# Full analysis from AVENANCE: a real-world study of avelumab first-line maintenance treatment in patients with advanced urothelial carcinoma


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## SCOPE

- **We report the effectiveness and safety of avelumab first-line (1L) maintenance in patients with advanced urothelial carcinoma (aUC) in France from the full analysis set of AVENANCE, an ongoing, real-world, ambispective (retrospective and prospective) study**

## CONCLUSIONS

- **These data for avelumab 1L maintenance treatment in patients with aUC are the first to be reported from the full analysis set of the ongoing, real-world, AVENANCE study and support the findings of the JAVELIN Bladder 100 trial[1,2]**
- **Data from AVENANCE also confirm the clinical activity and acceptable safety profile of avelumab 1L maintenance in a large cohort of patients (N=593) from a heterogeneous population outside of a clinical trial setting**
  - **The 12-month overall survival (OS) rate was 65.4%, and median OS was 20.7 months (95% CI, 17.1-not estimable [NE])**
  - **Median progression-free survival (PFS) from the start of avelumab treatment was 5.7 months (95% CI, 5.3-7.0)**
  - **The safety profile was consistent with that observed in other studies of avelumab monotherapy; no new safety concerns were identified[3]**
- **These results further support the recommendation of avelumab 1L maintenance as standard of care for patients with aUC that has not progressed with 1L platinum-based chemotherapy**




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## BACKGROUND

- In the phase 3 JAVELIN Bladder 100 trial (NCT02603432), avelumab 1L maintenance + best supportive care (BSC) significantly prolonged OS vs BSC alone in patients with aUC that had not progressed with 1L platinum-based chemotherapy[1,2]
  - Trial results led to the approval of avelumab 1L maintenance in various countries[4,5]
  - Longer-term results from JAVELIN Bladder 100 (≥2 years of follow-up in all patients) continued to show prolonged OS and investigator-assessed PFS with avelumab 1L maintenance + BSC vs BSC alone[2]
    - Median OS was 23.8 vs 15.0 months, respectively (hazard ratio [HR], 0.76 [95% CI, 0.631-0.915]; 2-sided p=0.0036)
    - Median PFS was 5.5 vs 2.1 months, respectively (HR, 0.54 [95% CI, 0.457-0.645]; 2-sided p<0.0001)
    - Avelumab 1L maintenance also demonstrated an acceptable long-term safety profile
  - The JAVELIN Bladder regimen (1L platinum-based chemotherapy followed by avelumab 1L maintenance in patients without disease progression) is now recommended as standard of care with level 1 evidence in international treatment guidelines[6-9]
- AVENANCE is an ongoing, real-world study evaluating the effectiveness and safety of avelumab 1L maintenance in patients with aUC in France
  - Preliminary results from this study in the first 267 patients enrolled who had started avelumab treatment ≥6 months prior to January 31, 2022 (data cutoff) have been published previously[10]
    - The 12-month OS rate from the start of avelumab treatment was 66.9%, and median PFS was 5.7 months

## METHODS

- AVENANCE (NCT04822350) is an ongoing, multicenter, ambispective, noninterventional study
- Eligible patients have locally advanced or metastatic UC that has not progressed with 1L platinum-based chemotherapy (ie, ongoing complete response, partial response, or stable disease) and have previous, ongoing, or planned avelumab 1L maintenance treatment
- Data collection started on July 13, 2021, and data cutoff for this analysis was December 1, 2022
- The primary endpoint is OS from the start of avelumab treatment
- Secondary endpoints include PFS, duration of treatment, and safety
- Effectiveness and safety were analyzed in patients who had received ≥1 dose of avelumab
- Because follow-up in the full analysis set was relatively short, an additional analysis was conducted in the first 267 patients who were enrolled (interim analysis population)

