

See the impact of pCR in your patients



With OPDIVO, 25% of patients achieved pCR^{1,2*}

Your choice for chemo flexibility: OPDIVO was studied using both carboplatin- and cisplatin-based doublet therapy.^{1,3}

- Limitation:** The pCR rate was assessed in a descriptive analysis of a pre-specified secondary endpoint; the statistical testing plan did not assign alpha control to this endpoint, so direct comparisons between the treatment arms cannot be made.
- Checkmate 77T primary endpoint:** Median EFS at the 15.7-month minimum follow-up (median 25.4 months) for patients receiving neoadjuvant OPDIVO + chemo with adjuvant OPDIVO was not reached (95% CI: 28.9–NR) vs 18.4 months (95% CI: 13.6–28.1) for those receiving neoadjuvant placebo + chemo with adjuvant placebo; HR=0.58 (95% CI: 0.43–0.78); P=0.00025.^{1,2}
- Checkmate 77T prespecified secondary endpoint:** pCR at the 15.7-month minimum follow-up (median 25.4 months) for patients receiving neoadjuvant OPDIVO + chemo with adjuvant OPDIVO was 25% (n=58/229; [95% CI: 20–31]) and 4.7% (n=11/232; [95% CI: 2.4–8]) for those receiving neoadjuvant placebo + chemo with adjuvant placebo.^{1,2}

Indication

OPDIVO® (nivolumab), in combination with platinum-doublet chemotherapy, is indicated for neoadjuvant treatment of adult patients with resectable (tumors ≥4 cm or node positive) non-small cell lung cancer (NSCLC) and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements, followed by single-agent OPDIVO as adjuvant treatment after surgery.

