A Treatment Option for Patients With Certain Types of Advanced Triple-Negative Breast Cancer (TNBC)

TNBC: Indication

- KEYTRUDA, in combination with chemotherapy, is indicated for the treatment of patients with locally recurrent unresectable, or metastatic triple-negative breast cancer (TNBC) whose tumors express programmed death-ligand 1 (PD-L1) [Combined Positive Score (CPS) ≥10], as determined by an FDA-approved test.
- This indication is approved under accelerated approval based on progression-free survival. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

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Selected Safety Information

Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue and can affect more than one body system simultaneously. Immune-mediated adverse reactions can occur at any time during or after treatment with KEYTRUDA, including pneumonitis, colitis, hepatitis, endocrinopathies, nephritis, dermatologic reactions, solid organ transplant rejection, and complications of allogeneic hematopoietic stem cell transplantation. Important immune-mediated adverse reactions listed here may not include all possible severe and fatal immune-mediated adverse reactions. Early identification and management of immune-mediated adverse reactions are essential to ensure safe use of KEYTRUDA. Based on the severity of the adverse reaction, KEYTRUDA should be withheld or permanently discontinued and corticosteroids administered if appropriate.

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 for Grade 1 or Grade 2 reactions. For Grade 3 or Grade 4 reactions, stop infusion and permanently discontinue KEYTRUDA.

Based on its mechanism of action, KEYTRUDA can cause **fetal harm when administered to a pregnant woman**. Female patients of reproductive potential should be advised of the potential hazard to a fetus.

For more information regarding adverse reactions, please see the chapter entitled KEYTRUDA: Safety Profile, Monitoring, and Management.

Before prescribing KEYTRUDA® (pembrolizumab), please read the accompanying Prescribing Information. The Medication Guide also is available. Select links to access.

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A Treatment Option for Patients With Certain Types of Advanced Triple-Negative Breast Cancer (TNBC)

Choose a Topic to Begin:

KEYNOTE-355: Study Design, Efficacy, Safety, and Case Study

KEYTRUDA: Safety Profile, Monitoring, and Management

Abbreviations

Prescribing Information

Medication Guide

KEYNOTE-355:
Study Design, Clinical Data, and Safety Profile, and Patient Case

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KEYNOTE-355: Study Design

Multicenter, double-blind, randomized, placebo-controlled study evaluating the efficacy of KEYTRUDA in combination with paclitaxel, paclitaxel protein-bound, or gemcitabine and carboplatin in patients (N=847) with locally recurrent unresectable, or metastatic TNBC, regardless of tumor PD-L1 expression, who had not been previously treated with chemotherapy in the metastatic setting.

Key Inclusion Criteria

- Patients with locally recurrent unresectable or metastatic TNBC, regardless of tumor PD-L1 expression, who had not been previously treated with chemotherapy in the metastatic setting

Key Exclusion Criteria

- Patients with active autoimmune disease that required systemic therapy within 2 years of treatment
- Patients with a medical condition that required immunosuppression

Stratification Factors

- Chemotherapy treatment (paclitaxel or paclitaxel protein-bound vs gemcitabine and carboplatin)
- Tumor PD-L1 expression (CPS ≥1 vs CPS <1), according to the PD-L1 IHC 22C3 pharmDx kit
- Prior treatment with the same class of chemotherapy in the neoadjuvant setting (yes vs no)

