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Efficacy of avelumab + axitinib (A + Ax) vs sunitinib (S) by IMDC risk group in advanced renal cell carcinoma (aRCC): extended follow-up results from JAVELIN Renal 101

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JAVELIN Renal 101

SCOPE

- **This analysis reports the efficacy of A + Ax vs S by the International Metastatic RCC Database Consortium (IMDC) risk groups in patients with aRCC from the third interim analysis (IA3) of overall survival (OS) in the phase 3 JAVELIN Renal 101 trial**

CONCLUSIONS

- **Longer follow-up confirms the efficacy benefits of A + Ax vs S across IMDC risk groups in patients with aRCC**
- **Progression-free survival (PFS) favored A + Ax vs S across prespecified subgroups, including ECOG PS score, PD-L1 status, and prognostic risk groups**
- **OS data were still immature at IA3; follow-up for the final analysis is ongoing**
- **Observed OS results show benefit of A + Ax vs S across prespecified subgroups**

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BACKGROUND

- The combination of avelumab, an anti–PD-L1 monoclonal antibody, and axitinib, a vascular endothelial growth factor receptor (VEGFR) tyrosine kinase inhibitor, is approved as a first-line treatment for patients with aRCC[1,2]
- In the phase 3 JAVELIN Renal 101 trial (NCT02684006), treatment-naive patients with aRCC receiving A + Ax showed improved PFS and objective response rate (ORR) across IMDC risk groups (favorable [F], intermediate [I], and poor [P]) compared with patients receiving S[3,4]
- At IA2 (data cutoff, January 2019), A + Ax showed improved PFS, ORR, and complete response (CR) rate[4]
  - A + Ax also demonstrated an efficacy benefit across the number of IMDC risk factors and target tumor sites compared with S[5]
- Here we report updated efficacy results from the IA3 of the JAVELIN Renal 101 study, stratified by IMDC risk groups

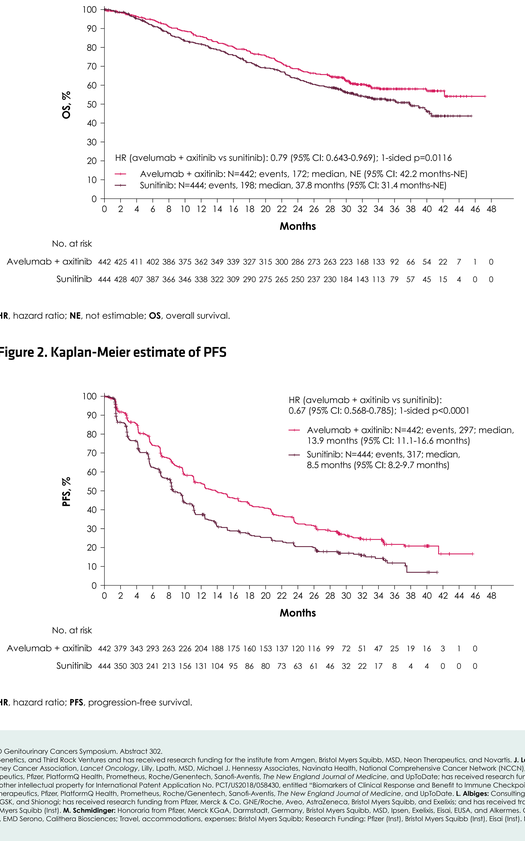
METHODS

- JAVELIN Renal 101 was a phase 3, multicenter, randomized, open-label trial in which the safety and efficacy of A + Ax was compared with those of S in treatment-naive patients with aRCC
  - Patients were randomized 1:1 to receive either A (10 mg/kg intravenously every 2 weeks) + Ax (5 mg orally twice daily) or S (50 mg orally once daily for 4 weeks of a 6-week cycle)
- Patients were categorized per IMDC risk group into F, I, and P subgroups, and outcomes were assessed for F, I, P, and I + P
- OS and PFS, ORR, CR, and duration of response (DOR) were assessed per investigator (RECIST version 1.1)

RESULTS

- As of the April 2020 data cutoff, the median (95% CI) OS was not reached (42.2 months-not estimable [NE]) with A + Ax vs 37.8 months (31.4 months-NE) with S
- The HR for OS favored A + Ax compared with S. However, this did not meet the criteria required to achieve statistical significance (**Figure 1**)
- A + Ax demonstrated an efficacy benefit for PFS compared with S (**Figure 2**)
- An efficacy benefit in ORR, CR, and DOR for A + Ax compared with S were also observed across all IMDC subgroups (**Table 1**)
- OS and PFS across prespecified subgroups, including ECOG PS, PD-L1 status, and prognostic risk groups, are reported (**Figures 3** and **4**)

Figure 1. Kaplan-Meier estimate of OS



HR, hazard ratio; **NE**, not estimable; **OS**, overall survival.