## RESULTS

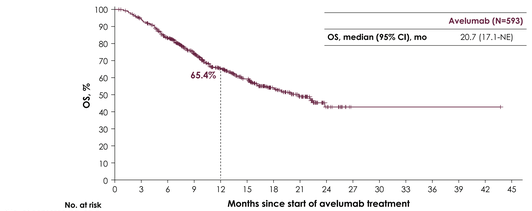
- A total of 593 patients received avelumab
- At data cutoff (December 1, 2022), median follow-up since avelumab initiation (by reverse Kaplan-Meier estimation) was 15.2 months (95% CI, 14.6-16.4) in the full analysis set
  - In the interim analysis population (n=267), median follow-up was 18.3 months (95% CI, 17.2-19.4)
- Baseline characteristics for the full analysis set are presented in **Table 1**
- At data cutoff, 200 patients (33.7%) were still receiving avelumab treatment
  - Of the 392/393 patients for whom the reason for discontinuing avelumab was reported, the most common reasons were disease progression (n=294; 75.0%), adverse event (n=43; 11.0%), and death (n=39; 9.9%)
- Median OS from the start of avelumab treatment was 20.7 months (95% CI, 17.1-NE); the 12-month OS rate was 65.4% (95% CI, 61.0-69.4) (**Figure 1**)
  - A subgroup analysis of OS is shown in **Table 2**
  - In the interim analysis population, median OS was 22.2 months (95% CI, 17.1-NE) (**Figure 2**)
- Median PFS was 5.7 months (95% CI, 5.3-7.0) (**Figure 3**)
- 282 patients (47.6%) reported receiving subsequent treatment (**Table 3**)
- Median duration of treatment with avelumab was 5.8 months (95% CI, 5.1-7.1)

**Table 1. Baseline characteristics**

| | N=593 |
|---|---|
| **Age, median (Q1-Q3), years** | 73.1 (67.0-78.1) |
| **Sex, n (%)** | |
| Male | 484 (82.5) |
| Female | 103 (17.5) |
| Missing data | 6 |
| **Location of primary tumor, n (%)** | |
| Bladder | 438 (74.9) |
| Upper tract | 113 (19.3) |
| Urethra | 34 (5.8) |
| Missing data | 8 |
| **Tumor histology, n (%)** | |
| Pure urothelial carcinoma | 531 (91.9) |
| Urothelial carcinoma with variant | 31 (5.4) |
| Epidermoid carcinoma | 8 (1.4) |
| Other* | 8 (1.4) |
| Missing data | 15 |
| **Tumor status at start of 1L chemotherapy, n (%)** | |
| Locally advanced | 50 (8.6) |
| Metastatic | 530 (91.2) |
| Patient with complete response | 1 (0.2) |
| Missing data | 12 |
| **Presence of visceral metastasis at start of 1L chemotherapy, n (%)** | **n=530** |
| Yes | 436 (82.4) |
| No | 93 (17.6) |
| Missing data | 1 |
| **Metastasis sites at start of 1L chemotherapy, n (%)** | **n=436** |
| Lymph nodes | 261 (59.9) |
| Liver | 81 (18.6) |
| Lung | 141 (32.3) |
| Bone | 161 (36.9) |
| Brain | 2 (0.5) |
| Other | 87 (20.0) |
| **ECOG PS at start of 1L chemotherapy, n (%)** | |
| 0 | 152 (31.8) |
| 1 | 255 (53.3) |
| 2 | 61 (12.8) |
| 3 | 9 (1.9) |
| 4 | 1 (0.2) |
| Missing data | 115 |
| **Type of 1L chemotherapy, n (%)** | |
| Cisplatin + gemcitabine | 170 (29.3) |
| Carboplatin + gemcitabine | 354 (60.9) |
| Cisplatin or carboplatin + gemcitabine† | 11 (1.9) |
| ddMVAC | 27 (4.6) |
| Other | 19 (3.3) |
| Missing data | 12 |
| **No. of 1L chemotherapy cycles, median (range)** | 5 (1-10) |
| **Response to last chemotherapy, n (%)** | |
| Complete response | 117 (20.3) |
| Partial response | 315 (54.6) |
| Stable disease | 132 (22.9) |
| Disease progression | 6 (1.0) |
| Nonevaluable | 7 (1.2) |
| Missing data | 16 |

Percentages reported were calculated using the denominator of patients with available data for each characteristic.
1L, first line; **ddMVAC**, dose-dense methotrexate, vinblastine, doxorubicin, and cisplatin.
*Including pure adenocarcinoma, pure small cell neuroendocrine carcinoma, and other. †This category includes patients who switched platinum-based regimens while receiving 1L chemotherapy.