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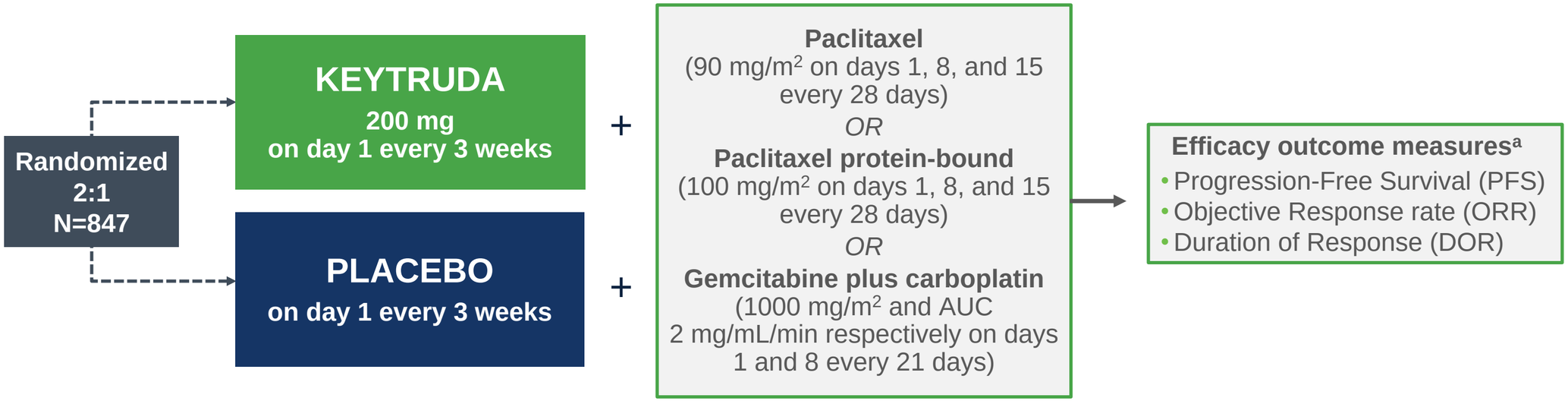
KEYNOTE-355: Study Design *(continued)*

Multicenter, double-blind, randomized, placebo-controlled study evaluating the efficacy of KEYTRUDA in combination with paclitaxel, paclitaxel protein-bound, or gemcitabine and carboplatin in patients (N=847) with locally recurrent unresectable, or metastatic TNBC, regardless of tumor PD-L1 expression, who had not been previously treated with chemotherapy in the metastatic setting.



- Assessment of tumor status was performed at weeks 8, 16, and 24, then every 9 weeks for the first year, and every 12 weeks thereafter.

[a]Assessed by BICR. PFS assessed by BICR according to Response Evaluation Criteria in Solid Tumors (RECIST) v1.1, modified to follow a maximum of 10 target lesions and a maximum of 5 target lesions per organ.

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KEYNOTE-355: Baseline Patient Characteristics (ITT; N=847)

Patient Characteristics	
Age, median (range), years	53 (22-85)
≥65 years of age, %	21
White, %	68
ECOG PS, %	
0	60
1	40
Postmenopausal, %	68
PD-L1 expression, %	
CPS ≥1	75
CPS ≥10	38

PD-L1 Expression (CPS ≥10) in KEYNOTE-355

38% of patients had PD-L1 expression (CPS ≥10) in the KEYNOTE-355 study.

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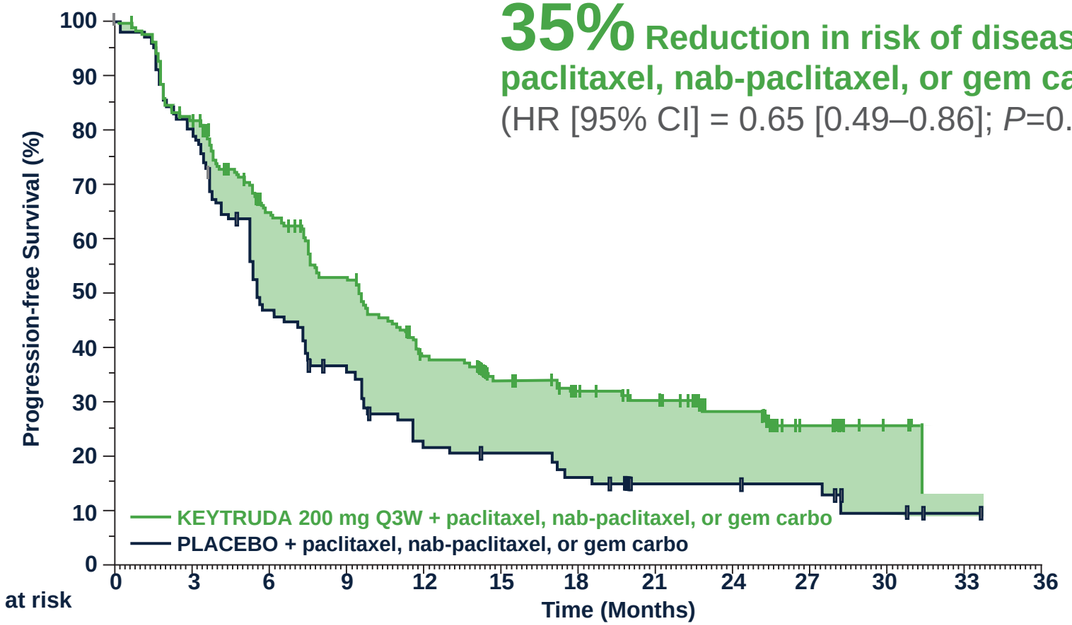
KEYNOTE-355: Progression-Free Survival (PFS) in Patients Whose Tumors Expressed PD-L1 With a CPS ≥10 (n=323)

