In patients with intermediate- or poor-risk aRCC1

WHEN LOOKING FOR A CHANCE FOR LONG-TERM DURABLE SURVIVAL²



Now with 4-year follow-up data²

Checkmate 214

OPDIVO®, in combination with YERVOY®, is indicated for the first-line treatment of patients with intermediateor poor-risk advanced renal cell carcinoma (aRCC).¹

In Checkmate 214 (OPDIVO + YERVOY):

Primary analysis results (median follow-up time of 25.2 months)^{1,3}

- Median OS was not reached for OPDIVO + YERVOY (95% CI: 28.2-NE) vs 25.9 months for sunitinib (95% CI: 22.1-NE); HR=0.63 (99.8% CI: 0.44-0.89); P<0.0001^{1,3}
- Median PFS* for OPDIVO + YERVOY was 11.6 months (95% CI: 8.7–15.5) vs 8.4 months (95% CI: 7.0–10.8) for sunitinib; HR=0.82 (99.1% CI: 0.64–1.05); P=NS¹³
- ORR* for OPDIVO + YERVOY was 41.6% (n=177/425 [95% CI: 36.9-46.5]) vs 26.5% for sunitinib (n=112/422 [95% CI: 22.4-31.0]); P<0.0001
 - OPDIVO + YERVOY: CR: 9.4% (n=40); PR: 32.2% (n=137)
 - Sunitinib: CR: 1.2% (n=5); PR: 25.4% (n=107)

Extended follow-up analysis results (minimum follow-up time of 48 months) for OPDIVO + YERVOY2

■ The 48-month OS rate for OPDIVO + YERVOY was 50.0% vs 35.8% for sunitinib. Median OS was 48.1 months (95% CI: 35.6−NE) for OPDIVO + YERVOY vs 26.6 months for sunitinib (95% CI: 22.1−33.5); HR=0.65 (95% CI: 0.54−0.78)

Please see the Checkmate 214 study design in BOX A on page 3.

*In both the primary analysis and extended follow-up analysis, PFS and ORR were assessed by an independent radiographic review committee per RECIST v1.1.1-3

aRCC=advanced renal cell carcinoma; CI=confidence interval; HR=hazard ratio; NE=not evaluable; NS=not significant; ORR=overall response rate; OS=overall survival; PFS=progression-free survival; RECIST=Response Evaluation Criteria In Solid Tumors.

SELECT IMPORTANT SAFETY INFORMATION

Summary of Warnings and Precautions

OPDIVO and YERVOY are 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.



In an extended follow-up analysis at 48 months in 1L intermediate-/poor-risk aRCC

OPDIVO® (nivolumab) + YERVOY® (ipilimumab): The only I-O combination with a chance for durable survival and durable responses at 4 years^{2*}

DURABLE SURVIVAL

Half of patients

OPDIVO + YERVOY 50.0%[†]

Sunitinib

mOS at primary analysis (median follow-up time of 25.2 months)^{1,3}

- OPDIVO + YERVOY: Not yet reached (95% CI: 28.2–NE)
- Sunitinib: 25.9 months (95% CI: 22.1–NE)
- HR=0.63 (99.8% CI: 0.44-0.89); P<0.0001

mOS at extended follow-up (minimum time of 48 months)²

- OPDIVO + YERVOY: 48.1 months (95% CI: 35.6–NE)
- Sunitinib: 26.6 months (95% CI: 22.1–33.5)
- HR=0.65 (95% CI: 0.54-0.78)

Please see the overall survival Kaplan-Meier curve in BOX B on page 3.

*In a phase 3 trial.2

[†]OS rates are based on Kaplan-Meier estimates.^{2,5}

[‡]In both the primary analysis and the extended follow-up analysis, ORR and PFS were assessed by an independent radiographic review committee per RECIST v1.1.1-3

1L=first line; aRCC=advanced renal cell carcinoma; CI=confidence interval; CR=complete response; HR=hazard ratio; I-O=immuno-oncology; mDOR=median duration of response; mOS=median overall survival; NE=not evaluable; ORR=overall response rate; PFS=progression-free survival; PR=partial response; RECIST=Response Evaluation Criteria In Solid Tumors.

