UK-PEN-0000-DEUK Anti-Approved Drawing

Hands Free

NOW APPROVED

KEYTRUDA QSub
(pembrolizumab/hyaluronidase) 2400 mg/20,000 units solution for subcutaneous injection

KEYTRUDA QSUB is approved for adult patients across all KEYTRUDA (pembrolizumab) solid tumor indications

- One such indication for KEYTRUDA QSub or KEYTRUDA is in combination with pemetrexed and platinum chemotherapy, as compared with the first-line treatment of patients with metastatic nonsquamous non-small cell lung cancer (NSCLC), with no EGFR or ALK genomic tumor aberrations

Selected Safety Information

- KEYTRUDA QSUB and KEYTRUDA are contraindicated in patients with connective tissue disease, ILD, and for enabled tumor mutation or tetanus toxoid, diphtheria, and acellular pertussis vaccine, quin-toxoid or tetanus toxoid, diphtheria, and acellular pertussis vaccine, or any of the excipients of KEYTRUDA QSUB, including hyaluronidase, or anaphylaxis with ever-chum dolore ed hurlad nulla cerebro. Excelsior

Expand to See Selected Safety Information

Selected Safety Information continues below.

Faster Administration Compared to KEYTRUDA

KEYTRUDA QSub Offers a Subcutaneous Administration in 1-2 minutes[1]

Minutes of Administration

KEYTRUDA QSUB	KEYTRUDA
1-2 minutes	30 minutes
SQ administration over 1-2 minutes	IV administration over 30 minutes

1. Based on the ratio of capacity of treatment. Actual clinic time may vary.

Tap arrows to see additional content.

1 / 3

Learn about efficacy for KEYTRUDA QSUB

Selected Safety Information *(continued)*

Immune-Mediated Pneumonitis

- KEYTRUDA can cause immune-mediated pneumonitis. Evaluate patients who have received prior thoracic radiation. Immune-mediated pneumonitis occurred in 2.4% (24/2700) of patients receiving KEYTRUDA, including Grade 5 (1.1%), Grade 4 (0.2%), Grade 3 (0.8%), and Grade 2 (1.2%) reactions. Systemic corticosteroids were required in 19 (0.8%) of patients. Pneumonitis led to permanent discontinuation of KEYTRUDA in 1.1% (29/2700) of patients, withheld in 1.4% of patients. All patients who were withheld KEYTRUDA after symptom improvement, of these, 22% had permanently discontinued or withheld in 59% of the 18 patients.
- Pneumonitis occurred in 3% (81/3850) of patients with resected non-small cell lung cancer (NSCLC) who received KEYTRUDA as a single agent for adjuvant treatment, including Grade 3 (0.3%), Grade 2 (2.3%), and Grade 1 (1%) adverse reactions. Patients received high-dose corticosteroids for a median duration of 15 days (range: 1 day to 2.3 months). Pneumonitis led to discontinuation of KEYTRUDA in 26 (0.3%) of patients, withheld in 1.4% of patients, and permanently discontinued KEYTRUDA, 50% withheld KEYTRUDA, and 71% had recurrence.

Immune-Mediated Colitis

- KEYTRUDA can cause immune-mediated colitis, which may present with diarrhea. Cytomegalovirus infection/reactivation has been reported in patients with immune-mediated colitis. In cases of unknown etiology, infectious colitis should be ruled out before an immune-mediated colitis is confirmed. Immune-mediated colitis occurred in 1.1% (30/2700) of patients receiving KEYTRUDA, including Grade 3 (0.1%), Grade 2 (0.7%), and Grade 1 (0.3%) reactions. Systemic corticosteroids were required in 90% (24/30) of patients. Colitis led to permanent discontinuation of KEYTRUDA in 0.3% (10) of patients, withheld in 0.3% (10) of patients. All patients who were withheld KEYTRUDA after symptom improvement, of these, none had permanently discontinued or withheld in 70% (7) of the 10 patients.