Kaplan-Meier Estimates of PFS in KEYNOTE-355



No. at risk													
KEYTRUDA 200 mg Q3W + paclitaxel, nab-paclitaxel, or gem carbo	220	173	122	96	63	52	44	37	25	12	5	0	0
PLACEBO + paclitaxel, nab-paclitaxel, or gem carbo	103	80	41	30	18	15	12	8	8	7	3	1	0

35% Reduction in risk of disease progression with KEYTRUDA in combination with paclitaxel, nab-paclitaxel, or gem carbo vs paclitaxel, nab-paclitaxel, or gem carbo alone (HR [95% CI] = 0.65 [0.49–0.86]; *P*=0.0012[a])

- **Median PFS** was 9.7 (95% CI, 7.6–11.3) months with KEYTRUDA + paclitaxel, nab-paclitaxel, or gem carbo and 5.6 (95% CI, 5.3–7.5) months with placebo + paclitaxel, nab-paclitaxel, or gem carbo.
- The **number of patients with an event** was 136 (62%) with KEYTRUDA + paclitaxel, nab-paclitaxel, or gem carbo vs 79 (77%) with placebo + paclitaxel, nab-paclitaxel, or gem carbo.

[a]Hazard ratio based on stratified Cox regression model. One-sided *P* value based on stratified log-rank test.

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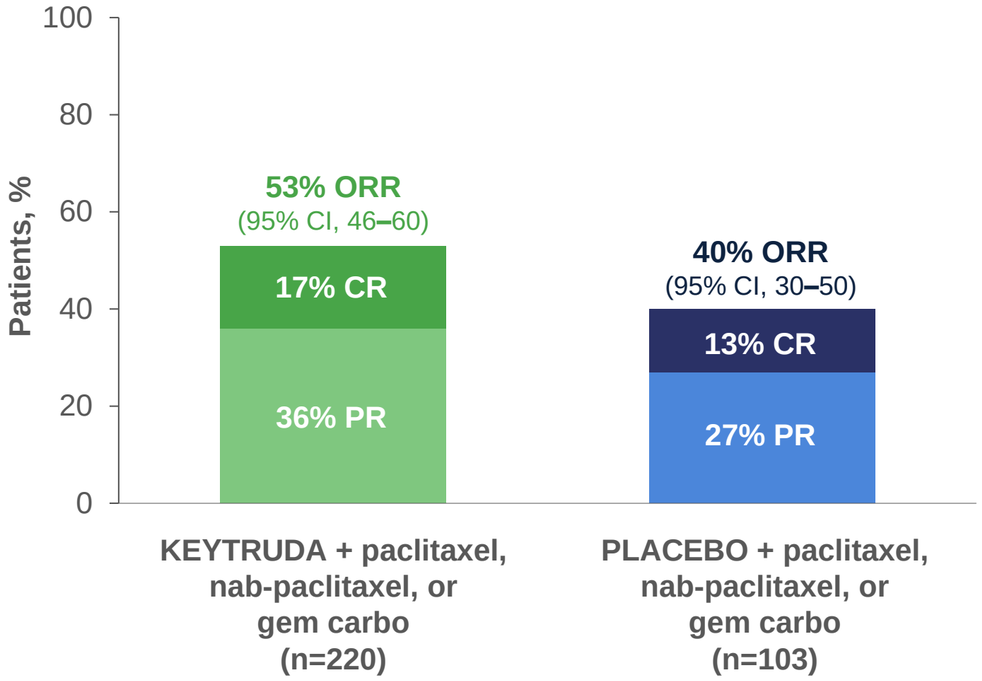
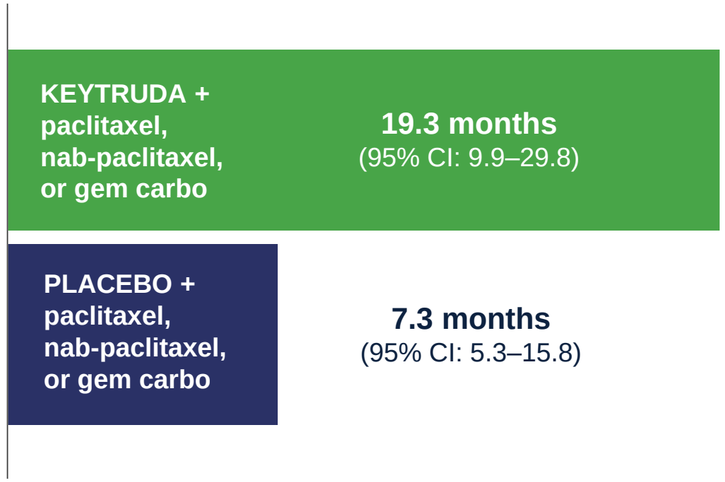
KEYNOTE-355: Response Rates in Patients Whose Tumors Expressed PD-L1 With a CPS ≥10

