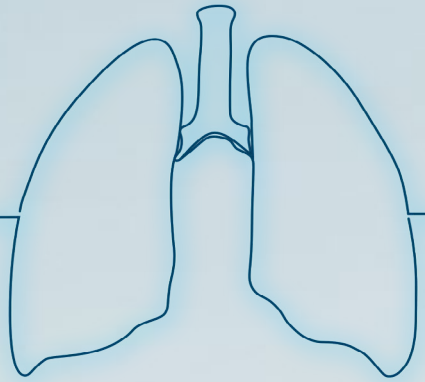


SECOND LINE IS A SECOND CHANCE FOR SURVIVAL[1,2*]

OPDIVO® (nivolumab): *5 years of OS data in 2L mNSCLC*[1,2]

INDICATION

OPDIVO is indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with progression on or after platinum-based chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving OPDIVO.

In the primary analysis for CM 057 and CM 017, the median OS was 12.2 months (95% CI: 9.7–15.0) with OPDIVO vs 9.4 months (95% CI: 8.0–10.7) with docetaxel (HR=0.73 [95% CI: 0.60–0.89] *P*=0.0015), and 9.2 months (95% CI: 7.3–13.3) with OPDIVO vs 6.0 months (95% CI: 5.1–7.3) with docetaxel (HR=0.59 [95% CI: 0.44–0.79] *P*=0.0002), respectively. In a pooled analysis of CM 057 and CM 017, the median OS was 11.1 months (95% CI: 9.2–13.1) with OPDIVO vs 8.1 months (95% CI: 7.2–9.2) with docetaxel (HR=0.68, 95% CI: 0.59–0.78); the landmark 5-year OS rate with OPDIVO was 13.4% vs 2.6% with docetaxel.[1,2]

*Vs docetaxel.[2]

2L=second line; ALK=anaplastic lymphoma kinase; CI=confidence interval; CM=Checkmate; EGFR=epidermal growth factor receptor; HR=hazard ratio; mNSCLC=metastatic NSCLC; OS=overall survival.

SELECT IMPORTANT SAFETY INFORMATION

Summary of Warnings and Precautions

- OPDIVO is associated with the following Warnings and Precautions: severe and fatal immune-mediated adverse reactions including pneumonitis, colitis, hepatitis and hepatotoxicity, endocrinopathies, nephritis with renal dysfunction, dermatologic adverse reactions, other immune-mediated adverse reactions; infusion-related reactions; complications of allogeneic hematopoietic stem cell transplantation (HSCT); embryo-fetal toxicity; and increased mortality in patients with multiple myeloma when OPDIVO is added to a thalidomide analogue and dexamethasone, which is not recommended outside of controlled clinical trials.

Severe and Fatal Immune-Mediated Adverse Reactions

- Immune-mediated adverse reactions listed herein may not include all possible severe and fatal immune-mediated adverse reactions.
- Immune-mediated adverse reactions, which may be severe or fatal, can occur in any organ system or tissue. While immune-mediated adverse reactions usually manifest during treatment, they can also occur after discontinuation of OPDIVO. Early identification and management are essential to ensure safe use of OPDIVO. Monitor for signs and symptoms that may be clinical manifestations of underlying immune-mediated adverse reactions. Evaluate clinical chemistries including liver enzymes, creatinine, and thyroid function at baseline and periodically during treatment with OPDIVO. 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 OPDIVO depending on severity (please see section 2 Dosage and Administration in the accompanying Full Prescribing Information). In general, if OPDIVO interruption or discontinuation is required, 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 immune-mediated adverse reactions are not controlled with corticosteroid therapy. Toxicity management guidelines for adverse reactions that do not necessarily require systemic steroids (e.g., endocrinopathies and dermatologic reactions) are discussed below.

Please see additional Important Safety Information throughout this brochure and US Full Prescribing Information for OPDIVO.