Hepatitis and Immune-Mediated Hepatitis

KEYTRUDA as a Single Agent

- KEYTRUDA can cause immune-mediated hepatitis. Immune-mediated hepatitis occurred in 0.7% (19/2700) of patients receiving KEYTRUDA, including Grade 4 (0.1%), Grade 3 (0.4%), and Grade 2 (0.1%). Twelve (0.4%) patients received KEYTRUDA, including Grade 4 (0.1%), Grade 3 (0.3%), and Grade 2 (0.1%) reactions. Systemic corticosteroids were required in 68% (13/19) of patients. Hepatitis led to permanent discontinuation of KEYTRUDA in 0.3% (8) of patients, withheld in 0.4% (11) of patients. All patients who were withheld KEYTRUDA after symptom improvement, of these, none had permanently discontinued or withheld in 73% (8) of the 11 patients.

Immune-Mediated Endocrinopathies

Adrenal Insufficiency

- KEYTRUDA can cause primary or secondary adrenal insufficiency. For Grade 2 or higher adrenal insufficiency, initiate hormone replacement as clinically indicated. Withhold KEYTRUDA depending on severity. Adrenal insufficiency occurred in 0.6% (20/2700) of patients receiving KEYTRUDA, including Grade 3 (0.3%) and Grade 2 (0.3%) reactions. Systemic corticosteroids were required in 17/20 of patients. Of these, the majority (9/17) of patients resumed corticosteroids. Adrenal insufficiency led to permanent discontinuation of KEYTRUDA in 0.1% (3) of patients, withheld in 0.3% (9) of patients. All patients who were withheld KEYTRUDA after symptom improvement, of these, none had permanently discontinued or withheld in 78% (7) of the 9 patients.

Hypophysitis

- KEYTRUDA 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 hypopituitism. Initiate hormone replacement as indicated. Withhold or permanently discontinue KEYTRUDA depending on severity. Hypophysitis occurred in 0.1% (2/2700) of patients receiving KEYTRUDA, including Grade 4 (0.1%). Grade 3 (0.1%), and Grade 2 (0.1%) reactions. Systemic corticosteroids were required in 2/2 of patients. Hypophysitis led to permanently withheld on systemic corticosteroids. Hypophysitis led to permanent discontinuation of KEYTRUDA in 0.1% (1) and withholding in 0.1% (1) of patients. All patients who were withheld KEYTRUDA after symptom improvement, of these, 33% had permanently discontinued or withheld in 50% of the 2 patients.

Thyroid Disorders

- KEYTRUDA can cause immune-mediated thyroid disorders. Thyroiditis can present with or subsequent hypothyroidism or hyperthyroidism. Initiate hormone replacement as clinically indicated. Withhold or permanently discontinue KEYTRUDA depending on severity. Thyroiditis occurred in 0.3% (8/2700) of patients receiving KEYTRUDA, including Grade 2 (0.3%) reactions. Thyroiditis led to permanent discontinuation of KEYTRUDA in <0.1% (1) of patients, withheld in <0.1% (1) of patients.
- Hypothyroidism occurred in 3.4% (92/2700) of patients receiving KEYTRUDA, including Grade 3 (0.1%), Grade 2 (2.9%), and Grade 1 (0.4%). Hypothyroidism led to permanent discontinuation of KEYTRUDA in <0.1% (1) of patients, withheld in 0.7% (19) of patients who were withheld KEYTRUDA after symptom improvement, of these, none had permanently discontinued or withheld in 37% (7) of patients requiring KEYTRUDA, including Grade 3 (0.1%) and Grade 2 (0.7%) reactions. Hyperthyroidism led to permanent discontinuation of KEYTRUDA in <0.1% (1) of patients, withheld in <0.1% (1) of patients. All patients who were withheld KEYTRUDA after symptom improvement, of these, none had permanently discontinued or withheld in 100% (1) of the 1 patients.