Objective Response Rate (ORR)



Duration of Response (DOR)



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KEYNOTE-355: Safety Profile (n=596)

Fatal and Serious Adverse Reactions

- Fatal adverse reactions occurred in 2.5% of patients receiving KEYTRUDA in combination with chemotherapy, including cardio-respiratory arrest (0.7%) and septic shock (0.3%).
- Serious adverse reactions occurred in 30% of patients receiving KEYTRUDA in combination with paclitaxel, paclitaxel protein-bound, or gemcitabine and carboplatin. Serious adverse reactions in ≥2% of patients were pneumonia (2.9%), anemia (2.2%), and thrombocytopenia (2%).

Treatment Discontinuation

- KEYTRUDA was discontinued for adverse reactions in 11% of patients.
- The most common adverse reactions resulting in permanent discontinuation of KEYTRUDA (≥1%) were increased ALT (2.2%), increased AST (1.5%), and pneumonitis (1.2%).

Adverse Reactions Leading to Interruption of KEYTRUDA

- Adverse reactions leading to the interruption of KEYTRUDA occurred in 50% of patients.

Most common adverse reactions leading to interruption of KEYTRUDA (≥2%)	
Neutropenia	22%
Thrombocytopenia	14%
Anemia	7%
Increased ALT	6%
Leukopenia	5%
Increased AST	5%
Decreased white blood cell count	3.9%
Diarrhea	2%

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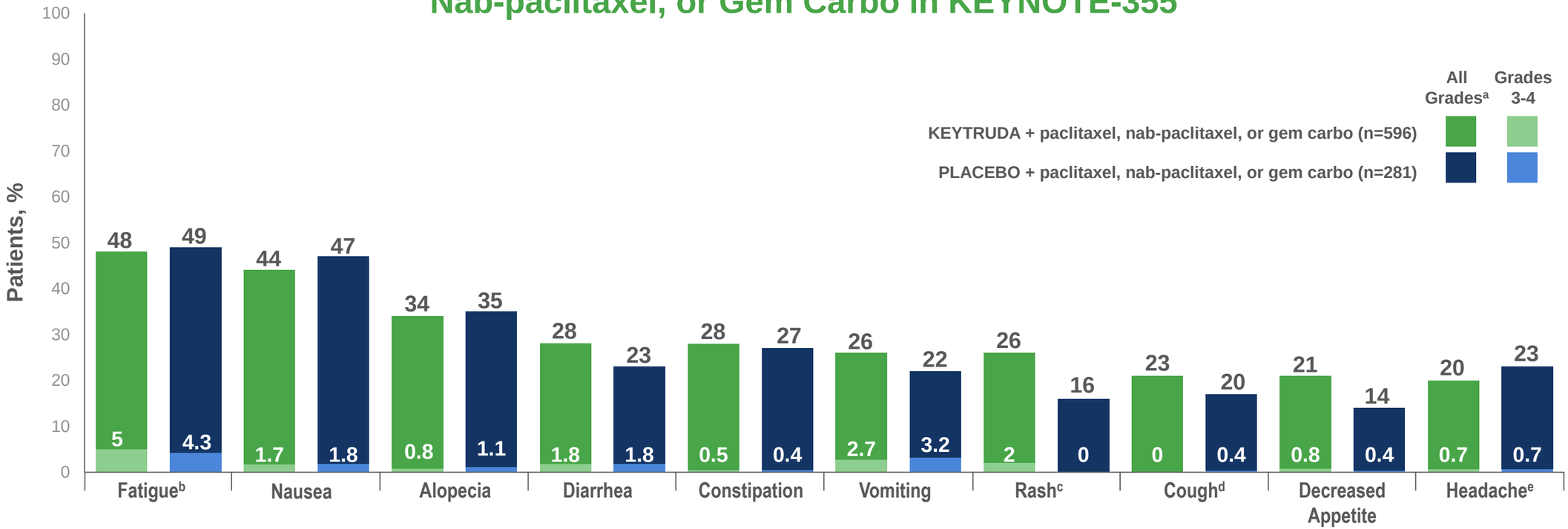
KEYNOTE-355: Safety Profile *(continued)*