Select Important Safety Information

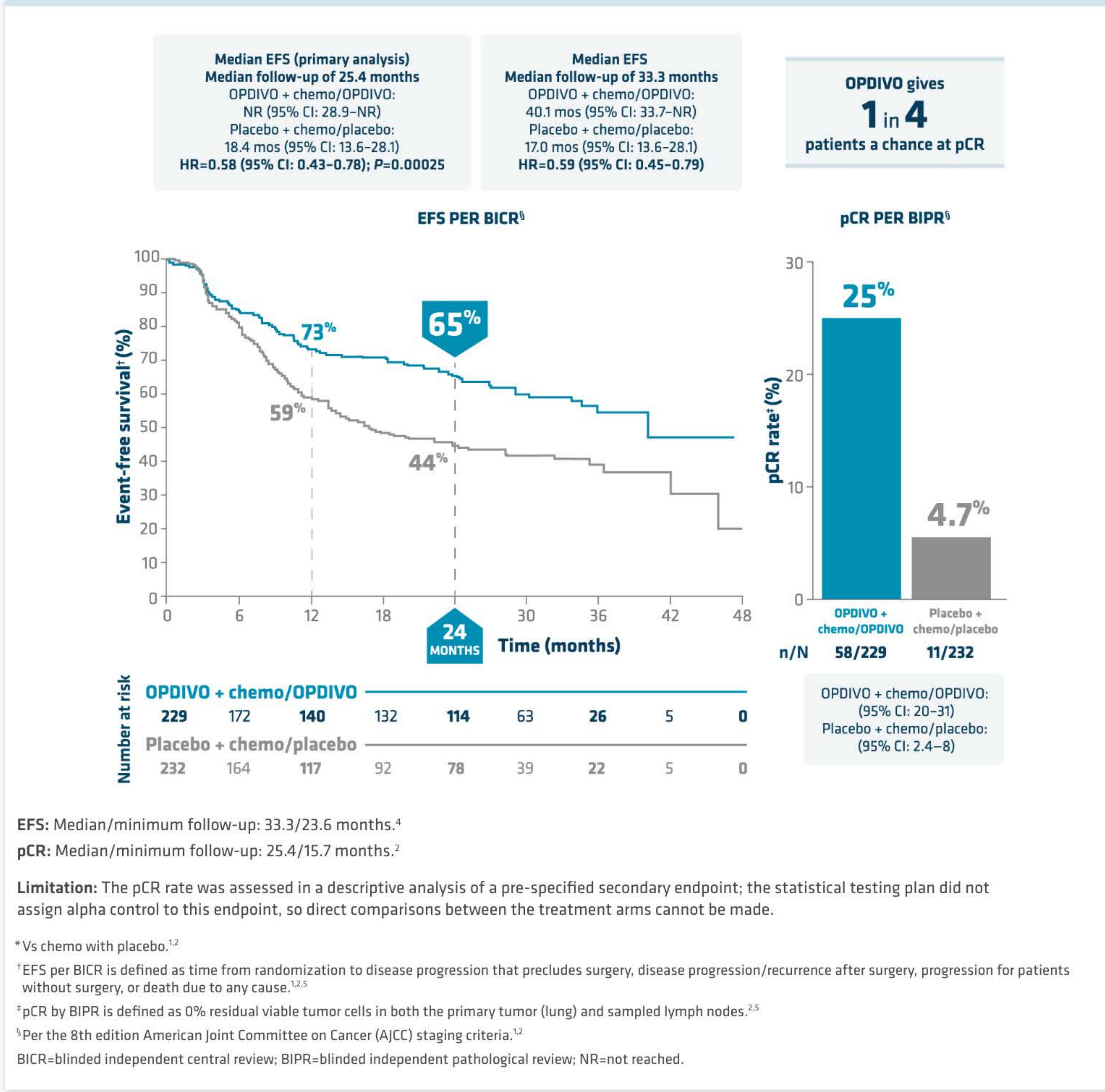
Summary of Warnings and Precautions

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.

Please see additional Important Safety Information for OPDIVO below and US Full Prescribing information for OPDIVO [here](#).

CHECKMATE 77T: NEOADJUVANT OPDIVO + CHEMO FOLLOWED BY ADJUVANT OPDIVO AFTER SURGERY

Give patients the opportunity for an extended EFS*† benefit and a high pCR‡ rate with perioperative OPDIVO^{1,2,4}