Immune-Mediated Dermatologic Adverse Reactions

- KEYTRUDA 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 therapies. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate nonbullous skin rashes. Withhold or permanently discontinue KEYTRUDA depending on severity. Immune-mediated dermatitis and rash occurred in 0.9% (25/2700) of patients receiving KEYTRUDA, including Grade 3 (0.1%) and Grade 2 (0.7%) reactions. Systemic corticosteroids were required in 48% (12/25) of patients. Dermatitis and rash led to permanent discontinuation of KEYTRUDA in <0.1% (1) of patients, withheld in 0.3% (8) of patients. All patients who were withheld KEYTRUDA after symptom improvement, of these, 63% had recurrence. This reactions resulted in 75% of the 8 patients.

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 or KEYTRUDA QSUB: Guillain-Barré syndrome (<0.1% (1) patients), Sarcoid, or Sarcoid-like lymphadenopathy, Myasthenia syndrome/myasthenia gravis, Vasculitis, Nephritis, Pancreatitis, Uveitis, Myocarditis, Myositis, Pseudomyositis, Polymyalgia rheumatica, Myelitis, Encephalitis, myelitis and demyelination, Autoimmune neuropathies, Hemolytic anemia, Autoimmune hemolysis, Sudden-Onset sensorine, nerve paralysis, autoimmune neuropathy, Hypophysitis, Uveitis, Eye and ocular inflammatory toxicities can cause Sorrie cases can be associated with retinal detachment, Ocular myasthenia, Optic neuritis, Scleritis, Episcleritis, Autoimmune hepatitis, Pancreatitis, Nephritis and other immune-mediated adverse reactions: Hypophysitis, Uveitis, Graves' disease, Autoimmune hemolytic anemia, Immune thrombocytopenic purpura, Autoimmune neutropenia, Autoimmune hemolysis, Sudden-Onset sensorine, nerve paralysis, Guillain-Barré syndrome, Myasthenia syndrome, Myelitis, Demyelination, Myocarditis, Pancreatitis, Hepatitis, Nephritis, Adrenal insufficiency, Hypophysitis, Hypothyroidism, Hyperthyroidism, Type 1 Diabetes Mellitus (DM), Without Clear Pre-exist ing DM, Diabetic Ketoacidosis

- Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Initiate treatment with insulin as clinically indicated. Withhold KEYTRUDA depending on severity. Type 1 DM, including diabetic ketoacidosis, occurred in 0.2% (6/2700) of patients receiving KEYTRUDA. Fourteen (0.5%) patients were withheld KEYTRUDA after symptom improvement. Of these, 36% of the 14 patients permanently discontinued or withheld KEYTRUDA after symptom improvement. Of these, 8% had recurrence. This reactions resulted in 75% of the 6 patients.

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 or KEYTRUDA QSUB: Guillain-Barré syndrome (<0.1% (1) patients), Sarcoid, or Sarcoid-like lymphadenopathy, Myasthenia syndrome/myasthenia gravis, Vasculitis, Nephritis, Pancreatitis, Uveitis, Myocarditis, Myositis, Pseudomyositis, Polymyalgia rheumatica, Myelitis, Encephalitis, myelitis and demyelination, Autoimmune neuropathies, Hemolytic anemia, Autoimmune hemolysis, Sudden-Onset sensorine, nerve paralysis, autoimmune neuropathy, Hypophysitis, Uveitis, Eye and ocular inflammatory toxicities can cause Sorrie cases can be associated with retinal detachment, Ocular myasthenia, Optic neuritis, Scleritis, Episcleritis, Autoimmune hepatitis, Pancreatitis, Nephritis and other immune-mediated adverse reactions: Hypophysitis, Uveitis, Graves' disease, Autoimmune hemolytic anemia, Immune thrombocytopenic purpura, Autoimmune neutropenia, Autoimmune hemolysis, Sudden-Onset sensorine, nerve paralysis, Guillain-Barré syndrome, Myasthenia syndrome, Myelitis, Demyelination, Myocarditis, Pancreatitis, Hepatitis, Nephritis, Adrenal insufficiency, Hypophysitis, Hypothyroidism, Hyperthyroidism, Type 1 Diabetes Mellitus (DM), Without Clear Pre-exist ing DM, Diabetic Ketoacidosis