OPDIVO® (nivolumab)
INJECTION FOR INTRAVENOUS USE 10 mg/mL

In previously treated non-squamous and squamous mNSCLC

OPDIVO® (nivolumab): the only I-O therapy to achieve superior OS vs chemotherapy* in two phase 3 studies designed to include PD-L1 expressors and non-expressors[1,3]

NON-SQUAMOUS†	SQUAMOUS†
Checkmate 057: OPDIVO (n=292) vs docetaxel (n=290)	Checkmate 017: OPDIVO (n=135) vs docetaxel (n=137)
Superior OS[1]	**Superior OS[1]**
OPDIVO mOS 12.2 months (95% CI: 9.7–15.0)	**OPDIVO mOS 9.2 months** (95% CI: 7.3–13.3)
Docetaxel mOS 9.4 months (95% CI: 8.0–10.7)	**Docetaxel mOS 6.0 months** (95% CI: 5.1–7.3)
HR=0.73, 95% CI: 0.60–0.89; *P*=0.0015	**HR=0.59**, 95% CI: 0.44–0.79; *P*=0.0002

Both trials stopped early due to superior OS[4,5]

More patients treated in 2L mNSCLC than any other I-O therapy[1,6]

NON-SQUAMOUS[1]

- OPDIVO ORR was 19% (4 CRs, 95% CI: 15–24) vs 12% with docetaxel (1 CR, 95% CI: 9–17), *P*=0.02
- mPFS was 2.3 months with OPDIVO vs 4.2 months with docetaxel; HR=0.92 (95% CI: 0.77–1.11), *P*=0.39

SQUAMOUS[1]

- OPDIVO ORR was 20% (1 CR, 95% CI: 14–28) vs 9% with docetaxel (0 CRs, 95% CI: 5–15), *P*=0.0083
- mPFS was 3.5 months with OPDIVO vs 2.8 months with docetaxel; HR=0.62 (95% CI: 0.47–0.81), *P*=0.0004

CM 057 (NSQ) and CM 017 (SQ) mNSCLC study designs: two registrational, phase 3, randomized (1:1), open-label studies, separated by histology, of OPDIVO 3 mg/kg IV over 60 minutes q2w‡ (n=292 for CM 057; n=135 for CM 017) versus docetaxel 75 mg/m^2 q3w (n=290 for CM 057; n=137 for CM 017) in patients with mNSCLC who had experienced disease progression on or after one prior platinum-based chemotherapy regimen and appropriate targeted therapy in patients with known sensitizing *EGFR* mutation or *ALK* translocation. The primary endpoint for both studies was OS; secondary endpoints included ORR and PFS.[1,7,8]

*Vs docetaxel.[1]

†Results were based on the pre-specified interim analysis. Minimum follow-up of 11 months for Checkmate 017 and 13.2 months for Checkmate 057.[1,7,8]

‡The recommended dose of OPDIVO is either 240 mg every 2 weeks or 480 mg every 4 weeks administered as an IV infusion over 30 minutes until disease progression or unacceptable toxicity.[1]

CR=complete response; I-O=immuno-oncology; IV=intravenous; mOS=median OS; mPFS=median PFS; NSQ=non-squamous; ORR=overall response rate; PD-L1=programmed death ligand 1; PFS=progression-free survival; q2w=every 2 weeks; q3w=every 3 weeks; SQ=squamous.

SELECT IMPORTANT SAFETY INFORMATION

Serious Adverse Reactions

- In Checkmate 017 and 057, serious adverse reactions occurred in 46% of patients receiving OPDIVO (n=418). The most frequent serious adverse reactions reported in ≥2% of patients receiving OPDIVO were pneumonia, pulmonary embolism, dyspnea, pyrexia, pleural effusion, pneumonitis, and respiratory failure. In Checkmate 057, fatal adverse reactions occurred; these included events of infection (7 patients, including one case of *Pneumocystis jirovecii* pneumonia), pulmonary embolism (4 patients), and limbic encephalitis (1 patient).

Common Adverse Reactions

- In Checkmate 017 and 057, the most common adverse reactions (≥20%) in patients receiving OPDIVO (n=418) were fatigue, musculoskeletal pain, cough, dyspnea, and decreased appetite.

