Early identification and management are essential to ensure safe use of anti–PD-1/PD-L1 treatments. Evaluate liver enzymes, creatinine, and thyroid function at baseline and periodically 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.

Before prescribing KEYTRUDA or KEYTRUDA QLEX, please read the additional Selected Safety Information (pages 2–6) and the accompanying Prescribing Information for KEYTRUDA and KEYTRUDA QLEX. The Medication Guides for KEYTRUDA and KEYTRUDA QLEX also are available.

KEYTRUDA® (pembrolizumab) Injection 100 mg | KEYTRUDA Qlex™ pembrolizumab + berahyaluronidase alfa-pmph Subcutaneous Injection | 165 mg + 2,000 units/mL

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 site as KEYTRUDA QLEX.
- Do not administer KEYTRUDA QLEX intravenously.

SELECTED SAFETY INFORMATION *(continued)*

Severe and Fatal Immune-Mediated Adverse Reactions *(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 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% (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.

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.

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.

Before prescribing KEYTRUDA or KEYTRUDA QLEX, please read the additional Selected Safety Information (pages 1 and 3–6) and the accompanying Prescribing Information for KEYTRUDA and KEYTRUDA QLEX. The Medication Guides for KEYTRUDA and KEYTRUDA QLEX also are available.

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Donald[a]
76-Year-Old Male

HYPOTHETICAL PATIENT CASE: **HYPOTHYROIDISM**

Diagnosed with BCG-unresponsive, high-risk, NMIBC with CIS and papillary tumors; he was ineligible for cystectomy.



Hypothetical patient

Baseline lab tests showed normal thyroid function.

- After 2 cycles of KEYTRUDA QLEX, follow-up showed a slightly elevated level of TSH.

As hypothyroidism was a concern, Donald was further observed for changes in thyroid function.

- After 4 cycles of KEYTRUDA QLEX, Donald experienced progressive fatigue and unexplained weight gain.
  - The lab tests revealed a high level of TSH (10.1 uIU/mL) and a low level of free T_4 in the blood.
- Presentation and workup were consistent with Grade 2 hypothyroidism.

	Date Collected	Test	Value	Units	Range
Baseline →	10/28/25	TSH	2.0	uIU/mL	0.4–5.3
	11/18/25	TSH	2.8	uIU/mL	0.4–5.3
Post 2 Cycles →	12/09/25	TSH	**5.6H**	uIU/mL	0.4–5.3
	12/30/25	TSH	**5.5H**	uIU/mL	0.4–5.3
Post 4 Cycles →	1/20/26	TSH	**10.1H**	uIU/mL	0.4–5.3

Representative readout of TSH testing.

Tip! **Patients with hypothyroidism may present with symptoms but can often be asymptomatic; it is important to regularly monitor labs such as TSH levels.[1]**

[a]This is a hypothetical patient case, and individual results may vary.

BCG = Bacillus Calmette-Guerin; CIS = carcinoma in situ; H = high; NMIBC = non-muscle invasive bladder cancer; T_4 = thyroxine; TSH = thyroid-stimulating hormone.

1. Chaker L et al. *Nat Rev Dis Primers.* 2022;8:30.

SELECTED SAFETY INFORMATION *(continued)*

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

Immune-Mediated Endocrinopathies *(continued)*

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.

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.

Before prescribing KEYTRUDA or KEYTRUDA QLEX, please read the additional Selected Safety Information (pages 1, 2, and 4–6) and the accompanying Prescribing Information for KEYTRUDA and KEYTRUDA QLEX. The Medication Guides for KEYTRUDA and KEYTRUDA QLEX also are available.

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Monitoring Immune-Mediated Hypothyroidism

Immune-mediated hypothyroidism:

Evaluate thyroid function at baseline and periodically during treatment.

Remember to ask patients to immediately report new or worsening signs and symptoms of immune-mediated endocrinopathies, which may include:

- Headaches that will not go away or unusual headaches
- Eye sensitivity to light
- Eye problems
- Rapid heartbeat
- Increased sweating
- Extreme tiredness
- Weight gain or weight loss
- Feeling more hungry or thirsty than usual
- Urinating more often than usual
- Hair loss
- Feeling cold
- Constipation
- Deepening voice
- Dizziness or fainting
- Changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness

Hypothyroidism occurred in 14% (35/251) of patients receiving KEYTRUDA QLEX in combination with chemotherapy, including Grade 2 (11%).

SELECTED SAFETY INFORMATION *(continued)*

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

Immune-Mediated Endocrinopathies *(continued)*

Thyroid Disorders (continued)

- 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%).