Infusion-Related Reactions

- KEYTRUDA can cause severe or life-threatening infusion-related reactions, including hypersensitivity and anaphylaxis. Monitor patients for signs and symptoms of infusion-related reactions. Interrupt or slow the rate of infusion in patients with mild or moderate infusion-related reactions. Permanently discontinue KEYTRUDA for Grade 3 or Grade 4 reactions. Infusion-related reactions occurred in 0.4% (12/2700) of patients receiving KEYTRUDA, including Grade 3 (0.1%) and Grade 2 (0.3%) reactions. Systemic corticosteroids were required in 75% (9/12) of patients. Infusion-related reactions led to permanent discontinuation of KEYTRUDA in 0.1% (2) of patients, withheld in 0.3% (8) of patients. All patients who were withheld KEYTRUDA after symptom improvement, of these, 63% had recurrence. This reactions resulted in 50% of the 8 patients.

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 pneumonitis. These complications may occur despite intervening therapy between anti-PD-1/PD-L1 and allogeneic HSCT. Follow patients closely for evidence of these complications and intervene promptly in accordance with standard of care. Long anti-PD-1/PD-L1 treatments prior to allogeneic HSCT may increase risk.

Increased Mortality in Patients With Multiple Myeloma

- In trials in patients with multiple myeloma, the addition of KEYTRUDA to thalidomide analogue plus dexamethasone resulted in increased mortality. Treatment of these patients with KEYTRUDA plus a thalidomide analogue plus dexamethasone is not recommended outside of controlled trials.

Embryofetal Toxicity

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

Adverse Reactions

- In KEYNOTE-054, when KEYTRUDA was administered as a single agent to patients with stage III melanoma, KEYTRUDA delayed permanently discontinued due to adverse reactions in 14% of patients. The most common (≥1%) were pneumonitis (1.4%), colitis (1.2%), and diarrhea (1%). Serious adverse reactions occurred in 25% of patients receiving KEYTRUDA. The most common serious reactions (≥0.2%) were KEYTRUDA was diarrhea (3%), colitis (1.2%), and pneumonitis (0.8%). When administered as a single agent to patients with stage III or IV melanoma, adverse reactions occurring in patients with stage III melanoma were similar to those occurring in 1011 patients with stage IV melanoma from KEYNOTE-006.

- In KEYNOTE-054, the most common adverse reactions for KEYTRUDA as a single agent (reported in ≥20% of patients) were fatigue, musculoskeletal pain, rash, diarrhea, cough, decreased appetite, pruritus, dyspnea, constipation, pain, nausea, upper respiratory tract infection, vomiting, and hypothyroidism.

- Adverse reactions observed in KEYNOTE-054 were generally similar to those occurring in other patients with melanoma who received KEYTRUDA as a single agent, with the exception of hypothyroidism (17%), hypophysitis (1%), and pneumonitis (3%). The most common reactions of myasthenic syndrome, Guillain-Barré syndrome, and myositis were observed in a single agent for the adjuvant treatment of renal cell carcinoma, melanoma, and non-small cell lung cancer. In patients receiving KEYTRUDA, the serious adverse reactions (≥1%) were pneumonitis, colitis, diarrhea, pneumonia, cellulitis, and dehydration. The most common adverse reactions occurred in 21% of patients, the most common (≥2%) were diarrhea (2.5%), colitis (1%), and pneumonitis (1.4%). The most common serious reactions (≥0.5%) were diarrhea (0.5%), colitis (0.5%), and pneumonitis (0.7%). Fatal adverse reactions occurred in 0.4% of patients, including Grade 5 (0.1%) reactions. Systemic corticosteroids were required in 21% of patients, the most common (≥1%) were diarrhea (0.5%), colitis (0.5%), and pneumonitis (0.7%). The most common adverse reactions (≥20%) were musculoskeletal pain (27%), fatigue (26%), rash (20%), diarrhea (20%), and pruritus (20%), and hypothyroidism (21%).