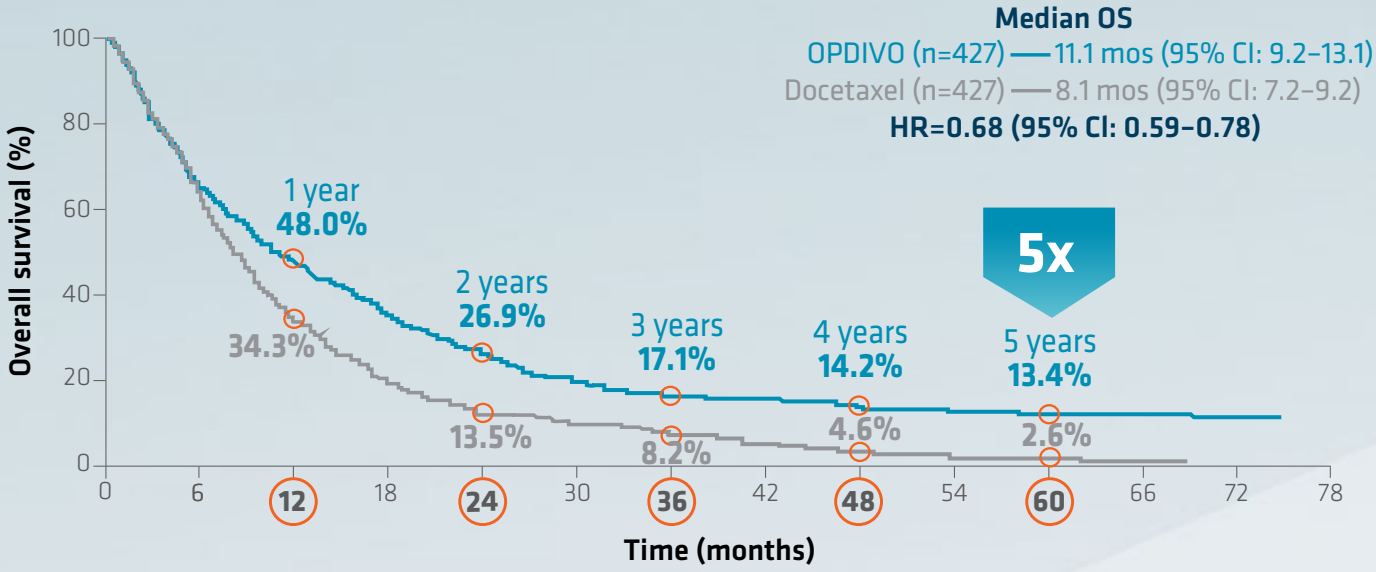
Please see additional Important Safety Information throughout this brochure and US Full Prescribing Information for OPDIVO.

OPDIVO® (nivolumab)
INJECTION FOR INTRAVENOUS USE 10 mg/mL

In a pooled analysis of two phase 3 trials

OPDIVO® (nivolumab) showed long-term 5-year OS in non-squamous and squamous mNSCLC[2]*

Pooled 5-year extended overall survival analysis[2†‡]



Number at risk

OPDIVO – 427	280	205	150	113	84	70	64	55	54	50	30	6	0
Docetaxel – 427	264	145	84	57	45	34	26	19	12	9	4	0	0

Minimum follow-up of 62.6 months (CM 017) and 62.7 months (CM 057).

Longest follow-up of two phase 3 trials in 2L mNSCLC regardless of PD-L1 expression[2]

*Vs docetaxel.[2]

†A pooled analysis of CM 017 and CM 057. CM 017 and CM 057 were registrational, randomized, phase 3 studies of OPDIVO vs docetaxel in patients with 2L SQ or 2L/3L NSQ mNSCLC, respectively.[3]

‡The pooled patient population (n=427) for OPDIVO consisted of 292 patients with NSQ and 135 with SQ histology. The pooled patient population (n=427) for docetaxel consisted of 290 patients with NSQ and 137 with SQ histology.[3]

3L=third line; mos=months.

IMPORTANT SAFETY INFORMATION

Severe and Fatal Immune-Mediated Adverse Reactions

Immune-Mediated Pneumonitis

- OPDIVO can cause immune-mediated pneumonitis. The incidence of pneumonitis is higher in patients who have received prior thoracic radiation. In patients receiving OPDIVO monotherapy, immune-mediated pneumonitis occurred in 3.1% (61/1994) of patients, including Grade 4 (<0.1%), Grade 3 (0.9%), and Grade 2 (2.1%).