Select Important Safety Information

Serious Adverse Reactions

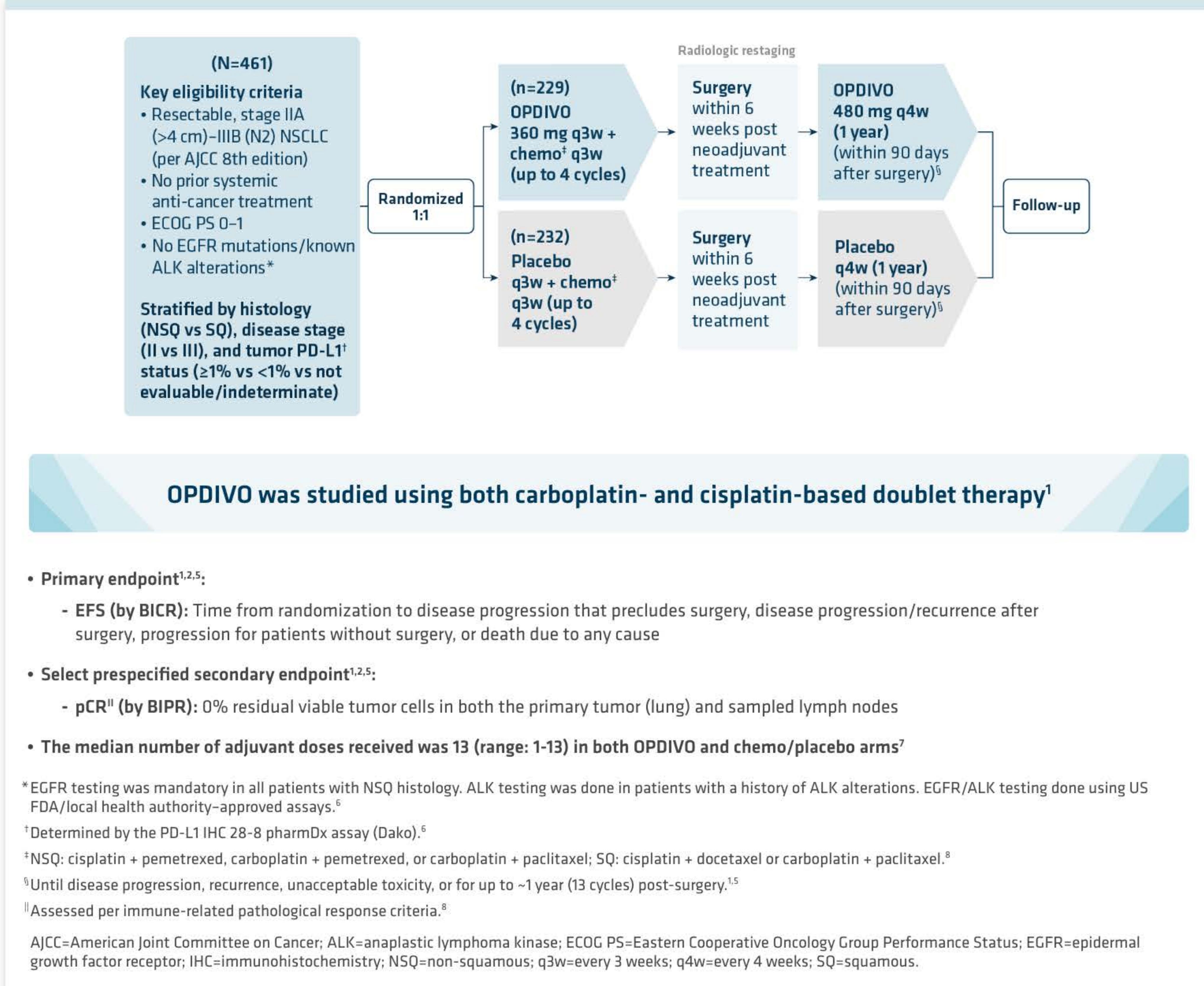
In Checkmate 77T, serious adverse reactions occurred in 21% of patients who received OPDIVO in combination with platinum-doublet chemotherapy as neoadjuvant treatment (n=228). The most frequent (≥2%) serious adverse reactions was pneumonia. Fatal adverse reactions occurred in 2.2% of patients, due to cerebrovascular accident, COVID-19 infection, hemoptysis, pneumonia, and pneumonitis (0.4% each). In the adjuvant phase of Checkmate 77T, 22% of patients experienced serious adverse reactions (n=142). The most frequent serious adverse reaction was pneumonitis/ILD (2.8%). One fatal adverse reaction due to COVID-19 occurred.

Common Adverse Reactions

In Checkmate 77T, the most common adverse reactions (reported in ≥20%) in patients receiving OPDIVO in combination with chemotherapy (n=228) were anemia (39.5%), constipation (32.0%), nausea (28.9%), fatigue (28.1%), alopecia (25.9%), and cough (21.9%).

Please see additional Important Safety Information below.

