# Avelumab first-line maintenance for advanced urothelial carcinoma: long-term outcomes from JAVELIN Bladder 100 in patients with low tumor burden


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JAVELIN Bladder 100

## CONCLUSIONS

- **We report long-term efficacy and safety outcomes from a post hoc analysis of subsets of patients with low tumor burden (ie, nonvisceral metastases or lymph node–only disease) from the JAVELIN Bladder 100 trial, which compared avelumab first-line (1L) maintenance + best supportive care (BSC) vs BSC alone in patients with advanced urothelial carcinoma (UC) that had not progressed with 1L platinum-based chemotherapy**
- **Overall survival (OS) and investigator-assessed progression-free survival (PFS) were prolonged with avelumab + BSC vs BSC alone in subsets of patients with low tumor burden**
- **The long-term safety of avelumab 1L maintenance in patients with low tumor burden was demonstrated and was generally consistent with results from the overall population[1,2]**
- **The findings indicate that avelumab 1L maintenance has pronounced efficacy and manageable toxicity in patients with advanced UC with low tumor burden, supporting the use of platinum-based chemotherapy followed by avelumab maintenance as an important 1L treatment option in these patients**

## PLAIN LANGUAGE SUMMARY

- **In the JAVELIN Bladder 100 study, avelumab maintenance treatment helped people with advanced urothelial cancer live longer**
  - **Maintenance treatment means treating people whose cancer disappeared, shrank, or stopped growing with chemotherapy with the aim of maintaining the benefit**
- **This new analysis from the JAVELIN Bladder 100 study looked at results with avelumab maintenance treatment in people who had low tumor burden**
  - **The people with low tumor burden had cancer that had spread to nearby tissues, bones, or lymph nodes but not other places, like the lung or liver**
- **In this analysis, people who were treated with avelumab had a 40% lower risk of dying than those not treated with avelumab**
  - **No new safety concerns were found in this subgroup compared with all people in the study**
- **Overall, these results provide more support for using avelumab maintenance as a standard treatment option for people with advanced urothelial cancer, including those with low tumor burden**

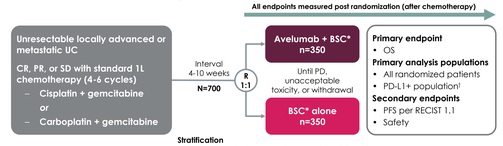
## BACKGROUND

- In the JAVELIN Bladder 100 trial, avelumab 1L maintenance + BSC significantly prolonged OS and PFS vs BSC alone in patients with advanced UC that had not progressed with 1L platinum-based chemotherapy[1,2]
  - After ≥2 years of follow-up (data cutoff: June 4, 2021), median OS (from randomization) was 23.8 vs 15.0 months, respectively (hazard ratio [HR], 0.76 [95% CI, 0.63-0.91]; 2-sided p=0.0036)[1]
  - The long-term safety of avelumab 1L maintenance was demonstrated, with no new safety concerns identified,[1] and no detrimental impact on quality of life was observed[3]
- Results from the trial led to avelumab 1L switch maintenance being recommended as a standard of care in international treatment guidelines for patients with advanced UC that has not progressed with 1L platinum-based chemotherapy[4-7]
- Prior analyses have shown that low tumor burden (ie, nonvisceral metastases or lymph node–only disease) is associated with better outcomes in patients with advanced UC receiving immune checkpoint inhibitors[8-10]
- Here, we report post hoc analyses of efficacy and safety in subsets of patients with low tumor burden from the JAVELIN Bladder 100 trial

## METHODS

- In the phase 3 JAVELIN Bladder 100 trial (NCT02603432), 700 patients with unresectable locally advanced or metastatic UC without progression after 4-6 cycles of 1L platinum-based chemotherapy were randomized 1:1 to receive avelumab + BSC or BSC alone (**Figure 1**)
- The primary endpoint was OS; secondary endpoints included investigator-assessed PFS and safety
- This post hoc analysis was performed in patients with low tumor burden, ie, those with nonvisceral metastases at start of 1L chemotherapy or the subset with lymph node–only disease at randomization
  - Patients with nonvisceral metastases included those with locally advanced disease in addition to those with only nonvisceral disease at randomization
  - In this trial, bone metastases were considered nonvisceral
- Adverse events were graded according to the National Cancer Institute Common Terminology Criteria for Adverse Events version 4.03