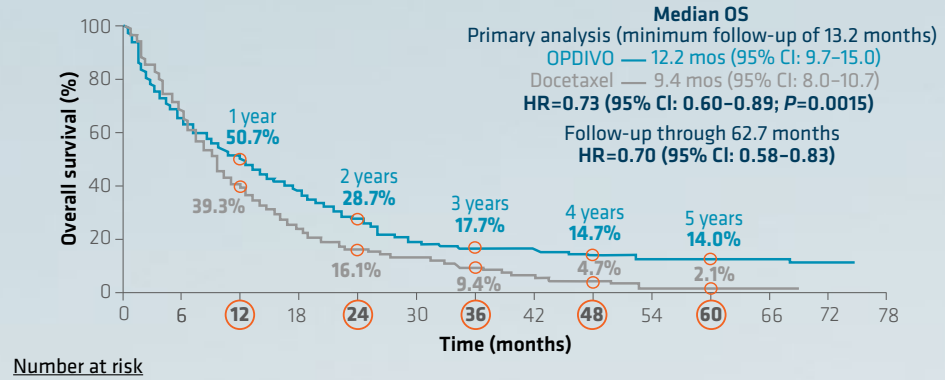
Please see additional Important Safety Information throughout this brochure and US Full Prescribing Information for OPDIVO.

OPDIVO® (nivolumab)
INJECTION FOR INTRAVENOUS USE 10 mg/mL

In two separate phase 3 trials that evaluated previously treated patients

At 5 years, OPDIVO® (nivolumab) increased OS in non-squamous mNSCLC[2,9]*

Checkmate 057: overall survival (extended follow-up analysis)[1,2,7,9]



Number at risk

OPDIVO – 292	194	148	112	82	58	49	46	39	38	36	19	2	0
Docetaxel – 290	195	112	67	46	35	26	18	13	7	5	3	0	0

Minimum follow-up of 62.7 months.

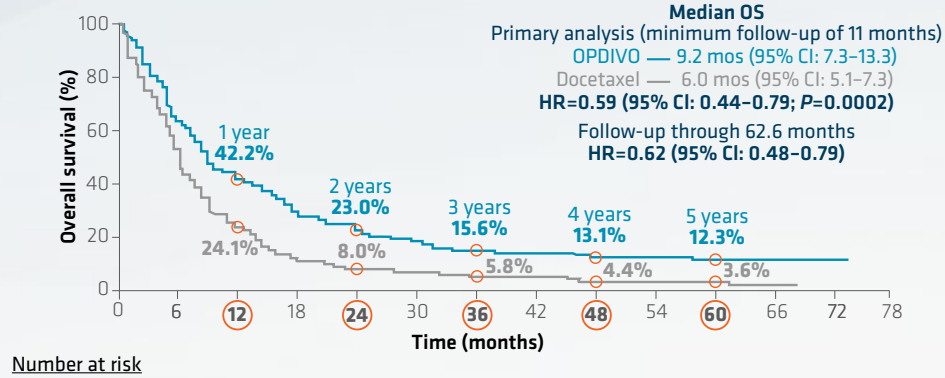
*Vs docetaxel.[9]

In the initial analysis from CM 057 (NSQ):

- ORR was 19% (56/292; 4 CRs) (95% CI: 15–24) with OPDIVO vs 12% (36/290; 1 CR) with docetaxel (95% CI: 9–17); *P*=0.02[1]
- mPFS was 2.3 months with OPDIVO vs 4.2 months with docetaxel; HR=0.92 (95% CI: 0.77–1.11), *P*=0.39[1]
- CM 057 results were based on the pre-specified interim analysis conducted when 413 events (93% of the planned number of events for final analysis) were observed (190 in the OPDIVO arm and 223 in the docetaxel arm). Minimum follow-up of 13.2 months[1,7]

At 5 years, OPDIVO increased OS in squamous mNSCLC[9]*

Checkmate 017: overall survival (extended follow-up analysis)[1,2,8,9]



Number at risk

OPDIVO – 135	86	57	38	31	26	21	18	16	16	14	11	4	0
Docetaxel – 137	69	33	17	11	10	8	8	6	5	4	1	0	0

Minimum follow-up of 62.6 months.