DURABLE RESPONSES

65.2% of responders

had an ongoing response at

86.4% of CRs were ongoing with OPDIVO + YERVDY (n=38/44)*

49.6% of responders to sunitinib had an ongoing response at 4 years (n=56/113)2

83.3% of CRs were ongoing with sunitinib (n=5/6)*

ORR[‡] at primary analysis (median follow-up time of 25.2 months)1,3

- OPDIVO + YERVOY: ORR: 41.6% (n=177/425 [95% CI: 36.9-46.5]; CR: 9.4% [n=40]; PR: 32.2% [n=137])
- Sunitinib: ORR: 26.5% (n=112/422 [95% CI: 22.4-31.0]; CR: 1.2% [n=5]; PR: 25.4% [n=107])
- P<0.0001 for ORR¹

mDOR at primary analysis (median follow-up time of 25.2 months)1,3

Not yet reached (95% CI: 21.8-NE) for OPDIVO + YERVOY vs 18.2 months (95% CI: 14.8-NE) for sunitinib

ORR[‡] at extended follow-up analysis (minimum follow-up time of 48 months)²

- OPDIVO + YERVOY: ORR: 41.9% (n=178/425 [95% CI: 37-47]; CR: 10.4% [n=44/425]; PR: 31.5% [n=134/425])
- Sunitinib: ORR: 26.8% (n=113/422 [95% CI: 23-31]; CR: 1.4% [n=6/422]; PR: 25.4% [n=107/422])

mDOR at extended follow-up analysis (minimum follow-up time of 48 months)²

- Not yet reached (95% CI: 45.8-NE) for OPDIVO + YERVOY vs 19.7 months (95% CI: 15.4-25.0) for sunitinib
- HR=0.45 (95% CI: 0.31–0.65)

SELECT IMPORTANT SAFETY INFORMATION

Serious Adverse Reactions

In Checkmate 214, serious adverse reactions occurred in 59% of patients receiving OPDIVO plus YERVOY (n=547). The most frequent serious adverse reactions reported in ≥2% of patients were diarrhea, pyrexia, pneumonia, pneumonitis, hypophysitis, acute kidney injury, dyspnea, adrenal insufficiency, and colitis.

Common Adverse Reactions

■ In Checkmate 214, the most common adverse reactions (≥20%) reported in patients treated with OPDIVO plus YERVOY (n=547) were fatigue (58%), rash (39%), diarrhea (38%), musculoskeletal pain (37%), pruritus (33%), nausea (30%), cough (28%), pyrexia (25%), arthralgia (23%), decreased appetite (21%), dyspnea (20%), and vomiting (20%).

Please see additional Important Safety Information OPDIVO and YERVOY throughout this piece and US Full Prescribing Information for **OPDIVO** and **YERVOY**.





Checkmate 214

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Checkmate 214 study information¹

Checkmate 214 was a phase 3, randomized (1:1), open-label study of OPDIVO® (nivolumab) 3 mg/kg IV and YERVOY® (ipilimumab) 1 mg/kg IV (n=425) every 3 weeks for four doses, followed by OPDIVO 3 mg/kg IV every 2 weeks* vs sunitinib (n=422) 50 mg administered orally once daily for four weeks, followed by 2 weeks off every cycle, in patients with previously untreated intermediate-/poor-risk aRCC. Patients were stratified by IMDC prognostic score and region, and treatment was continued until disease progression or unacceptable toxicity. The co-primary endpoints in IMDC intermediate-/poor-risk patients were 0S, ORR,† and PFS.†

*The recommended dose of OPDIVO in combination with YERVOY is OPDIVO 3 mg/kg administered as an IV infusion over 30 minutes, followed by YERVOY 1 mg/kg administered as an IV infusion over 30 minutes on the same day, every 3 weeks for 4 doses. The recommended subsequent dose of OPDIVO as a single agent is either 240 mg or 480 mg administered as an IV infusion over 30 minutes every 2 weeks or 4 weeks, respectively, until disease progression or unacceptable toxicity.¹

In both the primary analysis and the extended follow-up analysis, ORR and PFS were assessed by an independent radiographic review committee per RECIST v1.1.36

IMDC=International Metastatic RCC Database Consortium; IV=intravenous.