**Figure 1. JAVELIN Bladder 100 study design[1]**




**1L**, first line; **BSC**, best supportive care; **CR**, complete response; **OS**, overall survival; **PD**, progressive disease; **PFS**, progression-free survival; **PR**, partial response; **R**, randomization; **SD**, stable disease; **UC**, urothelial carcinoma.
*BSC (eg, antibiotics, nutritional support, hydration, and pain management) was administered per local practice based on patient needs and clinical judgment; other antitumor therapy was not permitted, but palliative local radiotherapy for isolated lesions was acceptable. †Assessed using the Ventana SP263 assay.

## RESULTS

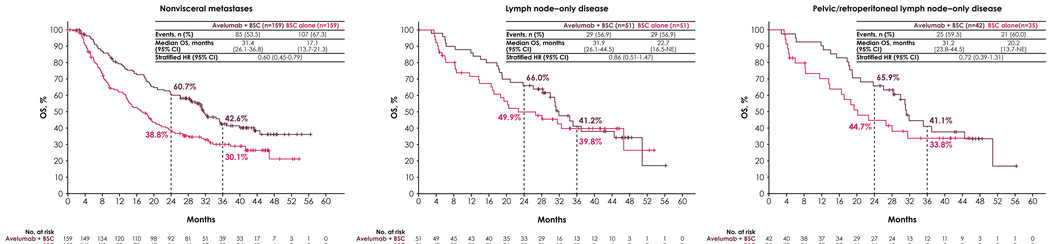
- At the efficacy data cutoff (June 4, 2021), median follow-up was ≥38 months in both arms
- In the avelumab + BSC and BSC alone arms, respectively, 159 and 159 patients had nonvisceral metastases at start of 1L chemotherapy and 51 and 51 patients had lymph node–only disease at randomization, of whom 42 and 35 patients had lymph node–only disease in the pelvic/retroperitoneal area only (**Table 1**)
- In all subgroups of patients with low tumor burden, OS was prolonged in the avelumab + BSC arm vs the BSC alone arm (**Figure 2**)
  - Median OS in the avelumab + BSC vs BSC alone arms was 31.4 vs 17.1 months in patients with nonvisceral metastases, 31.9 vs 22.7 months in patients with lymph node–only disease, and 31.2 vs 20.2 months in patients with pelvic/retroperitoneal lymph node–only disease
- Investigator-assessed PFS was also prolonged with avelumab + BSC vs BSC alone in patients with low tumor burden (**Figure 3**)
  - Median PFS in the avelumab + BSC vs BSC alone arms was 9.0 vs 3.3 months in patients with nonvisceral metastases, 8.7 vs 3.7 months in patients with lymph node–only disease, and 7.5 vs 3.7 months in patients with pelvic/retroperitoneal lymph node–only disease
- At the data cutoff of April 6, 2023, in the avelumab + BSC and BSC alone arms, respectively, subsequent anticancer drug treatment was received by 90 (56.6%) and 119 patients (74.8%) with nonvisceral metastases, 27 (52.9%) and 39 patients (76.5%) with lymph node–only disease, and 22 (52.4%) and 27 patients (77.1%) with lymph node–only disease in the pelvic/retroperitoneal area only
- The long-term safety of avelumab 1L maintenance (data cutoff: April 6, 2023) was acceptable in all subsets of patients with low tumor burden (**Table 2**)
  - Two patients (1.3%) in the nonvisceral metastases subgroup, of whom 1 had lymph node–only disease, had a treatment-related adverse event that led to death as assessed by the treating investigator (sepsis [n=1], and immune-related nephritis [n=1; patient with lymph node–only disease])