*Vs docetaxel.[9]

In the initial analysis from CM 017 (SQ):

- ORR was 20% (27/135; 1 CR) (95% CI: 14–28) with OPDIVO vs 9% (12/137; 0 CRs) with docetaxel (95% CI: 5–15); *P*=0.0083
- mPFS was 3.5 months with OPDIVO vs 2.8 months with docetaxel; HR=0.62 (95% CI: 0.47–0.81), *P*=0.0004[1]
- CM 017 results were based on the pre-specified interim analysis conducted when 199 events (86% of the planned number of events for final analysis) were observed (86 in the OPDIVO arm and 113 in the docetaxel arm). Minimum follow-up of 11 months[1,8]

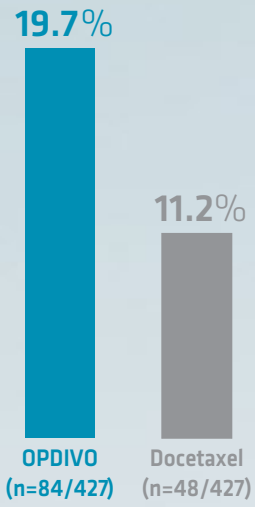
Please see additional Important Safety Information throughout this brochure and US Full Prescribing Information for OPDIVO.

OPDIVO® (nivolumab)
INJECTION FOR INTRAVENOUS USE 10 mg/mL

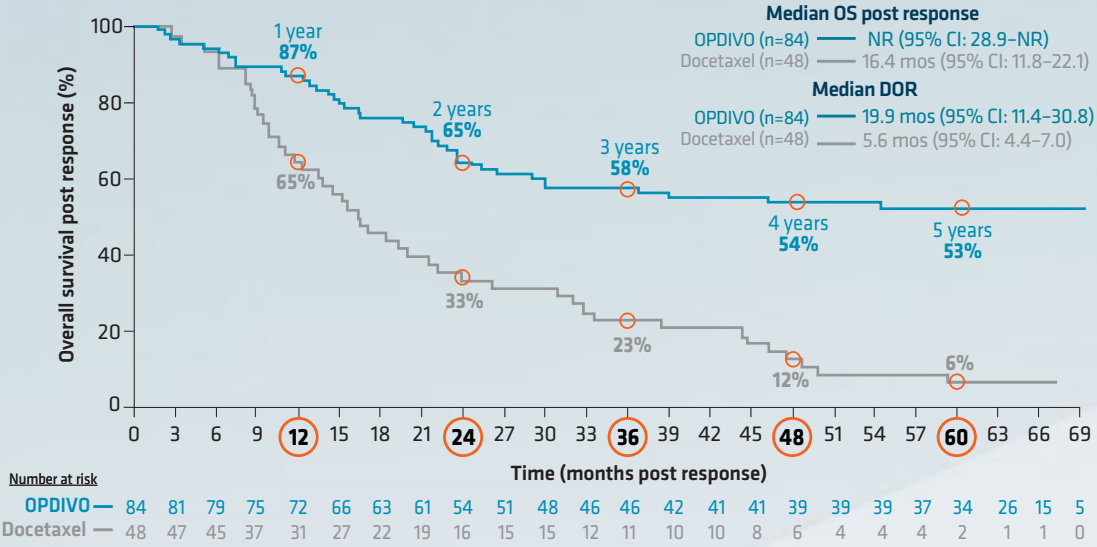
In a pooled analysis of two phase 3 trials that evaluated non-squamous and squamous mNSCLC

Among OPDIVO® (nivolumab) responders,* mOS was not reached at 5 years[2,3,10†]

CM 057 and CM 017 pooled ORR[2†‡§]



Pooled 5-year extended overall survival analysis of responders[2,3,10*†‡]



Minimum follow-up of 62.7 months (CM 057) and 62.6 months (CM 017).[2]

53% of OPDIVO responders* were alive at 5 years[3,10†]

*OS was calculated from the time of response (CR/PR) for each responder.[3]

†A pooled analysis of CM 017 and CM 057. CM 017 and CM 057 were registrational, randomized, phase 3 studies of OPDIVO vs docetaxel in patients with 2L SQ or 2L/3L NSQ mNSCLC, respectively. The pooled patient population (n=427) for OPDIVO consisted of 292 patients with NSQ and 135 with SQ histology. The pooled patient population (n=427) for docetaxel consisted of 290 patients with NSQ and 137 with SQ histology.[3]

‡Since the initial analysis of the CM 057 study, 1 patient's response changed from SD to PR, and 1 from PR to CR.[2]

§In CM 057, the ORR was 19% (56/292; 4 CRs) (95% CI: 15–24) with OPDIVO vs 12% (36/290; 1 CR) (95% CI: 9–17) with docetaxel; *P*=0.02. The median duration of response was 17 months in the OPDIVO arm (95% CI: 8.4–NR) and 6 months in the docetaxel arm (95% CI: 4.4–7.0). In CM 017, the ORR was 20% (27/135; 1 CR) (95% CI: 14–28) with OPDIVO vs 9% (12/137; 0 CRs) (95% CI: 5–15) with docetaxel, *P*=0.0083. The median duration of response was NR in the OPDIVO arm (95% CI: 9.8–NR) and 8.4 months in the docetaxel arm (95% CI: 3.6–10.8).[1]

DOR=duration of response; NR=not reached; PR=partial response; SD=stable disease.