Perioperative OPDIVO: Studied in patients with stage IIA-IIIb NSCLC^{1,2,6}



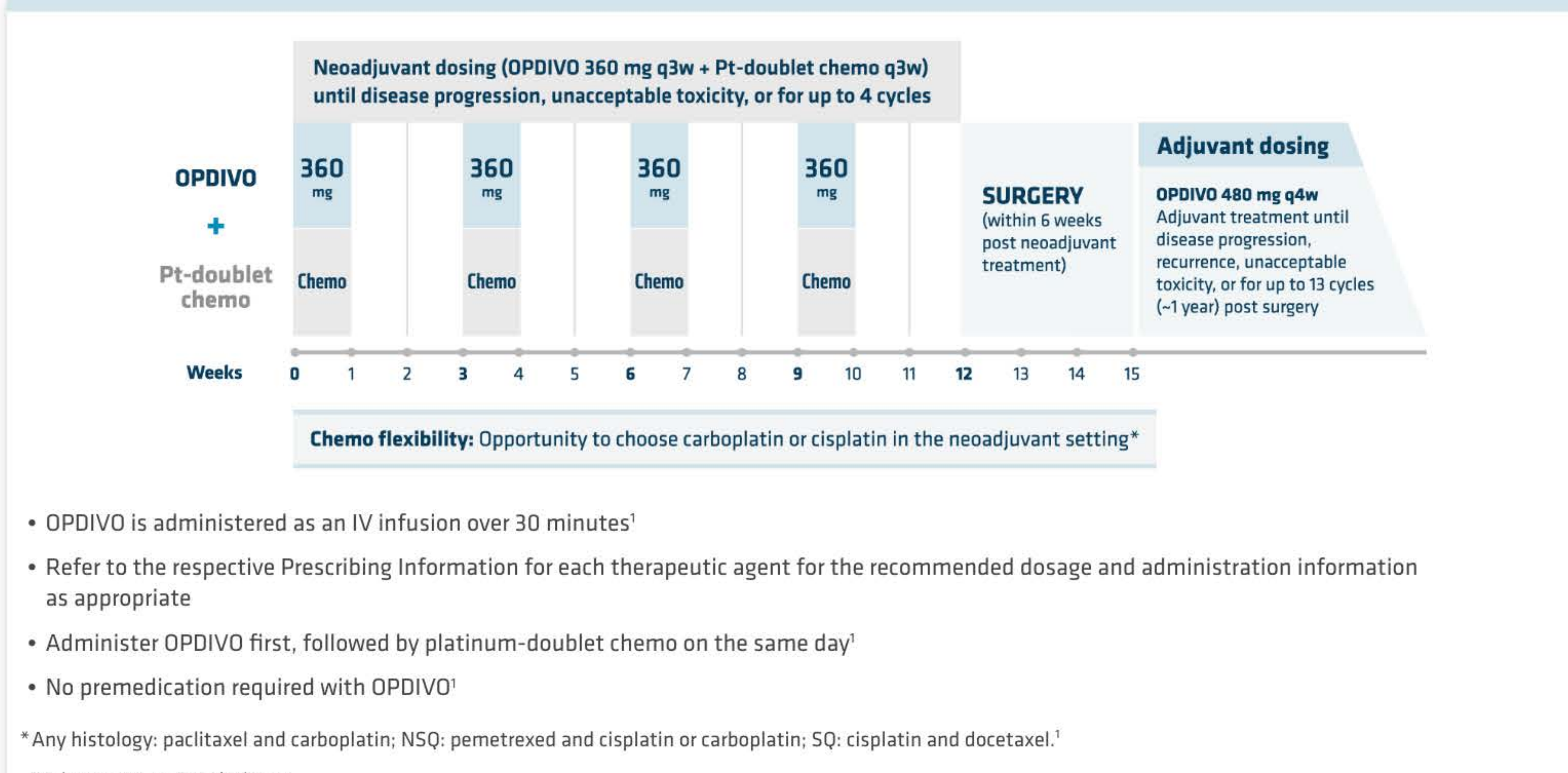
Checkmate 77T baseline characteristics^{2,6}

CHARACTERISTICS	OPDIVO + chemo/OPDIVO (n=229)	Placebo + chemo/placebo (n=232)*
Median age (range), years	66 (37–83)	66 (35–86)
Male, %	73	69
Platinum therapy type,¹ %		
Cisplatin	24	18
Carboplatin	73	78
ECOG PS, %		
0	64	61
1	36	39
Disease Stage,¹ (%)		
IIA-B	35	35
IIIA-B	64	64
Node stage,¹ %		
N0	35	38
N1	25	22
N2	40	39
Single-station	26	23
Multistation	14	16
Histology, %		
Squamous	51	51
Non-squamous	49	49
Smoking status, %		
Current/former	93	88
Never	7	12
Tumor PD-L1 expression, %		
Not evaluable	4	5
<1%	41	40
≥1%	56	55
1–49%	36	33
≥50%	20	22
Geographic region, %		
North America	10	9
Europe	54	55
Asia	28	22
Rest of the world**	8	15

Percentages may not total 100 due to rounding.