Figure 2. Kaplan-Meier estimate of PFS

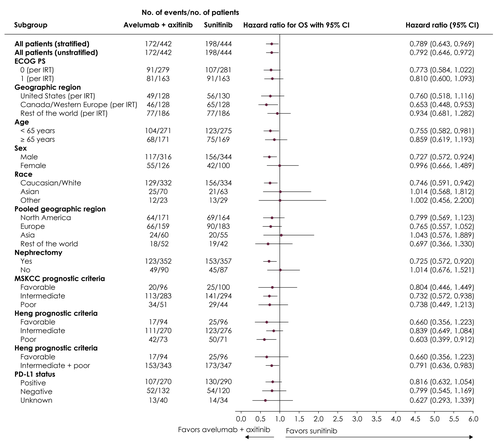
HR, hazard ratio; **PFS**, progression-free survival.

Table 1. Efficacy results with A + Ax vs S

IMDC risk group	Favorable A + Ax (N=442)	Favorable S (N=444)	Intermediate A + Ax (N=442)	Intermediate S (N=444)	Poor A + Ax (N=442)	Poor S (N=444)	Intermediate + Poor A + Ax (N=442)	Intermediate + Poor S (N=444)
n	94	96	270	276	73	71	343	347
mOS (95% CI), mo	NE (NE-NE)	NE (39.8-NE)	42.2 (33.1-NE)	37.8 (29.6-NE)	21.3 (14.7-33.1)	11.0 (7.8-16.5)	40.0 (30.5-NE)	29.5 (24.8-38.0)
HR (95% CI)*	0.66 (0.356-1.223)	Ref	0.84 (0.649-1.084)	Ref	0.60 (0.399-0.912)	Ref	0.79 (0.636-0.983)	Ref
mPFS (95% CI), mo	20.7 (16.6-26.3)	13.8 (11.1-23.5)	12.9 (11.1-6.6)	8.4 (7.9-10.1)	8.7 (5.6-11.1)	4.2 (2.8-5.5)	11.1 (9.8-14.6)	8.2 (6.9-8.4)
HR (95% CI)*	0.71 (0.490-1.016)	Ref	0.71 (0.578-0.866)	Ref	0.45 (0.304-0.678)	Ref	0.66 (0.550-0.787)	Ref
ORR (95% CI), %	75.5 (65.6-83.8)	45.8 (35.6-56.3)	59.6 (53.5-65.5)	31.2 (25.7-37.0)	38.4 (27.2-50.5)	15.5 (8.0-26.0)	55.1 (49.7-60.4)	28.0 (23.3-33.0)
CR, n (%)	9 (9.6)	5 (5.2)	11 (4.1)	8 (2.9)	1 (1.4)	1 (1.4)	12 (3.5)	9 (2.6)
DOR (95% CI), mo	22.6 (15.2-31.7) (n=71)	20.8 (14.5-24.9) (n=44)	19.3 (13.9-22.1) (n=161)	12.5 (7.1-16.6) (n=86)	18.2 (6.8-NE) (n=28)	5.6 (2.5-8.3) (n=11)	19.3 (13.9-22.1) (n=189)	9.8 (7.0-15.3) (n=97)

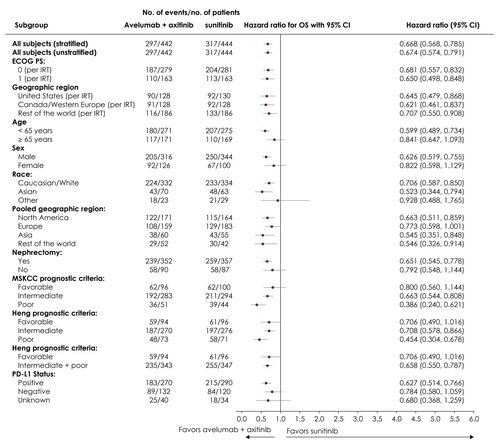
A, avelumab; **Ax**, axitinib; **CR**, complete response; **DOR**, duration of response; **HR**, hazard ratio; **mOS**, median overall survival; **mPFS**, median progression-free survival; **NE**, not estimable; **ORR**, overall response rate; **Ref**, reference; **S**, sunitinib.
*Unstratified.

Figure 3. Forest plot of OS by subgroups



IRT, interactive response technology; **MSKCC**, Memorial Sloan Kettering Cancer Center; **NE**, not estimable; **OS**, overall survival.

Figure 4. Forest plot of PFS by subgroups



IRT, interactive response technology; **MSKCC**, Memorial Sloan Kettering Cancer Center; **NE**, not estimable; **PFS**, progression-free survival.

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