SELECT IMPORTANT SAFETY INFORMATION

Severe and Fatal Immune-Mediated Adverse Reactions

Immune-Mediated Colitis

- OPDIVO can cause immune-mediated colitis. A common symptom included in the definition of colitis was diarrhea. Cytomegalovirus (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. In patients receiving OPDIVO monotherapy, immune-mediated colitis occurred in 2.9% (58/1994) of patients, including Grade 3 (1.7%) and Grade 2 (1%).

Immune-Mediated Hepatitis and Hepatotoxicity

- OPDIVO can cause immune-mediated hepatitis. In patients receiving OPDIVO monotherapy, immune-mediated hepatitis occurred in 1.8% (35/1994) of patients, including Grade 4 (0.2%), Grade 3 (1.3%), and Grade 2 (0.4%).

Please see additional Important Safety Information throughout this brochure and US Full Prescribing Information for OPDIVO.

OPDIVO® (nivolumab)
INJECTION FOR INTRAVENOUS USE 10 mg/mL

For previously treated mNSCLC

OPDIVO® (nivolumab) selected safety profile[1]

Adverse reactions occurring in ≥10% (all grades) of patients treated with OPDIVO and at a higher incidence than docetaxel (between-arm difference of ≥5% [all grades] or ≥2% [Grades 3-4]) in Checkmate 017 and 057[1]

	OPDIVO (n=418)		Docetaxel (n=397)	
	All grades	Grades 3–4	All grades	Grades 3–4
Respiratory, thoracic, and mediastinal disorders, %				
Cough	31	0.7	24	0
Metabolism and nutrition disorders, %				
Decreased appetite	28	1.4	23	1.5
Skin and subcutaneous tissue disorders, %				
Pruritus	10	0.2	2.0	0

- The safety profile of OPDIVO was evaluated across squamous and non-squamous histologies in patients with previously treated mNSCLC[1]
- The most common adverse reactions (reported in ≥20% of patients) were fatigue, musculoskeletal pain, cough, dyspnea, and decreased appetite[1]
- Serious adverse reactions occurred in 46% of patients receiving OPDIVO[1]
  - The most frequent serious adverse reactions reported in at least 2% of patients receiving OPDIVO were pneumonia, pulmonary embolism, dyspnea, pyrexia, pleural effusion, pneumonitis, and respiratory failure[1]
- OPDIVO was discontinued due to adverse reactions in 11% of patients[1]
- 28% of patients receiving OPDIVO had a drug delay for an adverse reaction[1]
- In Checkmate 057, fatal adverse reactions occurred; these included events of infection (7 patients, including one case of *Pneumocystis jirovecii* pneumonia), pulmonary embolism (4 patients), and limbic encephalitis (1 patient)
- With 5 years of minimum follow-up, no new safety signals were identified for OPDIVO[2]

