Now Approved | **Checkmate 9ER**

OPDIVO® (nivolumab)
Concentrate for Solution for Infusion 10mg/ml

With 44-month median follow-up data*[2]

Combining 2 familiar agents in **aRCC**[1,4]

OPDIVO® (nivolumab) + Cabozantinib

SUPERIOR EFFICACY VS SUNITINIB ACROSS **3 KEY ENDPOINTS**†[1,4,5]**:**

Primary endpoint†‡[1,5]

- mPFS‡ : 16.6 months (95% CI: 12.5–24.9) with OPDIVO® + Cabozantinib vs 8.3 months (95% CI: 7.0–9.7) with sunitinib (HR=0.51; 95% CI: 0.41–0.64; *P*<0.0001)[1,5]

Secondary endpoint†‡[1,5]

- ORR‡ : 55.7% (n=180/323 [95% CI: 50.1–61.2]) with OPDIVO + Cabozantinib vs 27.1% (n=89/328 [95% CI: 22.4–32.3]) with sunitinib (*P*<0.0001)[1]
  - 8% (n=26/323) CR and 48% (n=154/323) PR for OPDIVO + Cabozantinib vs 4.6% (n=15/328) CR and 23% (n=74/328) PR for sunitinib[1,5]

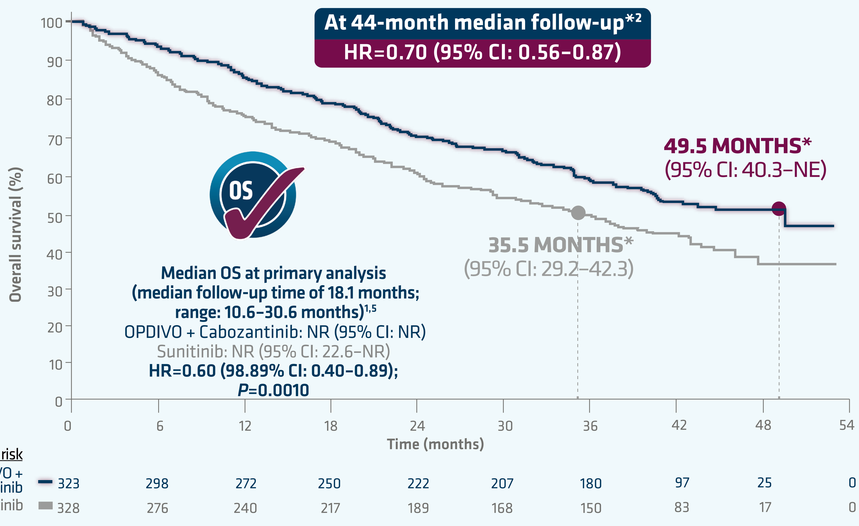
Secondary endpoint*[1,2]

- mOS: 49.5 months (95% CI: 40.3 - NE) with OPDIVO + Cabozantinib and 35.5 months (95% CI: 29.2 - 42.3) with sunitinib (HR=0.70; 95% CI : 0.56 - 0.87)[1,2]

*Based on extended follow-up analysis at a median follow-up time of 44.0 months (range: 36.5–56.5 months).[2]; †Based on primary analysis results at a median follow-up time of 18.1 months (range: 10.6–30.6 months).[1,5]; ‡BICR assessed.[1]
BICR=blinded independent central review; CI=confidence interval; CR=complete response; HR=hazard ratio; mOS=median OS; mPFS=median PFS; NR=not reached; ORR=overall response rate; OS=overall survival; PFS=progression-free survival; PR=partial response.

With 44-month median follow-up data (min 36.5 mos)*[2]

OS: Early separation between treatment arms was observed at the primary analysis†‡[1,2,5]



Median OS at extended follow-up analysis (median follow-up time of 44.0 months; range: 36.5–56.5 months)[2]

- OPDIVO + Cabozantinib: 49.5 months (95% CI: 40.3–NE)[2]
- Sunitinib: 35.5 months (95% CI: 29.2–42.3)[2]
- HR=0.70 (95% CI: 0.56–0.87)[2]

*Based on extended follow-up analysis at a median follow-up time of 44.0 months (range: 36.5–56.5 months).[2]; †Vs sunitinib in the ITT population.[1]; ‡Based on primary analysis at a median follow-up time of 18.1 months (range: 10.6–30.6 months).[1,5] ; DCR=disease control rate; ITT=intent to treat; NE=not estimable; SD=stable disease.

For Healthcare Professionals Only.

References: 1. Latest approved SG PI version is February 2023. 2. Burotto M, Powles T, Escudier B, et al. Nivolumab plus cabozantinib versus sunitinib for the treatment of advanced renal cell carcinoma from the phase 3 CheckMate 9ER trial. Presentation at ASCO GU 2022. Presentation 603. 3. Data on file. NIVO 462. Princeton, NJ: Bristol-Myers Squibb Company; 2021. 4. Cabozantinib [package insert]. Alameda, CA: Exelixis, Inc.; 2021. 5. Choueiri TK, Powles T, Burotto M, et al. Nivolumab plus cabozantinib versus sunitinib in first-line treatment for advanced renal cell carcinoma: first results from the randomized phase 3 CheckMate 9ER trial. Slide presentation at ESMO 2020. Presentation 6960.

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