Lactation

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

Pediatric Use

- In KEYNOTE-001, 173 pediatric patients with melanoma, 1 year to less than 18 years old (2 years and 1 month to 17 years old) received KEYTRUDA (2 mg/kg every 3 weeks). The safety of KEYTRUDA was consistent in pediatric patients.

- Adverse reactions that occurred at a ≥10% higher rate in pediatric patients when compared to adults were pyrexia (29%), abdominal pain (17%), upper respiratory tract infection (17%), headache (12%), pruritus (12%), diarrhea (12%), rash (12%), Grade 3 anemia (11%), decreased neutrophil count (11%), and decreased white blood cell count (11%).

Before prescribing KEYTRUDA® pembrolizumab, please read the accompanying Prescribing Information. The Medication Guide also is available.

Contact Us

Ready to start a conversation about KEYTRUDA? Contact Merck today!

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Merck is committed to helping you get your oncology product questions answered. Connect with a Merck Associate now or schedule a call by visiting Ask Merck. Merck Associates are available Monday through Friday, 8 AM to 8 PM ET.

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KEYTRUDA QSub
(pembrolizumab/hyaluronidase) 2400 mg/20,000 units solution for subcutaneous injection

KEYTRUDA QSUB is approved for adult patients across all KEYTRUDA (pembrolizumab) solid tumor indications

- One such indication for KEYTRUDA QSub or KEYTRUDA is in combination with pemetrexed and platinum chemotherapy, as compared with the first-line treatment of patients with metastatic nonsquamous non-small cell lung cancer (NSCLC), with no EGFR or ALK genomic tumor aberrations

Selected Safety Information

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Expand to See Selected Safety Information

Selected Safety Information continues below.

Faster Administration Compared to KEYTRUDA

KEYTRUDA QSub Offers a Subcutaneous Administration in 1-2 minutes[1]

Minutes of Administration

KEYTRUDA QSUB	KEYTRUDA
1-2 minutes	30 minutes
SQ administration over 1-2 minutes	IV administration over 30 minutes

1. Based on the ratio of capacity of treatment. Actual clinic time may vary.

Tap arrows to see additional content.

1 / 3

Learn about efficacy for KEYTRUDA QSUB

Selected Safety Information *(continued)*

Immune-Mediated Pneumonitis

- KEYTRUDA can cause immune-mediated pneumonitis. Evaluate patients who have received prior thoracic radiation. Immune-mediated pneumonitis occurred in 2.4% (24/2700) of patients receiving KEYTRUDA, including Grade 5 (1.1%), Grade 4 (0.2%), Grade 3 (0.8%), and Grade 2 (1.2%) reactions. Systemic corticosteroids were required in 19 (0.8%) of patients. Pneumonitis led to permanent discontinuation of KEYTRUDA in 1.1% (29/2700) of patients, withheld in 1.4% of patients. All patients who were withheld KEYTRUDA after symptom improvement, of these, 22% had permanently discontinued or withheld in 59% of the 18 patients.
- Pneumonitis occurred in 3% (81/3850) of patients with resected non-small cell lung cancer (NSCLC) who received KEYTRUDA as a single agent for adjuvant treatment, including Grade 3 (0.3%), Grade 2 (2.3%), and Grade 1 (1%) adverse reactions. Patients received high-dose corticosteroids for a median duration of 15 days (range: 1 day to 2.3 months). Pneumonitis led to discontinuation of KEYTRUDA in 26 (0.3%) of patients, withheld in 1.4% of patients, and permanently discontinued KEYTRUDA, 50% withheld KEYTRUDA, and 71% had recurrence.

