Real-world clinical characteristics and treatment patterns of patients with advanced renal cell carcinoma treated with first-line avelumab + axitinib in the United States

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SCOPE

- **This study examined real-world treatment patterns and duration in patients with advanced renal cell carcinoma (aRCC) and differing International Metastatic Renal Cell Carcinoma (RCC) Database Consortium (IMDC) prognostic risk groups who were receiving or had completed a course of first-line (1L) avelumab + axitinib in the United States (US)**

CONCLUSIONS

- **This study provides an early perspective on real-world treatment patterns in patients with aRCC treated with 1L avelumab + axitinib**
- **Due to the unique study methodology, most patients were receiving ongoing 1L treatment, which explains the limited duration of therapy**
- **Avelumab + axitinib was being used across all IMDC risk groups, but few poor-risk patients received it**
- **As most patients were still receiving 1L treatment at the time of data collection, a limited number of patients were receiving second-line (2L) therapy following discontinuation of avelumab + axitinib**
  - **At the time of data abstraction, the 2L patient sample size was too small to draw any meaningful conclusion; most patients had discontinued treatment due to disease progression**
- **These findings provided important insights into the patient characteristics and related outcomes in a heterogeneous patient population with aRCC treated with 1L avelumab + axitinib, including patients who would not be eligible for clinical trials**
- **Additional research may enhance understanding of treatment patterns and sequencing within the first 2 treatment lines in patients with aRCC**

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BACKGROUND

- In 2020, an estimated 73,750 new cases of kidney and renal pelvis cancer were diagnosed in the US, and approximately 14,830 people died of the disease[1]
- Approximately 30% of patients with RCC present with stage IV disease,[2] and it has been shown that patients with aRCC have a high disease burden.[3] Until recently, tyrosine kinase inhibitors (TKIs) have been the standard 1L treatment for patients with aRCC[4]
- The treatment landscape for aRCC continues to evolve, and approval of immuno-oncology (IO) agents used in combination with TKIs has widened the scope of available 1L treatment options; however, it has been shown that guideline-recommended therapies are not widely used[5]
- In the phase 3 JAVELIN Renal 101 trial, avelumab (an IO agent) plus axitinib (a TKI) demonstrated significantly longer progression-free survival and a higher objective response rate vs sunitinib in patients with previously untreated aRCC[6]
  - Efficacy benefits were observed across IMDC prognostic risk groups in patients with aRCC[7]
- In May 2019, the US Food and Drug Administration approved avelumab in combination with axitinib for 1L treatment of patients with aRCC,[8] widening the breadth of treatment options

METHODS

- Data were drawn from the Adelphi Real World RCC Disease Specific Programme (DSP™), a point-in-time survey conducted with medical oncologists, nephrologists, and urologists in clinical practice in the US between October 2020 and February 2021. The DSP methodology has been previously published and validated[9,10]
- Physician inclusion criteria: specialty in medical oncology, nephrology, or urology, treatment of ≥5 patients with RCC per month, and personal responsibility for prescribing decisions of patients with RCC
- Patient inclusion criteria: age ≥18 years, physician-confirmed diagnosis of aRCC, receiving 1L avelumab + axitinib for ≥3 months at data collection or receiving 2L treatment for aRCC at data collection after having completed 1L avelumab + axitinib
- Physicians compiled patient record forms which included demographics, clinical characteristics, and treatment patterns for the next 8 consecutive consenting adult patients with aRCC who met the above criteria
- Patients who had received 1L avelumab + axitinib for ≥3 months formed the primary analysis set
- This research obtained ethics exemption from the Western Institutional Review Board (WIRB study number1-1152003-1, study protocol number AG8622)
- Descriptive statistics were used, and any missing data were excluded; comparative analyses between the groups were not conducted

RESULTS

- A total of 27 physicians (20 medical oncologists, 3 nephrologists, and 4 urologists) provided data on 158 patients. Of these physicians, 52% were in community-based practice, and 48% were in academic-based practice
- At the time of data collection, 143 patients were receiving 1L avelumab + axitinib, while 15 patients were receiving 2L treatment after having completed 1L avelumab + axitinib

At time of study: patients receiving 1L avelumab + axitinib (n=143)

- Mean patient age was 64.8 years, 68% were male, and 60% had an Eastern Cooperative Oncology Group performance status (ECOG PS) of 0 or 1. Most patients (69%) had IMDC intermediate- or poor-risk disease (intermediate, 65%; poor, 4%), and 23% of patients had unknown or not assessed IMDC prognostic score (**Table 1**)
- 42% of patients had a physician-reported treatment response of complete response (15%) or partial response (27%) (**Figure 1**)
- Physician-reported duration data were available for 85 patients (who were all still on treatment). The median (interquartile range) duration of treatment was 5.0 (4.0-6.0) months (**Figure 2**)

At time of study: patients receiving 2L treatment after discontinuing avelumab + axitinib (n=15)