SELECT IMPORTANT SAFETY INFORMATION

Severe and Fatal Immune-Mediated Adverse Reactions

Immune-Mediated Endocrinopathies

- OPDIVO can cause primary or secondary adrenal insufficiency, immune-mediated hypophysitis, immune-mediated thyroid disorders, and Type 1 diabetes mellitus, which can present with diabetic ketoacidosis. Withhold OPDIVO depending on severity (please see section 2 Dosage and Administration in the accompanying Full Prescribing Information). For Grade 2 or higher adrenal insufficiency, initiate symptomatic treatment, including hormone replacement as clinically indicated. 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 clinically indicated. Thyroiditis can present with or without endocrinopathy. Hypothyroidism can follow hyperthyroidism; initiate hormone replacement or medical management as clinically indicated. Monitor patients for hyperglycemia or other signs and symptoms of diabetes; initiate treatment with insulin as clinically indicated.
- In patients receiving OPDIVO monotherapy, adrenal insufficiency occurred in 1% (20/1994), including Grade 3 (0.4%) and Grade 2 (0.6%).
- In patients receiving OPDIVO monotherapy, hypophysitis occurred in 0.6% (12/1994) of patients, including Grade 3 (0.2%) and Grade 2 (0.3%).
- In patients receiving OPDIVO monotherapy, thyroiditis occurred in 0.6% (12/1994) of patients, including Grade 2 (0.2%).
- In patients receiving OPDIVO monotherapy, hyperthyroidism occurred in 2.7% (54/1994) of patients, including Grade 3 (<0.1%) and Grade 2 (1.2%).
- In patients receiving OPDIVO monotherapy, hypothyroidism occurred in 8% (163/1994) of patients, including Grade 3 (0.2%) and Grade 2 (4.8%).
- In patients receiving OPDIVO monotherapy, diabetes occurred in 0.9% (17/1994) of patients, including Grade 3 (0.4%) and Grade 2 (0.3%), and 2 cases of diabetic ketoacidosis.

Please see additional Important Safety Information throughout this brochure and US Full Prescribing Information for OPDIVO.

OPDIVO® (nivolumab)
INJECTION FOR INTRAVENOUS USE 10 mg/mL

SELECT IMPORTANT SAFETY INFORMATION

Severe and Fatal Immune-Mediated Adverse Reactions

Immune-Mediated Nephritis with Renal Dysfunction

- OPDIVO® (nivolumab) can cause immune-mediated nephritis. In patients receiving OPDIVO monotherapy, immune-mediated nephritis and renal dysfunction occurred in 1.2% (23/1994) of patients, including Grade 4 (<0.1%), Grade 3 (0.5%), and Grade 2 (0.6%).

Immune-Mediated Dermatologic Adverse Reactions

- OPDIVO can cause immune-mediated rash or dermatitis. Exfoliative dermatitis, including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and drug rash with eosinophilia and systemic symptoms (DRESS) has occurred with PD-1/PD-L1 blocking antibodies. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate nonexfoliative rashes.
- Withhold or permanently discontinue OPDIVO depending on severity (please see section 2 Dosage and Administration in the accompanying Full Prescribing Information).
- In patients receiving OPDIVO monotherapy, immune-mediated rash occurred in 9% (171/1994) of patients, including Grade 3 (1.1%) and Grade 2 (2.2%).

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 OPDIVO monotherapy or were reported with the use of other PD-1/PD-L1 blocking antibodies. 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; *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, polymyalgia rheumatica; *endocrine:* hypoparathyroidism; *other (hematologic/immune):* hemolytic anemia, aplastic anemia, hemophagocytic lymphohistiocytosis (HLH), systemic inflammatory response syndrome, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), sarcoidosis, immune thrombocytopenic purpura, solid organ transplant rejection.
- Some ocular IMAR 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, which has been observed in patients receiving OPDIVO, as this may require treatment with systemic corticosteroids to reduce the risk of permanent vision loss.

Infusion-Related Reactions

- OPDIVO can cause severe infusion-related reactions. Discontinue OPDIVO in patients with severe (Grade 3) or life-threatening (Grade 4) infusion-related reactions. Interrupt or slow the rate of infusion in patients with mild (Grade 1) or moderate (Grade 2) infusion-related reactions. In patients receiving OPDIVO monotherapy as a 60-minute infusion, infusion-related reactions occurred in 6.4% (127/1994) of patients. In a separate trial in which patients received OPDIVO monotherapy as a 60-minute infusion or a 30-minute infusion, infusion-related reactions occurred in 2.2% (8/368) and 2.7% (10/369) of patients, respectively. Additionally, 0.5% (2/368) and 1.4% (5/369) of patients, respectively, experienced adverse reactions within 48 hours of infusion that led to dose delay, permanent discontinuation or withholding of OPDIVO.

Complications of Allogeneic Hematopoietic Stem Cell Transplantation

- Fatal and other serious complications can occur in patients who receive allogeneic hematopoietic stem cell transplantation (HSCT) before or after being treated with OPDIVO. Transplant-related complications include hyperacute graft-versus-host-disease (GVHD), acute GVHD, chronic GVHD, hepatic veno-occlusive disease (VOD) after reduced intensity conditioning, and steroid-requiring febrile syndrome (without an identified infectious cause). These complications may occur despite intervening therapy between OPDIVO and allogeneic HSCT.
- Follow patients closely for evidence of transplant-related complications and intervene promptly. Consider the benefit versus risks of treatment with OPDIVO prior to or after an allogeneic HSCT.