Immune-Mediated Colitis

- KEYTRUDA can cause immune-mediated colitis, which may present with diarrhea. Cytomegalovirus infection/reactivation has been reported in patients with immune-mediated colitis. In cases of unknown etiology, infectious colitis should be ruled out before an immune-mediated colitis is confirmed. Immune-mediated colitis occurred in 1.1% (30/2700) of patients receiving KEYTRUDA, including Grade 3 (0.1%), Grade 2 (0.7%), and Grade 1 (0.3%) reactions. Systemic corticosteroids were required in 90% (24/30) of patients. Colitis led to permanent discontinuation of KEYTRUDA in 0.3% (10) of patients, withheld in 0.3% (10) of patients. All patients who were withheld KEYTRUDA after symptom improvement, of these, none had permanently discontinued or withheld in 70% (7) of the 10 patients.

Hepatitis and Immune-Mediated Hepatitis

KEYTRUDA as a Single Agent

- KEYTRUDA can cause immune-mediated hepatitis. Immune-mediated hepatitis occurred in 0.7% (19/2700) of patients receiving KEYTRUDA, including Grade 4 (0.1%), Grade 3 (0.4%), and Grade 2 (0.1%). Twelve (0.4%) patients received KEYTRUDA, including Grade 4 (0.1%), Grade 3 (0.3%), and Grade 2 (0.1%) reactions. Systemic corticosteroids were required in 68% (13/19) of patients. Hepatitis led to permanent discontinuation of KEYTRUDA in 0.3% (8) of patients, withheld in 0.4% (11) of patients. All patients who were withheld KEYTRUDA after symptom improvement, of these, none had permanently discontinued or withheld in 73% (8) of the 11 patients.

Immune-Mediated Endocrinopathies

Adrenal Insufficiency

- KEYTRUDA can cause primary or secondary adrenal insufficiency. For Grade 2 or higher adrenal insufficiency, initiate hormone replacement as clinically indicated. Withhold KEYTRUDA depending on severity. Adrenal insufficiency occurred in 0.6% (20/2700) of patients receiving KEYTRUDA, including Grade 3 (0.3%) and Grade 2 (0.3%) reactions. Systemic corticosteroids were required in 17/20 of patients. Of these, the majority (9/17) of patients resumed corticosteroids. Adrenal insufficiency led to permanent discontinuation of KEYTRUDA in 0.1% (3) of patients, withheld in 0.3% (9) of patients. All patients who were withheld KEYTRUDA after symptom improvement, of these, none had permanently discontinued or withheld in 78% (7) of the 9 patients.

Hypophysitis

- KEYTRUDA 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 hypopituitism. Initiate hormone replacement as indicated. Withhold or permanently discontinue KEYTRUDA depending on severity. Hypophysitis occurred in 0.1% (2/2700) of patients receiving KEYTRUDA, including Grade 4 (0.1%), Grade 3 (0.1%), and Grade 2 (0.1%) reactions. Systemic corticosteroids were required in 2/2 of patients. Hypophysitis led to permanently withheld on systemic corticosteroids. Hypophysitis led to permanent discontinuation of KEYTRUDA in 0.1% (1) and withholding in 0.1% (1) of patients. All patients who were withheld KEYTRUDA after symptom improvement, of these, 33% had permanently discontinued or withheld in 50% of the 2 patients.