**Table 1. Patient characteristics at baseline**

| | Nonvisceral metastases | | Lymph node–only disease | | Pelvic/retroperitoneal lymph node–only disease | |
|---|---|---|---|---|---|---|
| | Avelumab + BSC (n=159) | BSC alone (n=159) | Avelumab + BSC (n=51) | BSC alone (n=51) | Avelumab + BSC (n=42) | BSC alone (n=35) |
| **Age, median (range), years** | 68 (39-90) | 69 (32-85) | 69 (39-85) | 68 (53-81) | 69 (39-85) | 67 (54-81) |
| **Sex, n (%)** | | | | | | |
| Male | 125 (78.6) | 125 (78.6) | 43 (84.3) | 39 (76.5) | 35 (83.3) | 28 (80.0) |
| Female | 34 (21.4) | 34 (21.4) | 8 (15.7) | 12 (23.5) | 7 (16.7) | 7 (20.0) |
| **Pooled geographic region, n (%)** | | | | | | |
| Europe | 91 (57.2) | 89 (56.0) | 32 (62.7) | 34 (66.7) | 27 (64.3) | 28 (80.0) |
| North America | 7 (4.4) | 9 (5.7) | 2 (3.9) | 0 | 1 (2.4) | 0 |
| Asia | 39 (24.5) | 37 (23.3) | 7 (13.7) | 13 (25.5) | 5 (11.9) | 5 (14.3) |
| Australasia | 16 (10.1) | 19 (11.9) | 8 (15.7) | 3 (5.9) | 7 (16.7) | 1 (2.9) |
| Rest of the world | 6 (3.8) | 5 (3.1) | 2 (3.9) | 1 (2.0) | 2 (4.8) | 1 (2.9) |
| **ECOG PS, n (%)** | | | | | | |
| 0 | 93 (58.5) | 101 (63.5) | 28 (54.9) | 33 (64.7) | 25 (59.5) | 21 (60.0) |
| ≥1 | 66 (41.5) | 58 (36.5) | 23 (45.1) | 18 (35.3) | 17 (40.5) | 14 (40.0) |
| **PD-L1 status, n (%)** | | | | | | |
| Positive | 101 (63.5) | 90 (56.6) | 35 (68.6) | 31 (60.8) | 30 (71.4) | 23 (65.7) |
| Negative | 49 (30.8) | 49 (30.8) | 13 (25.5) | 12 (23.5) | 10 (23.8) | 8 (22.9) |
| Unknown | 9 (5.7) | 20 (12.6) | 3 (5.9) | 8 (15.7) | 2 (4.8) | 4 (11.4) |
| **Site of metastasis at start of 1L chemotherapy, n (%)** | | | | | | |
| Visceral | 0 | 0 | 11 (21.6) | 8 (15.7) | 10 (23.8) | 7 (20.0) |
| Nonvisceral | 159 (100) | 159 (100) | 40 (78.4) | 43 (84.3) | 32 (76.2) | 28 (80.0) |
| **Best response to 1L chemotherapy, n (%)** | | | | | | |
| CR or PR | 113 (71.1) | 112 (70.4) | 32 (62.7) | 37 (72.5) | 27 (64.3) | 27 (77.1) |
| SD | 46 (28.9) | 47 (29.6) | 19 (37.3) | 14 (27.5) | 15 (35.7) | 8 (22.9) |

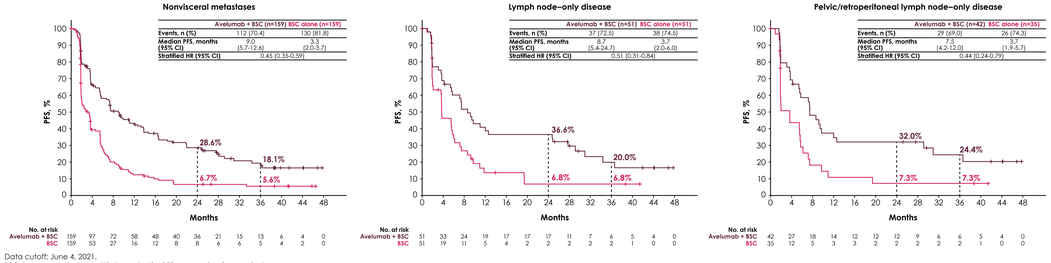
Data cutoff: April 6, 2023.
**1L**, first line; **BSC**, best supportive care; **CR**, complete response; **ECOG PS**, Eastern Cooperative Oncology Group performance status; **PR**, partial response; **SD**, stable disease.