OXE

Checkmate 214: Overall survival in intermediate- or poor-risk patients^{1-3,5}

- mOS at extended follow-up analysis (minimum time of 48 months): OPDIVO + YERVOY: 48.1 months (95% CI: 35.6–NE); sunitinib: 26.6 months (95% CI: 22.1–33.5); HR=0.65 (95% CI: 0.54–0.78)²
- The 48-month survival rate analysis was not pre-specified within the study protocol⁶
- In the primary analysis, the pre-specified 12-month overall survival rate was 80% (95% Cl: 76-84) with OPDIVO + YERVOY vs 72% (95% Cl: 67-76) with sunitinib. The median follow-up time was 25.2 months³



^{*}Performance status is based on IMDC prognostic score (0=favorable, 1-2=intermediate, 3+=poor).3

SELECT IMPORTANT SAFETY INFORMATION

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 or YERVOY. Early identification and management are essential to ensure safe use of OPDIVO and YERVOY. Monitor for signs and symptoms that may be clinical manifestations of underlying immune-mediated adverse reactions. Evaluate clinical chemistries including liver enzymes, creatinine, adrenocorticotropic hormone (ACTH) level, and thyroid function at baseline and periodically during treatment with OPDIVO and before each dose of YERVOY. 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 and YERVOY depending on severity (please see section 2 Dosage and Administration in the accompanying Full Prescribing Information). In general, if OPDIVO or YERVOY 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.

INDICATION

OPDIVO® (nivolumab), in combination with YERVOY® (ipilimumab), is indicated for the first-line treatment of patients with intermediate or poor risk advanced renal cell carcinoma (RCC).

IMPORTANT SAFETY INFORMATION

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 or YERVOY. Early identification and management are essential to ensure safe use of OPDIVO and YERVOY. Monitor for signs and symptoms that may be clinical manifestations of underlying immune-mediated adverse reactions. Evaluate clinical chemistries including liver enzymes, creatinine, adrenocorticotropic hormone (ACTH) level, and thyroid function at baseline and periodically during treatment with OPDIVO and before each dose of YERVOY. 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 and YERVOY depending on severity (please see section 2 Dosage and Administration in the accompanying Full Prescribing Information). In general, if OPDIVO or YERVOY 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.

Immune-Mediated Pneumonitis

• OPDIVO and YERVOY can cause immune-mediated pneumonitis. The incidence of pneumonitis is higher in patients who have received prior thoracic radiation. In patients receiving OPDIVO 3 mg/kg with YERVOY 1 mg/kg every 3 weeks, immune-mediated pneumonitis occurred in 3.9% (26/666) of patients, including Grade 3 (1.4%) and Grade 2 (2.6%).

Immune-Mediated Colitis

OPDIVO and YERVOY can cause immune-mediated colitis, which may be fatal. 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 3 mg/kg with YERVOY 1 mg/kg every 3 weeks, immune-mediated colitis occurred in 9% (60/666) of patients, including Grade 3 (4.4%) and Grade 2 (3.7%).

Immune-Mediated Hepatitis and Hepatotoxicity

 OPDIVO and YERVOY can cause immune-mediated hepatitis. In patients receiving OPDIVO 3 mg/kg with YERVOY 1 mg/kg every 3 weeks, immune-mediated hepatitis occurred in 7% (48/666) of patients, including Grade 4 (1.2%), Grade 3 (4.9%), and Grade 2 (0.4%).

Immune-Mediated Endocrinopathies

• OPDIVO and YERVOY 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 and YERVOY 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 3 mg/kg with YERVOY 1 mg/kg every 3 weeks, adrenal insufficiency occurred in 7% (48/666) of patients, including Grade 4 (0.3%), Grade 3 (2.5%), and Grade 2 (4.1%).
- In patients receiving OPDIVO 3 mg/kg with YERVOY 1 mg/kg every 3 weeks, hypophysitis occurred in 4.4% (29/666) of patients, including Grade 4 (0.3%), Grade 3 (2.4%), and Grade 2 (0.9%).
- In patients receiving OPDIVO 3 mg/kg with YERVOY 1 mg/kg every 3 weeks, thyroiditis occurred in 2.7% (22/666) of patients, including Grade 3 (4.5%) and Grade 2 (2.2%).
- In patients receiving OPDIVO 3 mg/kg with YERVOY 1 mg/kg every 3 weeks, hyperthyroidism occurred in 12% (80/666) of patients, including Grade 3 (0.6%) and Grade 2 (4.5%).
- In patients receiving OPDIVO 3 mg/kg with YERVOY 1 mg/kg every 3 weeks, hypothyroidism occurred in 18% (122/666) of patients, including Grade 3 (0.6%) and Grade 2 (11%).
- In patients receiving OPDIVO 3 mg/kg with YERVOY 1 mg/kg every 3 weeks, diabetes occurred in 2.7% (15/666) of patients, including Grade 4 (0.6%), Grade 3 (0.3%), and Grade 2 (0.9%).

Immune-Mediated Nephritis with Renal Dysfunction

 OPDIVO and YERVOY can cause immune-mediated nephritis. In patients receiving OPDIVO 3 mg/kg with YERVOY 1 mg/kg every 3 weeks, immune-mediated nephritis with renal dysfunction occurred in 4.1% (27/666) of patients, including Grade 4 (0.6%), Grade 3 (1.1%), and Grade 2 (2.2%).