Adverse Reactions Occurring in ≥20% of Patients Receiving KEYTRUDA With Paclitaxel, Nab-paclitaxel, or Gem Carbo in KEYNOTE-355



[a]The severity of adverse events was graded according to NCI-CTCAE v4.03. [b]Includes fatigue and asthenia. [c]Includes rash, rash maculo-papular, rash pruritic, rash pustular, rash macular, rash papular, butterfly rash, rash erythematous, and eyelid rash. [d]Includes cough, productive cough, and upper-airway cough syndrome. [e]Includes headache, migraine, and tension headache.

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Case Study: Tanya

Patient History and Initial Diagnosis | Recurrence and Subsequent Diagnosis | Metastatic Treatment | Follow-up

- 52-year-old White female.
- Previously treated for stage IIA breast cancer that has now recurred.
- Menarche at age 10; first child at age 32; BMI 28 kg/m^2.
- Reported a nonpainful lump in the right breast 20 months ago.
- Diagnosed with stage IIA invasive ductal carcinoma.
- Biomarker testing showed:
  - HER2-negative, ER-negative, and PR-negative status.
- Treated with a lumpectomy, subsequent adjuvant dose-dense AC (doxorubicin/cyclophosphamide) and paclitaxel plus whole breast radiation therapy.
- After 3 months, it was determined she was in remission.

Hypothetical patient case

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Case Study: Tanya

Patient History and Initial Diagnosis | **Recurrence and Subsequent Diagnosis** | Metastatic Treatment | Follow-up

- Fourteen months after Tanya entered remission, physical exam revealed a palpable mass in the right breast.
- CT scan: Confirmed recurrence of tumor in the right breast and liver metastases.
- ECOG PS of 0.
- Repeat biomarker testing confirmed:
  - HER2-negative, ER-negative, and PR-negative status.
  - PD-L1–positive[a]; CPS = 12.
- Diagnosis: Stage IV metastatic TNBC.

Hypothetical patient case

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[a]Tumor PD-L1 expression was determined using the PD-L1 IHC 22C3 pharmDx kit.

Case Study: Tanya

Patient History and Initial Diagnosis | Recurrence and Subsequent Diagnosis | **Metastatic Treatment** | Follow-up

Treatment: KEYTRUDA in combination with paclitaxel

Tanya was initiated with **KEYTRUDA** 200 mg IV on day 1 every 3 weeks PLUS **paclitaxel** on days 1, 8, and 15 every 28 days.