*1 patient had EGFR mutation and ALK translocation.⁶
[†]Five patients (2.2%) in the OPDIVO + chemo/OPDIVO group and 6 patients (2.6%) in the placebo + chemo/placebo group switched from cisplatin to carboplatin. Neoadjuvant platinum chemotherapy was not reported in 2 patients (0.9%) in the OPDIVO + chemo/OPDIVO group and 4 patients (1.7%) in the placebo + chemo/placebo group.²
[‡]Disease stage (per AJCC 8th edition) as reported in case report forms. 2 (1%) patients in the OPDIVO + chemo/OPDIVO arm had stage IIIC disease, and 2 (1%) patients in the placebo + chemo/placebo arm had stage IV disease.⁶
[§]Stage IIA was reported in 7% of patients in the OPDIVO + chemo/OPDIVO arm and 8% of patients in the placebo + chemo/placebo arm; stage IIB disease was reported in 29% and 27% of patients, respectively.²
^{||}Stage IIA was reported in 45% of patients in the OPDIVO + chemo/OPDIVO arm and 49% of patients in the placebo + chemo/placebo; stage IIIB disease was reported in 19% and 15% of patients, respectively.²
^{**}N3 node stage was reported in 2 patients (0.9%) in each treatment group.²
^{**}Determined using the PD-L1 IHC 28-8 pharmDx assay (Dako).⁶
^{**}Includes only Argentina, Australia, Brazil, and Mexico.⁴

Dosing: Up to 4 cycles of OPDIVO + chemo prior to surgery and OPDIVO every 4 weeks post surgery^{1,2,5}






Selected safety profile



CHECKMATE 77T: NEOADJUVANT OPDIVO + CHEMO FOLLOWED BY ADJUVANT OPDIVO AFTER SURGERY

Perioperative OPDIVO® has a well-known safety profile^{1,9}

 MOST SERIOUS ARs	 MOST COMMON ARs	 SURGERY-RELATED ARs
<p>Neoadjuvant</p> <ul style="list-style-type: none"> In Checkmate 77T, of the patients who received OPDIVO in combination with platinum-doublet chemotherapy as neoadjuvant treatment (n=228), 21% of patients experienced serious adverse reactions The most frequent (≥2%) serious adverse reaction was pneumonia. Fatal adverse events occurred in 2.2% of patients due to cerebrovascular accident, COVID-19 infection, hemoptysis, pneumonia, and pneumonitis (0.4% each) <p>Adjuvant</p> <ul style="list-style-type: none"> In the adjuvant phase of Checkmate 77T, of the patients who received OPDIVO (n=142), 22% of patients experienced serious adverse reactions. The most frequent serious adverse reaction was pneumonitis/ILD (2.8%). One fatal adverse event due to COVID-19 occurred <p>AR=adverse reactions; ILD=interstitial lung disease.</p>	<p>Neoadjuvant</p> <ul style="list-style-type: none"> In Checkmate 77T, the most common adverse reactions (reported in ≥20%) in patients receiving OPDIVO in combination with chemotherapy (n=228) were anemia (39.5%), constipation (32.0%), nausea (28.9%), fatigue (28.1%), alopecia (25.9%), and cough (21.9%) 	<p>Neoadjuvant</p> <ul style="list-style-type: none"> In Checkmate 77T, 5.3% (n=12) of the OPDIVO-treated patients who received neoadjuvant treatment did not receive surgery due to adverse reactions. The adverse reactions that led to cancellation of surgery in OPDIVO-treated patients were cerebrovascular accident, pneumonia, and colitis/diarrhea (2 patients each) and acute coronary syndrome, myocarditis, hemoptysis, pneumonitis, COVID-19, and myositis (1 patient each)



INDICATION

OPDIVO® (nivolumab), in combination with platinum-doublet chemotherapy, is indicated for neoadjuvant treatment of adult patients with resectable (tumors ≥4 cm or node positive) non-small cell lung cancer (NSCLC) and no known epidermal growth factor receptor (EGFR) mutations or anaplastic lymphoma kinase (ALK) rearrangements, followed by single-agent OPDIVO as adjuvant treatment after surgery.

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. 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.

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%).

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%).

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.

Immune-Mediated Nephritis with Renal Dysfunction

OPDIVO 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 palsy, 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, other transplant (including corneal graft) 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

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Surgery Related Adverse Reactions

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Please see US Full Prescribing Information for [OPDIVO](#).

References:

- OPDIVO [package insert]. Princeton, NJ: Bristol-Myers Squibb Company.
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- Awad MM, Cascone T, Spicer JD, et al. Clinical outcomes with perioperative nivolumab in patients with resectable NSCLC from the phase 3 CheckMate 77T study. Oral presentation at ELCC 2024. Abstract LBA2.
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