**Figure 1. OS from the start of avelumab treatment**




| No. at risk (No. of censored patients) | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Avelumab | 593 (0) | 549 (9) | 455 (41) | 350 (101) | 256 (156) | 180 (210) | 109 (267) | 62 (305) | 16 (347) | 1 (362) | 1 (362) | 1 (362) | 1 (362) | 1 (362) | 1 (362) | 1 (362) | 0 (363) |

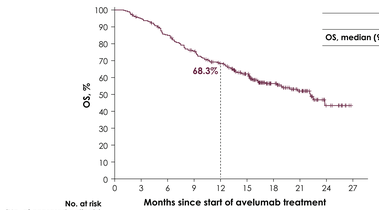
**NE**, not estimable; **OS**, overall survival.

**Table 2. Subgroup analysis of OS from the start of avelumab treatment**

| Subgroup | No. of patients | OS, median (95% CI), months |
|---|---|---|
| **Location of primary tumor** | | |
| Bladder | 438 | 19.9 (16.3-23.8) |
| Upper tract | 113 | NR (14.4-NE) |
| Urethra | 34 | 14.4 (9.1-NE) |
| **No. of 1L chemotherapy cycles** | | |
| <4 | 44 | 14.4 (8.1-NE) |
| 4-6 | 515 | 20.7 (16.3-NE) |
| >6 | 22 | 22.1 (19.9-NE) |
| **Type of 1L chemotherapy** | | |
| Cisplatin + gemcitabine | 170 | NR (19.0-NE) |
| Carboplatin + gemcitabine | 354 | 18.0 (14.4-22.5) |
| Cisplatin or carboplatin + gemcitabine* | 11 | NR (2.2-NE) |
| ddMVAC | 27 | NR (14.4-NE) |
| Other | 19 | 13.2 (8.8-NE) |
| **Response to last chemotherapy** | | |
| Complete response | 117 | 22.5 (20.7-NE) |
| Partial response | 315 | 20.9 (16.1-NE) |
| Stable disease | 132 | 14.0 (9.9-20.0) |
| Disease progression | 6 | NR (4.1-NE) |
| Nonevaluable | 7 | 9.7 (4.4-NE) |
| **Time from end of chemotherapy to initiation of avelumab** | | |
| <4 weeks | 208 | 23.8 (17.1-NE) |
| ≥4 weeks | 370 | 19.9 (15.3-22.5) |

**1L**, first line; **ddMVAC**, dose-dense methotrexate, vinblastine, doxorubicin, and cisplatin; **NE**, not estimable; **NR**, not reached; **OS**, overall survival.
*This category includes patients who switched platinum-based regimens while receiving 1L chemotherapy.

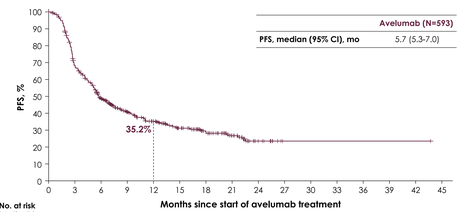
**Figure 2. OS from the start of avelumab treatment in the interim analysis population**




| No. at risk (No. of censored patients) | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Avelumab | 267 (0) | 251 (2) | 223 (4) | 196 (7) | 169 (15) | 132 (37) | 77 (81) | 44 (109) | 11 (138) | 0 (149) |

**NE**, not estimable; **OS**, overall survival.

**Figure 3. PFS from the start of avelumab treatment**




| No. at risk (No. of censored patients) | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Avelumab | 593 (1) | 379 (33) | 253 (54) | 172 (98) | 132 (115) | 93 (141) | 60 (169) | 34 (191) | 10 (212) | 1 (221) | 1 (221) | 1 (221) | 1 (221) | 1 (221) | 1 (221) | 1 (221) | 0 (222) |