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.
- YERVOY can cause immune-mediated rash or dermatitis, including bullous and exfoliative dermatitis, SJS, TEN, and DRESS. Topical emollients and/or topical corticosteroids may be adequate to treat mild to moderate non-bullous/exfoliative rashes.
- Withhold or permanently discontinue OPDIVO and YERVOY depending on severity (please see section 2 Dosage and Administration in the accompanying Full Prescribing Information).
- In patients receiving OPDIVO 3 mg/kg with YERVOY 1 mg/kg every 3 weeks, immune-mediated rash occurred in 16% (108/666) of patients, including Grade 3 (3.5%) and Grade 2 (4.2%).

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 OPDIVO in combination with YERVOY 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.

(Continued on the next page)



IMPORTANT SAFETY INFORMATION (cont'd)

Severe and Fatal Immune-Mediated Adverse Reactions (cont'd)

Other Immune-Mediated Adverse Reactions (cont'd)

- In addition to the immune-mediated adverse reactions listed above, across clinical trials of YERVOY monotherapy or in combination with OPDIVO, the following clinically significant immune-mediated adverse reactions, some with fatal outcome, occurred in <1% of patients unless otherwise specified: nervous system: autoimmune neuropathy (2%), myasthenic syndrome/myasthenia gravis, motor dysfunction; cardiovascular: angiopathy, temporal arteritis; ocular: blepharitis, episcleritis, orbital myositis, scleritis; gastrointestinal: pancreatitis (1.3%); other (hematologic/immune): conjunctivitis, cytopenias (2.5%), eosinophilia (2.1%), erythema multiforme, hypersensitivity vasculitis, neurosensory hypoacusis, psoriasis.</p>
- 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 and YERVOY, as this may require treatment with systemic corticosteroids to reduce the risk of permanent vision loss.

Infusion-Related Reactions

OPDIVO and YERVOY can cause severe infusion-related reactions. Discontinue OPDIVO and YERVOY 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 RCC patients receiving OPDIVO 3 mg/kg with YERVOY 1 mg/kg, infusion-related reactions occurred in 5.1% (28/547) of patients.

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 or YERVOY. 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 or YERVOY and allogeneic HSCT.
- Follow patients closely for evidence of transplant-related complications and intervene promptly. Consider the benefit versus risks of treatment with OPDIVO and YERVOY prior to or after an allogeneic HSCT.

Embryo-Fetal Toxicity

Based on its mechanism of action and findings from animal studies, OPDIVO and YERVOY can cause fetal harm when administered to a pregnant woman. The effects of YERVOY are likely to be greater during the second and third trimesters of pregnancy. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with OPDIVO and YERVOY 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 or YERVOY 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

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Common Adverse Reactions

■ In Checkmate 214, the most common adverse reactions (≥20%) reported in patients treated with OPDIVO plus YERVOY (n=547) were fatigue (58%), rash (39%), diarrhea (38%), musculoskeletal pain (37%), pruritus (33%), nausea (30%), cough (28%), pyrexia (25%), arthralgia (23%), decreased appetite (21%), dyspnea (20%), and vomiting (20%).

References: 1. OPDIVO [package insert]. Princeton, NJ: Bristol-Myers Squibb Company. 2. Albiges L, Tannir NM, Burotto M, et al. Nivolumab plus ipilimumab versus sunitinib for first-line treatment of advanced renal cell carcinoma in CheckMate 214: 4-year follow-up and subgroup analysis of patients without nephrectomy. Poster presentation at ESMO 2020. Abstract 711P. 3. Motzer RJ, Tannir NM, McDermott DF, et al; for CheckMate 214 Investigators. Nivolumab plus ipilimumab versus sunitinib in advanced renal-cell carcinoma. N Engl J Med. 2018;378(14):1277–1290. 4. Data on file. NIVO 587. Princeton, NJ: Bristol-Myers Squibb Company; 2020. 5. Data on file. NIVO 54859. Princeton, NJ: Bristol-Myers Squibb Company; 2020. 6. Motzer RJ, Tannir NM, McDermott DF, et al; for CheckMate 214 Investigators. Nivolumab plus ipilimumab versus sunitinib in advanced renal-cell carcinoma. N Engl J Med. 2018;378(14):1277–1290 [protocol].

Please see US Full Prescribing Information for OPDIVO and YERVOY.