Hypothetical patient case

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Case Study: Tanya

Patient History and Initial Diagnosis | Recurrence and Subsequent Diagnosis | Metastatic Treatment | **Follow-up**

- Monitoring for signs and symptoms of adverse reactions was completed as recommended.
- After 3 months of treatment Tanya developed a rash on her back, shoulders, and abdomen and experienced pruritus, burning, and tightness. She found it difficult to perform activities of daily living, including brushing her teeth.
- Dermatology consultation confirmed Grade 3 immune-mediated maculopapular rash.
- Treatment with KEYTRUDA was withheld. Maculopapular rash was treated with both topical and systemic corticosteroids.
- Maculopapular rash improved to Grade 1 over 1 month of treatment. Corticosteroids were tapered over the next month while treatment with KEYTRUDA resumed.
- **On KEYTRUDA plus paclitaxel for 9 months; experiencing an ongoing partial response to treatment.**

Hypothetical patient case

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KEYTRUDA: Safety Profile, Monitoring, and Management

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Severe and Fatal Immune-Mediated Adverse Reactions

KEYTRUDA is a monoclonal antibody that belongs 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 depending on severity of the immune-mediated adverse reaction. In general, if KEYTRUDA requires 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.

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Incidence of Selected Immune-Mediated Adverse Reactions

Adverse Reaction	KEYTRUDA (N=2,799)				
	All Grades % (n)	Grade 2 %	Grade 3 %	Grade 4 %	Fatal %
Pneumonitis	3.4 (94)	1.3	0.9	0.3	0.1
Colitis	1.7 (48)	0.4	1.1	<0.1	--
Hepatitis	0.7 (19)	0.1	0.4	<0.1	--
Adrenal insufficiency	0.8 (22)	0.3	0.3	<0.1	--
Hypophysitis	0.6 (17)	0.2	0.3	<0.1	--
Hyperthyroidism	3.4 (96)	0.8	0.1	--	--
Hypothyroidism	8 (237)	6.2	0.1	--	--
Nephritis	0.3 (9)	0.1	0.1	<0.1	--
Dermatologic adverse reactions	1.4 (38)	0.1	1	--	--

- The incidence of pneumonitis is higher in patients who have received prior thoracic radiation.
- Of 2,799 patients receiving KEYTRUDA, thyroiditis occurred in 16 (0.6%) patients, including Grade 2 (0.3%), and type 1 diabetes mellitus, which can present with diabetic ketoacidosis, occurred in 6 (0.2%) patients.

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Management of Selected Immune-Mediated Adverse Reactions

Adverse Reaction	KEYTRUDA (N=2,799)			
	Permanently Discontinued, % (n)	Withheld, % (n)	Systemic Corticosteroids Required, % (n/N)	Resolution Rate
Pneumonitis	1.3 (36)	0.9 (26)	67 (63/94)	59% of 94
Colitis	0.5 (15)	0.5 (13)	69 (33/48)	85% of 48
Hepatitis	0.2 (6)	0.3 (9)	68 (13/19)	79% of 19
Adrenal insufficiency	<0.1 (1)	0.3 (8)	77 (17/22)	--
Hypophysitis	0.1 (4)	0.3 (7)	94 (16/17)	--
Thyroiditis	0	<0.1 (1)	--	--
Hyperthyroidism	<0.1 (2)	0.3 (7)	--	--
Hypothyroidism	<0.1 (1)	0.5 (14)	--	--
Type 1 diabetes mellitus	<0.1 (1)	<0.1 (1)	--	--
Nephritis	0.1 (3)	0.1 (3)	89 (8/9)	56% of 9
Dermatologic adverse reactions	0.1 (2)	0.6 (16)	40 (15/38)	79% of 38

- Additional immunosuppressant therapy was required in 4.2% of patients with colitis and in 11% of patients with hepatitis.
- Of those with adrenal insufficiency or hypophysitis who required systemic corticosteroids, the majority of patients remained on systemic corticosteroids.
- The majority of patients with hypothyroidism required long-term thyroid hormone replacement.
- All patients with type 1 diabetes mellitus required long-term insulin therapy.
- All patients who were withheld[a] reinitiated KEYTRUDA after symptom improvement; of those:
  - 23% had recurrence of pneumonitis or colitis.
  - None had recurrence of hepatitis or nephritis.
  - 6% had recurrence of dermatologic adverse reactions.

[a]This is applicable to all patients who were withheld KEYTRUDA due to the immune-mediated adverse reactions presented, except thyroiditis.

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Selected Immune-Mediated and Other 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 treatments.