**PFS**, progression-free survival.

**Table 3. Subsequent treatment (second line)**

| Subsequent treatment, n (%) | n=282 |
|---|---|
| Antibody-drug conjugate | 32 (11.3) |
| Chemotherapy | 228 (80.9) |
| Immunotherapy | 9 (3.2) |
| Other | 9 (3.2) |
| Targeted therapy | 4 (1.4) |

- A summary of safety data in the full analysis set is presented in **Table 4**
  - Any-grade treatment-emergent adverse events (TEAEs) occurred in 428 patients (72.2%); the most common TEAE was asthenia (n=115, 19.4%) (**Table 5**)
  - 5 patients (0.8%) had a treatment-related adverse event (TRAE) that led to death (disease progression [n=3, 0.5%], hematuria [n=1, 0.2%], and lung disorder [n=1, 0.2%])
- In the interim analysis population (n=267), any-grade TEAEs occurred in 192 patients (71.9%), including serious TEAEs in 98 (36.7%)
  - In this subgroup, any-grade TRAEs occurred in 123 patients (46.1%), including serious TRAEs in 15 (5.6%)

**Table 4. Summary of AEs**

| Events, n (%) | N=593 |
|---|---|
| **TEAE*** | 428 (72.2) |
| Serious TEAE | 200 (33.7) |
| TEAE leading to temporary/permanent discontinuation | 171 (28.8) |
| TEAE leading to death | 99 (16.7) |
| **TRAE** | 254 (42.8) |
| Serious TRAE | 31 (5.2) |
| TRAE leading to temporary/permanent discontinuation | 78 (13.2) |
| TRAE leading to death | 5 (0.8) |

**AE**, adverse event; **TEAE**, treatment-emergent adverse event; **TRAE**, treatment-related and -emergent adverse event.
*AEs were considered "treatment-emergent" if their start date was on or after avelumab initiation.

**Table 5. Most common TEAEs of any grade**

| Events, n (%) | N=593 |
|---|---|
| **Any TEAE** | 428 (72.2) |
| Asthenia | 115 (19.4) |
| Pruritus | 59 (9.9) |
| General physical health deterioration | 44 (7.4) |
| Neoplasm progression | 44 (7.4) |
| Intentional product misuse | 43 (7.3) |
| Diarrhea | 36 (6.1) |
| Nausea | 34 (5.7) |
| Arthralgia | 28 (4.7) |
| Hematuria | 28 (4.7) |
| Constipation | 27 (4.6) |
| Urinary tract infection | 27 (4.6) |
| Rash | 25 (4.2) |
| Anemia | 24 (4.0) |
| COVID-19 | 23 (3.9) |
| Fatigue | 20 (3.4) |
| Neuropathy peripheral | 20 (3.4) |
| Myalgia | 18 (3.0) |
| Not coded | 24 (4.0) |

Table shows TEAEs of any grade occurring in ≥3% of patients.
**TEAE**, treatment-emergent adverse event.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Barthélémy** has served in consulting or advisory roles for Amgen, Bristol Myers Squibb, Ipsen, Janssen-Cilag, Merck & Co., Kenilworth, NJ, Pfizer, and the healthcare business of Merck KGaA, Darmstadt, Germany; has received travel and accommodations expenses from Astellas Pharma, Bristol Myers Squibb, Ipsen, Janssen-Cilag, Merck & Co., Kenilworth, NJ, and Pfizer; and has received honoraria from Astellas Pharma, Bristol Myers Squibb, Ipsen, Janssen-Cilag, Merck & Co., Kenilworth, NJ, Novartis, Pfizer, Seattle Genetics, and the healthcare business of Merck KGaA, Darmstadt, Germany. **Y. 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Please note that this summary contains information from the **full scientific poster presentation**

# Avelumab maintenance treatment in people with advanced urothelial cancer: results from all the people taking part in the real-world AVENANCE study in France

View scientific poster presentation

**The full title of this poster is:** Full analysis from AVENANCE: a real-world study of avelumab first-line maintenance treatment in patients with advanced urothelial carcinoma