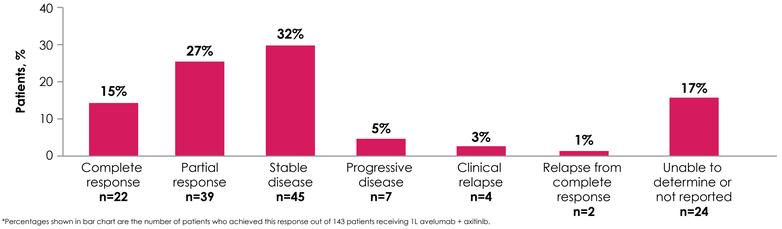
- Mean patient age was 68.0 years; of these 15 patients, 7 were male, and 6 had an ECOG PS of 0 or 1; 9 patients had known IMDC status: 6 had intermediate-risk disease and 3 had poor-risk disease (**Table 1**)
- The most common reason for stopping 1L avelumab + axitinib treatment was disease progression (13 patients). No patients stopped treatment due to unacceptable tolerability, e.g., adverse events (data not shown)

Table 1. Patient demographics and clinical characteristics

	At data collection		
	All (n=158)	**1L (receiving avelumab + axitinib) (n=143)**	**2L (completed avelumab + axitinib at 1L) (n=15)**
Age, mean (SD), years	65.1 (9.0)	64.8 (9.0)	68.0 (8.3)
Clear cell histology, n (%)	113 (72)	102 (71)	11 (73)
Male, n (%)	104 (66)	97 (68)	7 (47)
Employed, n (%)	67 (42)	63 (44)	4 (27)
Health insurance, n (%)			
Commercial	63 (40)	59 (41)	4 (27)
Medicare	59 (37)	52 (36)	7 (47)
Other insurance*	24 (15)	22 (15)	2 (13)
No insurance	4 (3)	2 (1)	2 (13)
Don't know	8 (5)	8 (6)	0
Current TNM stage, n (%)			
III (T1/T2, N1, M0)	8 (5)	8 (6)	0
III (T3, any N, M0)	25 (16)	22 (15)	3 (20)
IV (T4, any N, M0)	16 (10)	15 (10)	1 (7)
IV (any T, any N, M1)	109 (69)	98 (69)	11 (73)
IMDC risk, n (%)			
Favorable	11 (7)	11 (8)	0
Intermediate	99 (63)	93 (65)	6 (40)
Poor	9 (6)	6 (4)	3 (20)
Unknown/not assessed	39 (25)	33 (23)	6 (40)
Most recent ECOG PS, n (%)			
0	27 (17)	27 (19)	0
1	65 (41)	59 (41)	6 (40)
2+	58 (37)	50 (35)	8 (53)
Unknown/not assessed	8 (5)	7 (5)	1 (7)

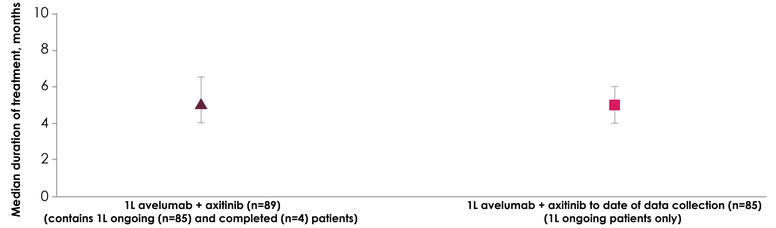
1L, first-line; **2L**, second-line; **ECOG PS**, Eastern Cooperative Oncology Group performance status; **IMDC**, International Metastatic RCC Database Consortium; **RCC**, renal cell carcinoma; **SD**, standard deviation, **TNM**, tumor, nodes, and metastases.
*Includes Medicaid (or state equivalent), health insurance exchange plan, TRICARE/veterans health care, non-Medicare retired benefit, and COBRA (continuation coverage).

Figure 1. Physician-reported response in patients receiving 1L avelumab + axitinib at time of study (n=143)*



*Percentages shown in bar chart are the number of patients who achieved this response out of 143 patients receiving 1L avelumab + axitinib.
1L, first-line.

Figure 2. Median treatment duration on 1L avelumab + axitinib*



*Bars indicate interquartile ranges. 2L patients had received 1L avelumab + axitinib.
1L, first-line; 2L, second-line.

LIMITATIONS

- Participating patients may not reflect the general aRCC population as they were visiting their physician and may have been those who visit more frequently and more severely affected than those who did not consult their physician
- Patients visiting primary care physicians and patients visiting physicians who see <5 patients with aRCC per month were not represented in this sample
- Physicians were asked to provide data for a consecutive series of patients to avoid selection bias, but no formal patient selection verification procedures were in place
- The point-in-time design of this survey prevented any conclusions about causal relationships
- Recall bias, a common limitation of surveys, might have also affected responses of physicians to the questionnaires
- Response data were not verified with the primary source. Missing data were not imputed; therefore, the base of patients for analysis could vary from variable to variable and was reported separately for each analysis
- Sample size was small for patients receiving 2L therapy

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