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Avelumab first-line maintenance treatment for advanced urothelial carcinoma in France: conditional survival and long-term safety in patients treated for ≥1 or ≥2 years in the AVENANCE real-world study

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CONCLUSIONS

• Post hoc analyses from the AVENANCE real-world study examined the probability of additional overall survival (OS) and progression-free survival (PFS) in addition to long-term safety in patients with advanced urothelial carcinoma (UC) that had not progressed with first-line (1L) platinum-based chemotherapy and who received ≥1 or ≥2 years of avelumab 1L maintenance treatment

• In patients who had received 1 year of avelumab treatment (197/595 [33.1%]), the probability of an additional 1 or 2 years of OS was 87.69% and 73.94%, respectively

• In patients who had received 2 years of avelumab treatment (105/595 [17.6%]), the probability of an additional 1 or 2 years of OS was 90.32% and not estimable (NE), respectively

• Patients who had received 1 or 2 years of avelumab treatment had a high probability of having an additional 1 year of PFS (60.67% and 66.03%, respectively)

• No new safety concerns were identified with prolonged treatment

• Overall, these findings are consistent with similar analyses from the JAVELIN Bladder 100 phase 3 trial¹ and inform prognosis for patients receiving avelumab 1L maintenance in a real-world setting

PLAIN LANGUAGE SUMMARY

• Based on clinical trial results, avelumab maintenance is a standard treatment for people with advanced urothelial cancer

– Maintenance treatment means treating people whose cancer disappeared, shrank, or stopped growing after chemotherapy

• In a French study called AVENANCE, researchers found that real-world results in people treated with avelumab maintenance outside of a clinical trial were similar to clinical trial results

• In this new analysis, researchers looked at survival in people who had lived for at least 1 or 2 years while receiving avelumab maintenance treatment

– In people who had received 1 year of avelumab treatment, the likelihood of surviving for an additional 1 or 2 years was 88% and 74%, respectively

– In people who had received 2 years of avelumab treatment, the likelihood of surviving for an additional 1 year was 90%

– In people who received avelumab treatment for at least 1 or 2 years, serious side effects occurred after 1 year in 2% of patients and after 2 years in 1%

• Overall, these results suggest that people with advanced urothelial cancer who live for at least 1 year while receiving avelumab maintenance treatment have a high likelihood of surviving for another 1 or 2 years or longer and a very low likelihood of serious side effects

BACKGROUND

• In the JAVELIN Bladder 100 trial, avelumab 1L maintenance + best supportive care (BSC) significantly prolonged OS and PFS vs BSC alone in patients with advanced UC that had not progressed with 1L platinum-based chemotherapy^{2,3}

- After ≥2 years of follow-up in all patients, median OS (from start of maintenance) was 23.8 vs 15.0 months, respectively (hazard ratio, 0.76 [95% CI, 0.63-0.91]; p=0.0036)³
- Avelumab 1L maintenance is approved worldwide and is a recommended treatment option in international guidelines^{4,5}

• In post hoc analyses from JAVELIN Bladder 100, patients who had received 1 or 2 years of avelumab 1L maintenance treatment had a high probability of having an additional 1 year of OS or PFS¹

- In patients who had received 1 year of avelumab treatment, the probability of an additional 1 or 2 years of OS was 93.2% and 79.6%, respectively
- In patients who had received 2 years of avelumab treatment, the probability of an additional 1 or 1.5 years of OS was 95.8% and 90.3%, respectively

• The real-world effectiveness and safety of avelumab 1L maintenance in patients with advanced UC was confirmed in AVENANCE, a large noninterventional study in France⁶

• In a previously reported analysis in the overall population (N=595) with a median follow-up of 26.3 months¹:

- Median OS from the start of avelumab 1L maintenance treatment was 21.3 months (95% CI, 17.6-24.6)
- Median PFS was 5.7 months (95% CI, 5.2-6.5)

• Here, we report post hoc analyses from AVENANCE that examined the probability of additional OS and PFS in addition to long-term safety in subgroups treated with avelumab for ≥1 or ≥2 years

