U.S. Food and Drug Administration Approves Opdivo® (nivolumab) + Yervoy® (ipilimumab) Combination as First-Line Treatment for Patients with Intermediate- and Poor-Risk Advanced Renal Cell Carcinoma

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The Opdivo® + low-dose Yervoy combination is the first and only treatment to show significantly superior overall survival versus sunitinib in intermediate- and poor-risk advanced renal cell carcinoma, including a survival benefit regardless of PD-L1 expression.1,2

In the CheckMate -214 trial, which used dosing optimized for advanced renal cell carcinoma, Opdivo® + Yervoy® was associated with fewer overall 3 or 4 adverse reactions than sunitinib 1,2

Results from the CheckMate -214 trial in patients with previously untreated intermediate- and poor-risk advanced RCC include:

- **Overall Survival**: Opdivo + Yervoy reduced the risk of death by 37% versus sunitinib (hazard ratio [HR] 0.63; 99.8% confidence interval [CI]: 0.44 to 0.89; p<0.0001).1,2 The median OS was not yet reached for Opdivo + Yervoy (95% CI: 28.2 to not estimable [NE]) and was 25.9 months for sunitinib (95% CI: 22.1 to NE).2,3
- **Objective Response Rate**: Opdivo + Yervoy was associated with a 41.6% ORR (95% CI: 36.9 to 46.3; p<0.0001) versus 26.5% for sunitinib (95% CI: 22.4 to 31.0; p=0.0112).1,2
- **Progression-Free Survival**: The complete response rate (CR) was 9.4% for Opdivo + Yervoy (n=46/425) and 1.2% for sunitinib (n=5/422), and the partial response (PR) rate was 32.2% for Opdivo + Yervoy (n=137/425) and 25.4% for sunitinib (n=107/422).1,2,4
- **Duration of Response**: Among patients who responded, median duration of response (durations for CR and PR) for Opdivo + Yervoy was not yet reached (95% CI: 21.8 to NE), compared to 18.2 months for sunitinib (95% CI: 14.8 to NE).5
- **Progression-Free Survival (PFS)**: 11.6 months for the Opdivo + Yervoy combination, compared to 8.4 months for sunitinib (HR 0.82; 99.1% CI: 0.64 to 1.05; p<0.001), which did not reach statistical significance.5,6

Among those with advanced RCC, 75% to 80% have one or more risk factors and are considered intermediate- and poor-risk patients according to International Metastatic Renal Cell Carcinoma Database Consortium criteria.6,7 These patients historically had a poor prognosis, and although there have been a number of treatment advances over the past decade, additional options to improve overall survival are still needed.6,8 Currently, only 36% of patients with advanced RCC survive beyond one year, and only 8% will live past five years.9

"Physicians treating advanced RCC have few options to help achieve the goal of improved survival," said Robert J. Motzer, M.D., medical oncologist, Jack and Dorothy Byrne Chair in clinical oncology, Memorial Sloan Kettering Cancer Center. "Data from the CheckMate -214 trial demonstrated superior overall survival with Opdivo + Yervoy, showing the potential for the combination to become a new standard of care for patients with intermediate- and poor-risk advanced RCC. What’s more, the combination resulted in fewer overall Grade 3 and 4 adverse reactions compared to sunitinib. Because of these encouraging results, we now have a new treatment option for newly diagnosed advanced RCC patients across PD-L1 expression levels."

In CheckMate -214, the combination was associated with fewer overall Grade 3 or 4 adverse events than sunitinib (65% versus 76%).1,2 Treatment discontinuation due to adverse events occurred in 31% of patients in the Opdivo + Yervoy arm, compared to 21% in the sunitinib arm. Fifty-four percent (54%) of patients receiving Opdivo + Yervoy and 43% of patients receiving sunitinib had a dose delay for an adverse event. In the sunitinib group, 53% of patients required a dose reduction, which was not permitted for patients treated with the Opdivo + Yervoy combination. Serious adverse reactions occurred in 59% of patients receiving Opdivo + Yervoy and in 43% of patients receiving sunitinib.1,2

"Kidney cancer is the deadliest of all urological cancers, and too many patients are faced with this grim diagnosis," said Dena Battle, president, KCCure. "Today’s approval of Opdivo + Yervoy for advanced RCC has the potential to transform the first-line treatment landscape for kidney cancer. But for patients, it is more than just a new therapy option - it represents hope for a longer life."
majority of these immune-mediated reactions initially manifested during treatment; however, a minority occurred weeks to months after discontinuation of YERVYO.

Assess patients for signs and symptoms of enterocolitis, dermatitis, neuropathy, and endocrinopathy and evaluate clinical laboratory findings including liver function tests (LFTs), adrenocorticotropic hormone (ACTH) level, and thyroid function tests at baseline and before each dose.

Permanently discontinue YERVYO and initiate systemic high-dose corticosteroid therapy for severe immune-mediated reactions.

Immune-Mediated Pneumonitis

OPDIVO can cause immune-mediated pneumonitis. Fatal cases have been reported. Monitor patients for signs with radiographic imaging and for symptoms of pneumonitis. Administer corticosteroids for Grade 2 or more. Withhold OPDIVO if Grade 3 or 4 pneumonitis.

In 2011, through a collaboration agreement with Ono Pharmaceutical Co., Bristol-Myers Squibb expanded its territorial rights to develop and commercialize Opdivo globally except in Japan, South Korea and Taiwan, where Ono had retained all rights to the compound at the time. On July 23, 2014, Ono and Bristol-Myers Squibb further expanded the companies' strategic collaboration agreement to jointly develop and commercialize multiple immunotherapies – as single agents and combination regimens – for patients with cancer in Japan, South Korea and Taiwan.

About Bristol-Myers Squibb

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References

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#FDA approves BMY combination therapy as first-line treatment for certain patients with advanced #KidneyCancer