**Figure 2. OS in subgroups with low tumor burden**




Data cutoff: June 4, 2021.
**BSC**, best supportive care; **HR**, hazard ratio; **NE**, not evaluable; **OS**, overall survival.

**Figure 3. Investigator-assessed PFS in subgroups with low tumor burden**




Data cutoff: June 4, 2021.
**BSC**, best supportive care; **HR**, hazard ratio; **PFS**, progression-free survival.

**Table 2. Summary of long-term safety in subgroups with low tumor burden**

| | Nonvisceral metastases | | Lymph node–only disease | | Pelvic/retroperitoneal lymph node–only disease | |
|---|---|---|---|---|---|---|
| **Patients, n (%)** | Avelumab + BSC (n=158) | BSC alone (n=157) | Avelumab + BSC (n=50) | BSC alone (n=50) | Avelumab + BSC (n=41) | BSC alone (n=34) |
| **AE of any grade** | 156 (98.7) | 133 (84.7) | 50 (100) | 37 (74.0) | 41 (100) | 24 (70.6) |
| Grade ≥3 AE | 93 (58.9) | 43 (27.4) | 33 (66.0) | 11 (22.0) | 29 (70.7) | 7 (20.6) |
| **TRAE of any grade** | 122 (77.2) | 2 (1.3) | 44 (88.0) | 0 | 36 (87.8) | 0 |
| Grade ≥3 TRAE | 30 (19.0) | 0 | 8 (16.0) | 0 | 6 (14.6) | 0 |
| **Serious AE** | 55 (34.8) | 40 (25.5) | 20 (40.0) | 12 (24.0) | 18 (43.9) | 9 (26.5) |
| Serious TRAE | 18 (11.4) | 0 | 7 (14.0) | 0 | 5 (12.2) | 0 |
| **AE leading to discontinuation of study drug** | 24 (15.2) | 0 | 5 (10.0) | 0 | 4 (9.8) | 0 |
| TRAE leading to discontinuation of study drug | 21 (13.3) | 0 | 3 (6.0) | 0 | 2 (4.9) | 0 |
| **AE leading to death** | 2 (1.3) | 11 (7.0) | 3 (6.0) | 4 (8.0) | 2 (4.9) | 2 (5.9) |
| TRAE leading to death | 2 (1.3) | 0 | 1 (2.0) | 0 | 0 | 0 |
| **irAE of any grade** | 52 (32.9) | 5 (3.2) | 17 (34.0) | 3 (6.0) | 15 (36.6) | 3 (8.8) |
| **IRR of any grade** | 33 (20.9) | 0 | 12 (24.0) | 0 | 9 (22.0) | 0 |

Data cutoff: April 6, 2023.
**AE**, adverse event; **BSC**, best supportive care; **irAE**, immune-related AE; **IRR**, infusion-related reaction; **TRAE**, treatment-related AE.

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**REFERENCES** 1. Powles T, et al. J Clin Oncol. 2023;41(19):3486-92. 2. Powles T, et al. N Engl J Med. 2020;383(13):1218-30. 3. Grivas P, et al. Eur Urol. 2023;83(4):320-8. 4. NCCN Clinical Practice Guidelines in Oncology: Bladder Cancer. V3.2024. 5. Powles T, et al. Ann Oncol. Published online March 13, 2024. 7. Cathomas R, et al. Eur Urol. 2022;81(1):95-103. 8. Yuen J, et al. J Clin Oncol. 2020;38(23):2638-46. 9. Bolar AV, et al. Lancet. 2017;389(10064):67-76. 10. Nassar AH, et al. Br J Cancer. 2020;122(4):555-63.


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