**Please note that this summary contains information from the scientific poster presentation**

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**Date of summary:** February 2023

For more information on this study, go to: **https://clinicaltrials.gov/ct2/show/NCT04822350**

Pronunciations

**Medical terms pronunciations**

**Avelumab** <a-VEL-yoo-mab>
**Carboplatin** <kar-bow-PLA-tin>
**Urothelial** <YOOR-oh-THEE-lee-ul>
**Cisplatin** <sis-PLA-tin>

Key takeaways

## What are the key takeaways from this summary?

- In the real-world AVENANCE study, researchers looked at how well avelumab maintenance treatment works when given as normal treatment (outside of a clinical trial) for people with newly diagnosed advanced urothelial cancer in France
  - Researchers also looked at side effects related to the treatment
- In this summary, results from all the people who are taking part in the AVENANCE study were collected for the first time
  - On average, people had taken part in the study for 15 months
- Researchers found that on average, people in the AVENANCE study lived for 21 months after starting avelumab maintenance treatment
  - They also found that on average, people lived for 6 months after starting avelumab maintenance treatment without their cancer getting worse
  - Side effects reported in this study were similar to those reported in previous clinical trials of avelumab
- AVENANCE is the first study of avelumab maintenance treatment given as normal treatment and confirms the findings seen in a clinical trial called JAVELIN Bladder 100
- Overall, the results from this study provide additional support for using avelumab maintenance treatment as a standard treatment for people with advanced urothelial cancer that does not get worse after first-line chemotherapy

Background

## What did this study look at?

### What is advanced urothelial cancer?

- Urothelial cancer is a cancer that develops in the urinary tract
- The urinary tract contains the parts of the body that move urine from the kidneys to the outside of the body. It includes:
  - The bladder
  - The inner part of the kidneys
  - Tubes that connect the kidneys to the bladder and the bladder to the outside of the body
- Urothelial cancer is called advanced when it has spread outside of the urinary tract
- Urothelial cancer can spread to nearby tissues or other parts of the body such as bones, lungs, and the liver


### How are people with advanced urothelial cancer usually treated?

- Platinum-containing chemotherapy is often the first main treatment given to people with newly diagnosed advanced urothelial cancer. This is called first-line treatment
  - Platinum-containing means that the treatment includes a drug that contains platinum (cisplatin or carboplatin)
- Several types of chemotherapy can be given. These include:
  - Carboplatin plus gemcitabine
  - Cisplatin plus gemcitabine
  - DD-MVAC (a combination of chemotherapy drugs)
- Although the cancer may get better at first with first-line chemotherapy, it is likely to start growing again after the chemotherapy has ended
- If a person's cancer stops growing or shrinks after first-line chemotherapy, they may then receive avelumab maintenance treatment
  - Maintenance treatment aims to stop the cancer from getting worse or coming back. In other words, it aims to maintain or increase the benefit of first-line treatment

### What is avelumab?

Avelumab is a type of immunotherapy. Immunotherapy can help the body's immune system find and destroy cancer cells. Avelumab is given as a drip (infusion) into a vein for about an hour once every 2 weeks

In a previous clinical trial called JAVELIN Bladder 100, researchers found that, on average, people treated with avelumab maintenance treatment + best supportive care lived longer than people who received only best supportive care. Best supportive care includes treatments that help to manage symptoms but do not affect the cancer. A plain language summary of the results is available at **this link**

Avelumab is the only approved maintenance treatment available for people with advanced urothelial cancer that has stopped growing or has shrunk after first-line chemotherapy

### What is the AVENANCE study?

- The AVENANCE study is looking at avelumab maintenance treatment for people with advanced urothelial cancer in France
- AVENANCE is a real-world study. This means that information is collected from people receiving standard treatment. Real-world studies help to show how a drug works when given as normal treatment, outside of a clinical trial
- People who took part in the study received first-line chemotherapy and their cancer had disappeared, shrunk, or stopped growing. They then received avelumab maintenance treatment
- Researchers started collecting results in July 2021