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

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

Immune-Mediated Nephritis With Renal Dysfunction

- KEYTRUDA and KEYTRUDA QLEX can cause immune-mediated nephritis.
- Immune-mediated nephritis occurred in 0.3% (9/2799) of patients receiving KEYTRUDA, including Grade 4 (<0.1%), Grade 3 (0.1%), and Grade 2 (0.1%) reactions. Systemic corticosteroids were required in 89% (8/9) of patients. Nephritis led to permanent discontinuation of KEYTRUDA in 0.1% (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 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.

Before prescribing KEYTRUDA or KEYTRUDA QLEX, please read the additional Selected Safety Information (pages 1–3, 5, and 6) and the accompanying Prescribing Information for KEYTRUDA and KEYTRUDA QLEX. The Medication Guides for KEYTRUDA and KEYTRUDA QLEX also are available.

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Managing Immune-Mediated Hypothyroidism

Severity[a]	Dosage Modification Based on Prescribing Information for KEYTRUDA QLEX
Grade 1	**Initiate** hormone replacement for hypothyroidism as clinically indicated.
Grade 2	**Initiate** hormone replacement for hypothyroidism as clinically indicated.
Grade 3	**Initiate** hormone replacement and **withhold** until clinically stable, or **permanently discontinue** KEYTRUDA QLEX depending on severity.
Grade 4	**Initiate** hormone replacement and **withhold** until clinically stable, or **permanently discontinue** KEYTRUDA QLEX depending on severity.



Donald
Hypothetical patient

Results

- Donald's hypothyroidism was treated with thyroid replacement therapy while treatment with KEYTRUDA QLEX was continued.
- Three cycles later, his free T_4 increased to normal levels, his TSH levels were back to normal, and he had symptom improvement.
- Treatment with KEYTRUDA QLEX was continued while TSH and free T_4 levels were monitored.

	Date Collected	Test	Value	Units	Range
Baseline →	10/28/25	TSH	2.0	uIU/mL	0.4–5.3
	11/18/25	TSH	2.8	uIU/mL	0.4–5.3
Post 2 Cycles →	12/09/25	TSH	**5.6H**	uIU/mL	0.4–5.3
	12/30/25	TSH	**5.5H**	uIU/mL	0.4–5.3
Post 4 Cycles →	01/20/26	TSH	**10.1H**	uIU/mL	0.4–5.3
	02/10/26	TSH	**8.3H**	uIU/mL	0.4–5.3
	03/03/26	TSH	**7.9H**	uIU/mL	0.4–5.3
Post 7 Cycles →	03/24/26	TSH	3.0	uIU/mL	0.4–5.3

Representative readout of TSH testing.

[a]The severity grades for adverse reactions are based on Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.

H = high; T_4 = thyroxine; TSH = thyroid-stimulating hormone.

SELECTED SAFETY INFORMATION *(continued)*

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

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; *Other*: Myocarditis-Myositis-Myasthenia Gravis (or Myasthenia-Like) Overlap syndrome, reported as the co-occurrence of either two or all three adverse reactions.

Before prescribing KEYTRUDA or KEYTRUDA QLEX, please read the additional Selected Safety Information (pages 1–4 and 6) and the accompanying Prescribing Information for KEYTRUDA and KEYTRUDA QLEX. The Medication Guides for KEYTRUDA and KEYTRUDA QLEX also are available.

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SELECTED SAFETY INFORMATION *(continued)*

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.

Complications of Allogeneic Hematopoietic Stem Cell Transplantation (HSCT)

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

Increased Mortality in Patients With Multiple Myeloma

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

Embryofetal Toxicity

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

Adverse Reactions

- In study MK-3475A-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%), respiratory failure (1.2%), 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 and pneumonitis. Dosage interruptions of KEYTRUDA QLEX due to an adverse reaction occurred in 45% of patients. Adverse reactions which required dosage interruption in ≥2% of patients included neutropenia, anemia, thrombocytopenia, pneumonia, rash, and increased aspartate aminotransferase. The most common adverse reactions (≥20%) were nausea (25%), fatigue (25%), and musculoskeletal pain (21%).
- In KEYNOTE-057, KEYTRUDA was discontinued due to adverse reactions in 11% of 148 patients with high-risk NMIBC. The most common adverse reaction resulting in permanent discontinuation of KEYTRUDA was pneumonitis (1.4%). Serious adverse reactions occurred in 28% of patients; those ≥2% were pneumonia (3%), cardiac ischemia (2%), colitis (2%), pulmonary embolism (2%), sepsis (2%), and urinary tract infection (2%). The most common adverse reactions (≥20%) were fatigue (29%), diarrhea (24%), and rash (24%).

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 additional Selected Safety Information (pages 1–5) and the accompanying Prescribing Information for KEYTRUDA and KEYTRUDA QLEX. The Medication Guides for KEYTRUDA and KEYTRUDA QLEX also are available.

For additional copies of the Prescribing Information, please call 800-672-6372, visit keytrudahcp.com/qlex, or contact your Merck representative.

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