The following **clinically significant immune-mediated adverse reactions** occurred at an incidence of <1% (unless otherwise noted) in patients who received KEYTRUDA 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 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, 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

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Selected Immune-Mediated and Other Adverse Reactions *(continued)*

KEYTRUDA can cause **severe or life-threatening infusion-related reactions**, including hypersensitivity and anaphylaxis, which have been reported in 0.2% of 2,799 patients.

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 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.

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.

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Monitoring and Management of 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 depending on severity of the immune-mediated adverse reaction.

- In general, if KEYTRUDA requires 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.

Toxicity management guidelines for adverse reactions that do not necessarily require systemic steroids (eg, endocrinopathies and dermatologic reactions) are discussed on the following slides.

Additional monitoring and management considerations for selected immune-mediated adverse reactions are also discussed.

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Monitoring and Management of Select Immune-Mediated Adverse Reactions

Adverse Reaction	Monitoring and Management of Patients
Colitis	• Colitis may present with diarrhea. • CMV 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.

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Monitoring and Management of Select Immune-Mediated Adverse Reactions *(continued)*

Adverse Reaction	Monitoring and Management of Patients
Endocrinopathies	
Adrenal insufficiency	• KEYTRUDA can cause primary or secondary adrenal insufficiency. • For Grade 2 or higher adrenal insufficiency, initiate symptomatic treatment, including hormone replacement as clinically indicated. Withhold KEYTRUDA depending on severity.
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 depending on severity.
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 depending on severity.
Type 1 diabetes mellitus	• Type 1 diabetes mellitus 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 depending on severity.

Monitoring and Management of Select Immune-Mediated Adverse Reactions *(continued)*

Adverse Reaction	Monitoring and Management of Patients
Dermatologic adverse reactions	• Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate nonexfoliative rashes. Withhold or permanently discontinue KEYTRUDA depending on severity.
Other immune-mediated adverse reactions ***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.

Infusion-Related Reactions

Adverse Reaction	Monitoring and Management of Patients
Infusion-related reactions	• Monitor for signs and symptoms of infusion-related reactions, including rigors, chills, wheezing, pruritus, flushing, rash, hypotension, hypoxemia, and fever. • For Grade 1 or Grade 2 reactions, interrupt or slow the rate of infusion. • For Grade 3 or Grade 4 reactions, stop infusion and permanently discontinue KEYTRUDA.

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Complications of Allogeneic Hematopoietic Stem Cell Transplantation (HSCT)

Allogeneic HSCT before or after anti–PD-1/PD-L1 treatments

Monitoring Patients

- Follow patients closely for evidence of transplant-related complications such as hyperacute GVHD, acute and chronic GVHD, hepatic VOD, and steroid-requiring febrile syndrome.

Management of Patients

- Intervene promptly.

- Consider the benefit vs risks of using anti–PD-1/PD-L1 treatments prior to or after an allogeneic HSCT.

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Use in Specific Populations

Pregnancy

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 prior to initiating KEYTRUDA and advise them to use effective contraception during treatment and for 4 months after the last dose.

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 final dose.

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Abbreviations

A
ALT = alanine aminotransferase
AST = aspartate aminotransferase
AUC = area under the curve

B
BICR = blinded independent central review
BMI = body mass index

C
CI = confidence interval
CPS = combined positive score
CR = complete response
CT = computed tomography

D
DOR = duration of response

E
ECOG PS = Eastern Cooperative Oncology Group Performance Status
ER = estrogen receptor

F
FDA = US Food and Drug Administration

G
gem carbo = gemcitabine and carboplatin
GVHD = graft-versus-host disease

H
HER2 = human epidermal growth factor receptor 2
HR = hazard ratio
HSCT = hematopoietic stem cell transplantation

I
IHC = immunohistochemistry
ITT = intention-to-treat
IV = intravenous

N
nab-paclitaxel = paclitaxel protein-bound
NCI CTCAE = National Cancer Institute Common Terminology Criteria for Adverse Events

O
ORR = objective response rate

P
PD-1 = programmed death receptor-1
PD-L1 = programmed death ligand 1
PFS = progression-free survival
PR = partial response

Q
Q3W = every 3 weeks

R
RECIST v1.1 = Response Evaluation Criteria In Solid Tumors v1.1

S
SJS = Stevens-Johnson syndrome

T
TEN = toxic epidermal necrolysis
TNBC = triple-negative breast cancer

V
VOD = veno-occlusive disease

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