Thyroid Disorders

- KEYTRUDA can cause immune-mediated thyroid disorders. Thyroiditis can present with or subsequent hypothyroidism or hyperthyroidism. Initiate hormone replacement as clinically indicated. Withhold or permanently discontinue KEYTRUDA depending on severity. Thyroiditis occurred in 0.3% (8/2700) of patients receiving KEYTRUDA, including Grade 2 (0.3%) reactions. Thyroiditis led to permanent discontinuation of KEYTRUDA in <0.1% (1) of patients, withheld in <0.1% (1) of patients.
- Hypothyroidism occurred in 3.4% (92/2700) of patients receiving KEYTRUDA, including Grade 3 (0.1%), Grade 2 (2.9%), and Grade 1 (0.4%). Hypothyroidism led to permanent discontinuation of KEYTRUDA in <0.1% (1) of patients, withheld in 0.7% (19) of patients who were withheld KEYTRUDA after symptom improvement, of these, none had permanently discontinued or withheld in 37% (7) of patients requiring KEYTRUDA, including Grade 3 (0.1%) and Grade 2 (0.7%) reactions. Hyperthyroidism led to permanent discontinuation of KEYTRUDA in <0.1% (1) of patients, withheld in <0.1% (1) of patients. All patients who were withheld KEYTRUDA after symptom improvement, of these, 100% had permanently discontinued or withheld in 100% (1) of the 1 patients.

Type 1 Diabetes Mellitus (DM), Without Clear Pre-exist ing DM, Diabetic Ketoacidosis

- Monitor patients for hyperglycemia or other signs and symptoms of diabetes. Initiate treatment with insulin as clinically indicated. Withhold KEYTRUDA depending on severity. Type 1 DM, including diabetic ketoacidosis, occurred in 0.2% (6/2700) of patients receiving KEYTRUDA. Fourteen (0.5%) patients were withheld KEYTRUDA after symptom improvement. Of these, 36% of the 14 patients permanently discontinued or withheld KEYTRUDA after symptom improvement. Of these, 8% had recurrence. This reactions resulted in 75% of the 6 patients.

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 or KEYTRUDA QSUB: Guillain-Barré syndrome (<0.1% (1) patients), Sarcoid, or Sarcoid-like lymphadenopathy, Myasthenia syndrome/myasthenia gravis, Vasculitis, Nephritis, Pancreatitis, Uveitis, Myocarditis, Myositis, Pseudomyositis, Polymyalgia rheumatica, Myelitis, Encephalitis, myelitis and demyelination, Autoimmune neuropathies, Hemolytic anemia, Autoimmune hemolysis, Sudden-Onset sensorine, nerve paralysis, autoimmune neuropathy, Hypophysitis, Uveitis, Eye and ocular inflammatory toxicities can cause Sorrie cases can be associated with retinal detachment, Ocular myasthenia, Optic neuritis, Scleritis, Episcleritis, Autoimmune hepatitis, Pancreatitis, Nephritis and other immune-mediated adverse reactions: Hypophysitis, Uveitis, Graves' disease, Autoimmune hemolytic anemia, Immune thrombocytopenic purpura, Autoimmune neutropenia, Autoimmune hemolysis, Sudden-Onset sensorine, nerve paralysis, Guillain-Barré syndrome, Myasthenia syndrome, Myelitis, Demyelination, Myocarditis, Pancreatitis, Hepatitis, Nephritis, Adrenal insufficiency, Hypophysitis, Hypothyroidism, Hyperthyroidism, Type 1 Diabetes Mellitus (DM), Without Clear Pre-exist ing DM, Diabetic Ketoacidosis

Infusion-Related Reactions

- KEYTRUDA can cause severe or life-threatening infusion-related reactions, including hypersensitivity and anaphylaxis. Monitor patients for signs and symptoms of infusion-related reactions. Interrupt or slow the rate of infusion in patients with mild or moderate infusion-related reactions. Permanently discontinue KEYTRUDA for Grade 3 or Grade 4 reactions. Infusion-related reactions occurred in 0.4% (12/2700) of patients receiving KEYTRUDA, including Grade 3 (0.1%) and Grade 2 (0.3%) reactions. Systemic corticosteroids were required in 75% (9/12) of patients. Infusion-related reactions led to permanent discontinuation of KEYTRUDA in 0.1% (2) of patients, withheld in 0.3% (8) of patients. All patients who were withheld KEYTRUDA after symptom improvement, of these, 63% had recurrence. This reactions resulted in 50% of the 8 patients.