### What did the researchers want to find out?

**Researchers wanted to look at results from all the people taking part in the real-world AVENANCE study. They wanted to look at results with avelumab maintenance treatment given as part of normal care for people with advanced urothelial cancer in France, outside of a clinical trial setting**

Study design

## What happened during the study?

### Who took part in the study?

People with advanced urothelial cancer who received first-line chemotherapy in France → **593** people whose cancer had not gotten worse received avelumab maintenance treatment

- Researchers collected results from the AVENANCE study in December 2022. At that time:
  - All 593 people had received avelumab
  - People had taken part in the study for 15 months, on average

Aims of this summary

## What did the researchers look at for this summary?

- Researchers looked at the following:
  - Characteristics of people before they received avelumab
  - How long people received avelumab and why they stopped receiving it
  - How long people lived overall
  - How long people lived without their cancer getting worse
  - What different treatments people received after stopping avelumab
  - How many people had side effects related to avelumab

Results

## What were the results of the study?

### What were the characteristics of people before they were treated with avelumab?

**Before receiving chemotherapy**

- **91%** had cancer that had spread to other parts of the body
- **9%** had cancer that had spread to nearby tissues only
- **85%** were able to be active
- **15%** had difficulty doing physical activities

**Type of chemotherapy received**

- **61%** received carboplatin plus gemcitabine
- **29%** received cisplatin plus gemcitabine
- **5%** received DD-MVAC
- **5%** received other treatments

The average number of chemotherapy cycles was **5**

At the start of this study, the average age was **73 years**

### How long did people receive avelumab, on average?

**6 MONTHS**

### How many people were still receiving avelumab when results were collected?

**34%**

### What were the most common reasons why people stopped receiving avelumab?

- **75%** Their cancer got worse
- **11%** They had side effects
- **10%** They died

### What were the outcomes after people were treated with avelumab?

- **21 MONTHS** was how long people lived, on average
- **65%** of people were still alive after 12 months
- **6 MONTHS** was how long people lived without their cancer getting worse, on average

### How long did people in the following groups live, on average, after starting avelumab treatment?

People who had received **carboplatin plus gemcitabine**

**18 MONTHS**

People who had received **cisplatin plus gemcitabine** or **DD-MVAC**

**It is too early to tell how long these people lived because more than half are still alive**

### What different treatments did people receive after they stopped receiving avelumab?

**282** people received a different treatment after avelumab

- **81%** More chemotherapy
- **11%** Another type of treatment called an antibody-drug conjugate
- **3%** A different immunotherapy
- **5%** Another type of treatment

### How many people had side effects related to avelumab?

- **43%** Any side effect
- **5%** Any serious side effect*

*A side effect is considered severe when it limits daily activities such as bathing and dressing, is disabling or medically significant, could be life threatening, needs hospital care, or causes lasting problems.

Conclusions

## What were the main conclusions reported by the researchers?

- This is the first analysis of results from all of the people taking part in the real-world AVENANCE study in France
- Results from the AVENANCE study show how well avelumab works and how safe it is when given as a standard treatment outside of a clinical trial
- Results of this study are similar to the findings of a previous clinical trial of avelumab
- These results provide additional support for the use of avelumab maintenance as a standard treatment for people with advanced urothelial cancer

**Disclaimers**

Avelumab is approved to treat the condition that is discussed in this summary. This summary reports the results of a single study. The results of this study may differ from those of other studies. Health professionals should make treatment decisions based on all available evidence, not on the results of a single study. The study described is still ongoing, therefore the final outcomes of this study may differ from the outcomes described in this summary

Study sponsors

## Who sponsored this study?

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**The sponsors would like to thank all of the people who took part in this study**

More information

## Where can I find more information?

**For more information on this study, please visit:**
2023 ASCO Genitourinary Cancers Symposium Scientific Poster Presentation
**https://clinicaltrials.gov/ct2/show/NCT04822350**

**For more information on clinical studies in general, please visit:**
**https://www.clinicaltrials.gov/ct2/about-studies/learn**
**https://www.cancer.org/treatment/treatments-and-side-effects/clinical-trials.html**

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