METHODS

• AVENANCE (NCT04822350) is a multicenter, noninterventional, ambispective (retrospective and prospective) study

• Eligible patients had locally advanced or metastatic UC that had not progressed with 1L platinum-based chemotherapy (ie, ongoing complete response, partial response, or stable disease) and previous, ongoing, or planned avelumab 1L maintenance treatment

• Data collection started on 13 July 2021, and additional follow-up was ongoing at the time of this analysis

• No study-specific visits were required, and patients were assessed and followed up per standard clinical practice

• The primary endpoint was OS from the start of avelumab treatment

- The effectiveness population included all patients who received ≥1 dose of avelumab and met all eligibility criteria, and the safety population included all patients who received ≥1 dose of avelumab

• In this post hoc analysis, subgroups of patients who received ≥1 or ≥2 years of avelumab treatment were analyzed

- Conditional survival was assessed using Kaplan-Meier analysis
- Adverse events were analyzed descriptively

RESULTS

• Of 604 screened patients, 595 were included in the effectiveness population, and 596 were included in the safety population

• At data cutoff (2 December 2024) in the overall effectiveness population:

- Median follow-up from start of avelumab was 33.2 months (95% CI, 31.7-34.0)
- Avelumab treatment duration was ≥1 year in 197 patients (33.1%) and ≥2 years in 105 (17.6%)

• Compared with the overall effectiveness population, a higher proportion of patients treated for ≥2 years had received prior neoadjuvant treatment (35.5% vs 23.6%), had an Eastern Cooperative Oncology Group performance status of 0 (40.9% vs 31.7%), and had received 1L cisplatin + gemcitabine (42.9% vs 27.5%) (Table 1)

Table 1. Baseline characteristics in the overall effectiveness population and subgroups with ≥1 or ≥2 years of avelumab 1L maintenance treatment

	Overall effectiveness population (N=595)	≥1 year of treatment (n=197)	≥2 years of treatment (n=105)
Age, median (IQR), years	73.0 (67.0-78.2)	72.2 (66.6-77.6)	71.3 (65.9-75.1)
Sex, n (%)			
Female	102 (17.1)	34 (17.3)	19 (18.1)
Male	493 (82.9)	163 (82.7)	86 (81.9)
ECOG PS at start of avelumab, n (%)	n=502	n=171	n=88
0	159 (31.7)	64 (37.4)	36 (40.9)
≥1	343 (68.3)	107 (62.6)	52 (59.1)
Primary tumor site, n (%)	n=593	n=195	n=104
Lower tract	472 (79.6)	155 (79.5)	84 (80.8)
Upper tract	121 (20.4)	40 (20.5)	20 (19.2)
Prior treatment for localized invasive UC, n (%)	n=216	n=63	n=31
Received neoadjuvant chemotherapy	51 (23.6)	20 (31.7)	11 (35.5)
Received adjuvant chemotherapy	53 (24.5)	13 (20.6)	4 (12.9)
Disease stage at start of 1L chemotherapy, n (%)	n=593	n=197	n=105
Metastatic	546 (92.1)	174 (88.3)	93 (88.6)
Locally advanced	47 (7.9)	23 (11.7)	12 (11.4)
1L chemotherapy regimen, n (%)	n=593	n=197	n=105
Carboplatin + gemcitabine	364 (61.4)	109 (55.3)	46 (43.8)
Cisplatin + gemcitabine	163 (27.5)	67 (34.0)	45 (42.9)
Methotrexate, vinorelbine, doxorubicin, and cisplatin	25 (4.2)	11 (5.6)	6 (5.7)
Other or switched*	41 (6.9)	10 (5.1)	8 (7.6)
No. of 1L chemotherapy cycles, median (range)	5 (1-15)	5 (2-10)	5 (3-10)
Response to 1L chemotherapy, n (%)	n=591	n=196	n=105
Complete response	113 (19.1)	44 (22.4)	19 (18.1)
Partial response	335 (56.7)	112 (57.1)	64 (61.0)
Stable disease	137 (23.2)	39 (19.9)	22 (21.0)
Other	6 (1.0)	1 (0.5)	0

1L, first line; ECOG PS, Eastern Cooperative Oncology Group performance status; UC, urothelial carcinoma. *Patients who switched platinum regimens while receiving 1L chemotherapy.