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 pneumonitis. These complications may occur despite intervening therapy between anti-PD-1/PD-L1 and allogeneic HSCT. Follow patients closely for evidence of these complications and intervene promptly in accordance with standard of care. Long anti-PD-1/PD-L1 treatments prior to allogeneic HSCT may increase risk.

Increased Mortality in Patients With Multiple Myeloma

- In trials in patients with multiple myeloma, the addition of KEYTRUDA to thalidomide analogue plus dexamethasone resulted in increased mortality. Treatment of these patients with KEYTRUDA plus a thalidomide analogue plus dexamethasone is not recommended outside of controlled trials.

Embryofetal Toxicity

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

Adverse Reactions

- In KEYNOTE-054, when KEYTRUDA was administered as a single agent to patients with stage III melanoma, KEYTRUDA delayed permanently discontinued due to adverse reactions in 14% of patients. The most common (≥1%) were pneumonitis (1.4%), colitis (1.2%), and diarrhea (1%). Serious adverse reactions occurred in 25% of patients receiving KEYTRUDA. The most common serious reactions (≥0.2%) were KEYTRUDA was diarrhea (3%), colitis (1.2%), and pneumonitis (0.8%). When administered as a single agent to patients with stage III or IV melanoma, adverse reactions occurring in patients with stage III melanoma were similar to those occurring in 1011 patients with stage IV melanoma from KEYNOTE-006.

- In KEYNOTE-054, the most common adverse reactions for KEYTRUDA as a single agent (reported in ≥20% of patients) were fatigue, musculoskeletal pain, rash, diarrhea, cough, decreased appetite, pruritus, dyspnea, constipation, pain, nausea, upper respiratory tract infection, vomiting, and hypothyroidism.

- Adverse reactions observed in KEYNOTE-054 were generally similar to those occurring in other patients with melanoma who received KEYTRUDA as a single agent, with the exception of hypothyroidism (17%), hypophysitis (1%), and pneumonitis (3%). The most common reactions of myasthenic syndrome, Guillain-Barré syndrome, and myositis were observed in a single agent for the adjuvant treatment of renal cell carcinoma, melanoma, and non-small cell lung cancer. In patients receiving KEYTRUDA, the serious adverse reactions (≥1%) were pneumonitis, colitis, diarrhea, pneumonia, cellulitis, and dehydration. The most common adverse reactions occurred in 21% of patients, the most common (≥2%) were diarrhea (2.5%), colitis (1%), and pneumonitis (1.4%). The most common serious reactions (≥0.5%) were diarrhea (0.5%), colitis (0.5%), and pneumonitis (0.7%). Fatal adverse reactions occurred in 0.4% of patients, including Grade 5 (0.1%) reactions. Systemic corticosteroids were required in 21% of patients, the most common (≥1%) were diarrhea (0.5%), colitis (0.5%), and pneumonitis (0.7%). The most common adverse reactions (≥20%) were musculoskeletal pain (27%), fatigue (26%), rash (20%), diarrhea (20%), and pruritus (20%), and hypothyroidism (21%).

Lactation

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

Pediatric Use

- In KEYNOTE-001, 173 pediatric patients with melanoma, 1 year to less than 18 years old (2 years and 1 month to 17 years old) received KEYTRUDA (2 mg/kg every 3 weeks). The safety of KEYTRUDA was consistent in pediatric patients.

- Adverse reactions that occurred at a ≥10% higher rate in pediatric patients when compared to adults were pyrexia (29%), abdominal pain (17%), upper respiratory tract infection (17%), headache (12%), pruritus (12%), diarrhea (12%), rash (12%), Grade 3 anemia (11%), decreased neutrophil count (11%), and decreased white blood cell count (11%).

Before prescribing KEYTRUDA® pembrolizumab, please read the accompanying Prescribing Information. The Medication Guide also is available.

Contact Us

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