Embryo-Fetal Toxicity

- Based on its mechanism of action and findings from animal studies, OPDIVO can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with OPDIVO and for at least 5 months after the last dose.

Increased Mortality in Patients with Multiple Myeloma when OPDIVO is Added to a Thalidomide Analogue and Dexamethasone

- In randomized clinical trials in patients with multiple myeloma, the addition of OPDIVO to a thalidomide analogue plus dexamethasone resulted in increased mortality. Treatment of patients with multiple myeloma with a PD-1 or PD-L1 blocking antibody in combination with a thalidomide analogue plus dexamethasone is not recommended outside of controlled clinical trials.

Lactation

- There are no data on the presence of OPDIVO in human milk, the effects on the breastfed child, or the effects on milk production. Because of the potential for serious adverse reactions in breastfed children, advise women not to breastfeed during treatment and for 5 months after the last dose.

Serious Adverse Reactions

- In Checkmate 017 and 057, serious adverse reactions occurred in 46% of patients receiving OPDIVO (n=418). The most frequent serious adverse reactions reported in ≥2% of patients receiving OPDIVO were pneumonia, pulmonary embolism, dyspnea, pyrexia, pleural effusion, pneumonitis, and respiratory failure. In Checkmate 057, fatal adverse reactions occurred; these included events of infection (7 patients, including one case of *Pneumocystis jirovecii* pneumonia), pulmonary embolism (4 patients), and limbic encephalitis (1 patient).

Common Adverse Reactions

- In Checkmate 017 and 057, the most common adverse reactions (≥20%) in patients receiving OPDIVO (n=418) were fatigue, musculoskeletal pain, cough, dyspnea, and decreased appetite.

References: 1. OPDIVO [package insert]. Princeton, NJ: Bristol-Myers Squibb Company. **2.** Gettinger S, Borghaei H, Brahmer J, et al. Five-year outcomes from the randomized, phase 3 trials CheckMate 017/057: nivolumab vs docetaxel in previously treated NSCLC. Oral presentation at WCLC 2019. Abstract OA14.04. **3.** Brahmer J, Borghaei H, Ramalingam SS, et al. Long-term survival outcomes with nivolumab in patients with previously treated advanced non-small cell lung cancer: impact of early disease control and response. Poster presentation at AACR 2019. Abstract CT195. **4.** Bristol-Myers Squibb Company. CheckMate-057, a pivotal phase III Opdivo (nivolumab) lung cancer trial, stopped early [press release]. April 17, 2015. https://news.bms.com/press-release/checkmate-057-pivotal-phase-iii-opdivo-nivolumab-lung-cancer-trial-stopped-early. Accessed June 19, 2019. **5.** Bristol-Myers Squibb Company. CheckMate-017, a phase 3 study of Opdivo (nivolumab) compared to docetaxel in patients with second-line squamous cell non-small cell lung cancer, stopped early [press release]. January 11, 2015. https://news.bms.com/press-release/checkmate-017-phase-3-study-opdivo-nivolumab-compared-docetaxel-patients-second-line-s. Accessed June 19, 2019. **6.** IMS APLD data. March 2015-August 2019. **7.** Borghaei H, Paz-Ares L, Horn L, et al. Nivolumab versus docetaxel in advanced nonsquamous non–small-cell lung cancer. *N Engl J Med.* 2015;373(17):1627-1639. **8.** Brahmer J, Reckamp KL, Baas P, et al. Nivolumab versus docetaxel in advanced squamous-cell non–small-cell lung cancer. *N Engl J Med.* 2015;373(2):123-135. **9.** Gettinger S, Borghaei H, Brahmer J, et al. Five-year outcomes from the randomized, phase 3 trials CheckMate 017/057: nivolumab vs docetaxel in previously treated NSCLC. Poster presentation at FLASCO 2019. **10.** Data on file. NIVO 532. Princeton, NJ: Bristol-Myers Squibb Company; 2019.

Please see US Full Prescribing Information for OPDIVO.

Bristol Myers Squibb™

7356-US-2100364 03/21

OPDIVO® (nivolumab)
INJECTION FOR INTRAVENOUS USE 10 mg/mL