• In patients with 1 year of avelumab treatment, the probability of an additional 1 or 2 years of OS was 87.69% and 73.94%, respectively (Figure 1A)

– In this subgroup, the probability of an additional 6 months or 1 year of PFS was 69.94% and 60.67%, respectively (Figure 2A)

• In patients with 2 years of avelumab treatment, the probability of an additional 1 or 2 years of OS was 90.32% and NE, respectively (Figure 1B)

– In this subgroup, the probability of an additional 6 months or 1 year of PFS was 74.85% and 66.03%, respectively (Figure 2B)

• In patients treated for ≥1 or ≥2 years, any-grade treatment-related adverse events (TRAEs) occurred after 1 year in 111 (56.3%) and after 2 years in 32 (30.5%), including serious TRAEs in 4 (2.0%) and 1 (1.0%), respectively (Table 2)

Figure 1. Additional OS in patients who had received 1 or 2 years of avelumab

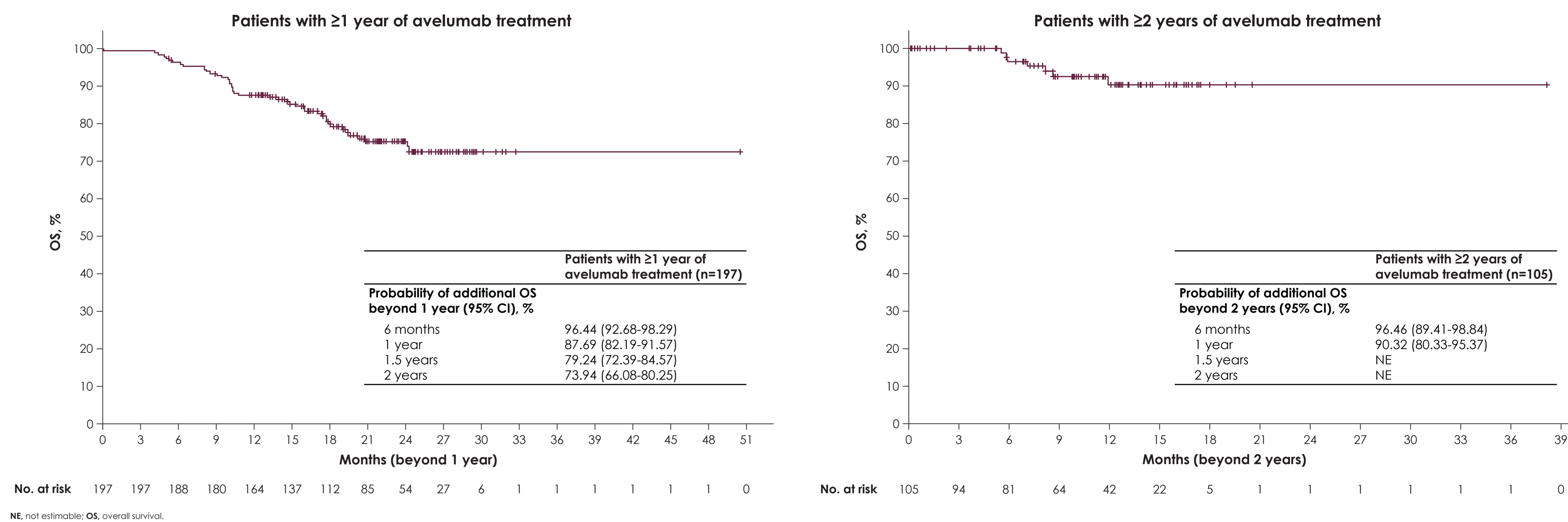


Figure 2. Additional PFS in patients who had received 1 or 2 years of avelumab

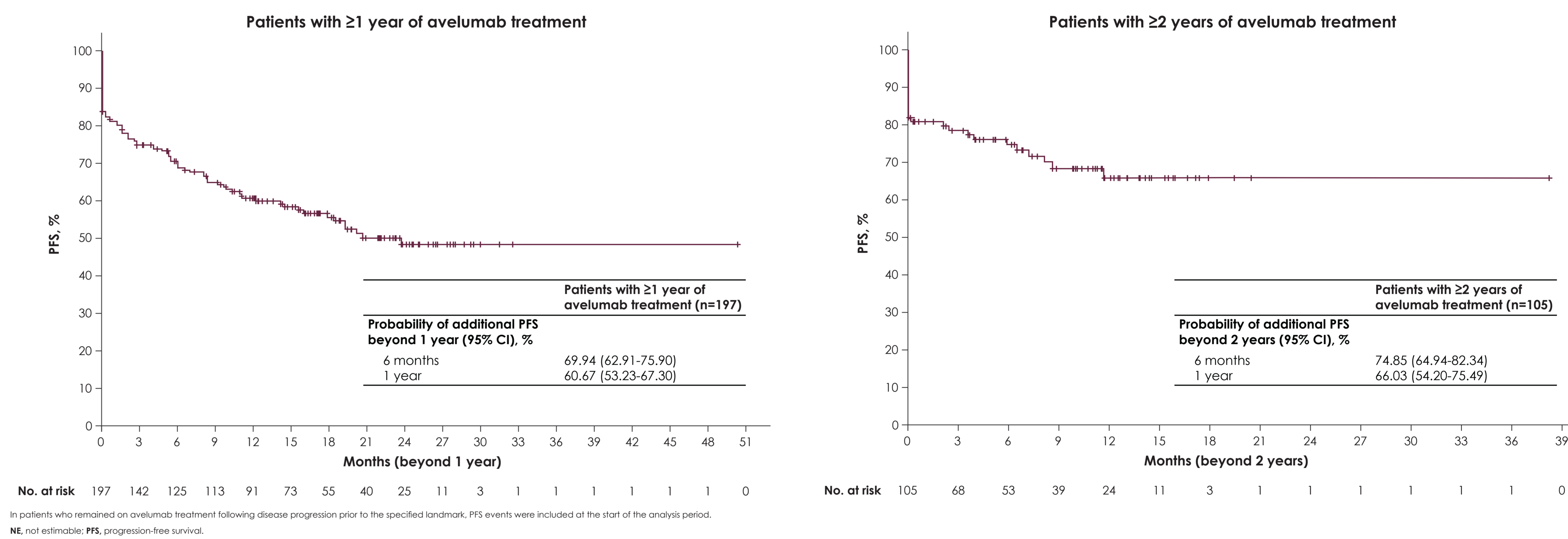


Table 2. Summary of AEs occurring at any time and after 1 or 2 years of avelumab treatment

Patients, n (%)	Occurred at any time (all treated patients; N=596)	Occurred after 1 year (patients with ≥1 year of treatment; n=197)	Occurred after 2 years (patients with ≥2 years of treatment; n=105)
TEAE, n (%)	453 (76.0)	163 (82.7)	58 (55.2)
Serious TEAE	143 (24.0)	41 (20.8)	12 (11.4)
TEAE leading to temporary/permanent discontinuation	274 (46.0)	98 (49.7)	28 (26.7)
TEAE leading to death	26 (4.4)	5 (2.5)	0
TRAE, n (%)	346 (58.1)	111 (56.3)	32 (30.5)
Serious TRAE	36 (6.0)	4 (2.0)	1 (1.0)
TRAE leading to temporary/permanent discontinuation	206 (34.6)	68 (34.5)	20 (19.0)
TRAE leading to death	3 (0.5)	0	0

AEs reported occurred during the on-treatment period (date of first avelumab dose until 30 days after the last dose of avelumab or the day before the start of new anticancer drug therapy, whichever occurred first).

AE, adverse event; TEAE, treatment-emergent adverse event; TRAE, treatment-related and -emergent adverse event.

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