

Results from the JAVELIN Bladder 100 study investigating avelumab maintenance treatment in different groups of people with advanced urothelial cancer

JAVELIN

Study number: NCT02603432

Study start date: April 2016

Study end date: June 2022

The full title of this abstract is: Avelumab first-line maintenance for advanced urothelial carcinoma: analysis of clinical and genomic subgroups from the JAVELIN Bladder 100 trial

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.

More information can be found in the scientific abstract of this study, which you can access here:

[2021 ASCO Annual Meeting Scientific Abstract](#)



Medical terms pronunciations

Avelumab <a-VEL-yoo-mab>

Metastatic <meh-tuh-STA-tik>

Urothelial <yoo-roh-THEE-lee-al>

What did this study look at?

What was the background to the study?

- Urothelial cancer can affect the bladder or other parts of the urinary tract.
 - Urothelial cancer is called advanced when it has spread beyond the urinary tract into nearby tissues (known as locally advanced cancer) or to other parts of the body (known as metastatic cancer).
- Chemotherapy is often the first treatment given to people with advanced urothelial cancer (called first-line treatment). Although the cancer may get better with chemotherapy at first, in most people the cancer will start growing again.
 - If a person's cancer stops growing or shrinks during first-line chemotherapy, they may receive a different type of treatment after they have finished chemotherapy. This is called maintenance treatment. It aims to stop the cancer from growing again and help people live longer.
 - People may also receive additional treatments that help to manage their symptoms but not have an effect on their cancer. This is called best supportive care. It includes antibiotics, pain relief, and treatment to help get enough nutrition.

What was the overall aim of the study?

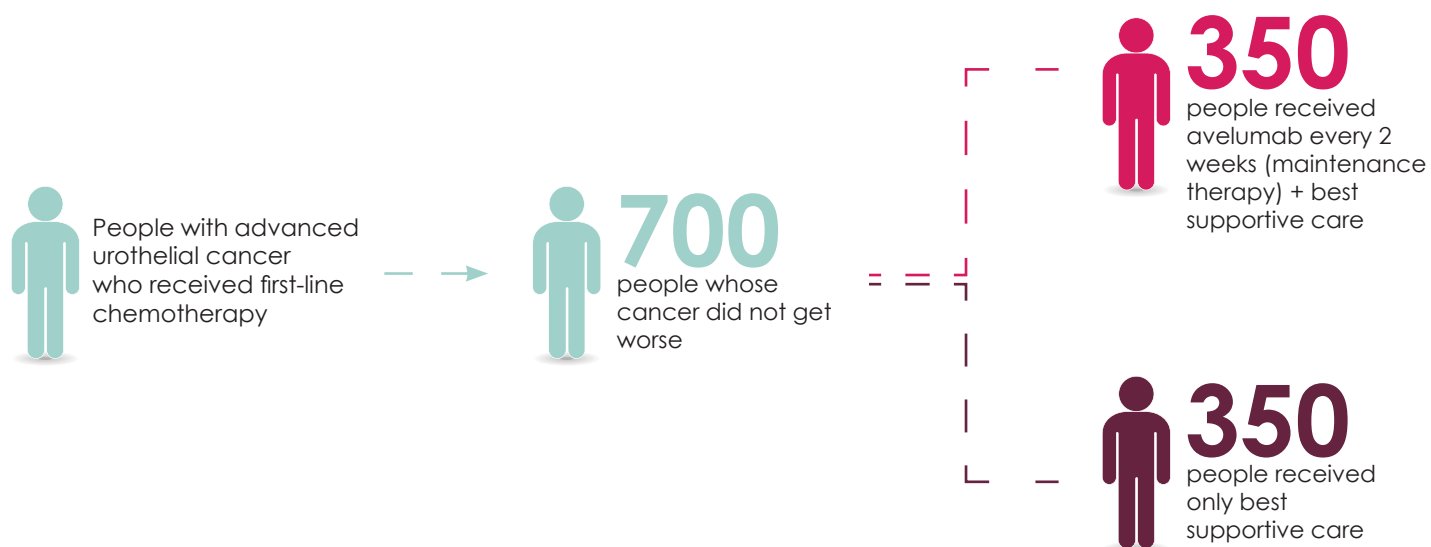
- In this study, called the JAVELIN Bladder 100 trial, researchers wanted to find out if maintenance treatment with a medicine called avelumab could help people with advanced urothelial cancer live longer.
- Avelumab is a type of medicine called immunotherapy, which helps the body's immune system fight the cancer. Avelumab is given as a drip (infusion) into a vein every 2 weeks.
 - Avelumab attaches to a protein called PD-L1, which is found on the surface of cancer cells and some cells of the immune system (the body's system that fights invaders like bacteria and viruses).

- PD-L1 hides cancer cells from the immune system. This stops the immune system from finding and killing the cancer cells. PD-L1 can also switch off some parts of the immune system.
- When avelumab attaches to PD-L1, it can stop PD-L1 from hiding the cancer cells from the immune system, which may help immune cells find and destroy cancer cells.
- People taking part in the study had received chemotherapy as their first treatment (first-line treatment) and their cancer had shrunk or stayed the same. They were put into one of two groups:
 - Group 1 was treated with avelumab maintenance treatment + best supportive care.
 - Group 2 was treated with only best supportive care.
- The people who were treated with avelumab maintenance treatment + best supportive care lived longer than people who received only best supportive care.

What was the focus for this report?

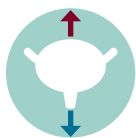
- This summary looks at how long different groups of people lived after being treated in the study. They were grouped by:
 - Whether their cancer started in the urinary tract above the bladder, in the bladder itself, or below the bladder.
 - Whether their cancer had spread into nearby tissues only, into lymph nodes (small glands found throughout the body that are part of the body's immune system), or to other parts of the body (metastatic cancer).
 - Whether they had PD-L1 on their cancer cells and had received a certain type of chemotherapy, called gemcitabine and carboplatin.
 - Whether their cancer had specific features identified by genetic tests.

Who took part in this study?



What were the results of the study?

- Across various groups in the study, people who received avelumab + best supportive care had a lower risk of dying than those who received only best supportive care:



- 11%** lower risk of dying for people whose cancer started in the urinary tract above the bladder
- 38%** lower risk of dying for people whose cancer started in the bladder itself or below the bladder



- 60%** lower risk of dying for people whose cancer had spread into nearby tissues only
- 45%** lower risk of dying for people whose cancer had spread into lymph nodes
- 12%** lower risk of dying for people with metastatic cancer (cancer that has spread to other parts of the body)



- 33%** lower risk of dying for people who had PD-L1 on their cancer cells and had received gemcitabine and carboplatin chemotherapy

- In most groups of people whose cancers had had specific features identified by genetic tests, the people who received avelumab + best supportive care lived longer than those who received only best supportive care.

More results from this study can be found here: [View Scientific Abstract](#)

What was the main conclusion reported by the researchers?

- Across various groups of people with advanced urothelial cancer in this study, the people who received avelumab + best supportive care as maintenance treatment lived longer than those who received only best supportive care.
- The results in different groups were similar to the overall results in all people who took part in the trial.

Who sponsored this study?

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

Further information

For more information on this study, please visit:
[2021 ASCO Annual Meeting Scientific Abstract](https://www.clinicaltrials.gov/ct2/show/NCT02603432)
[https://clinicaltrials.gov/ct2/show/NCT02603432](https://www.clinicaltrials.gov/ct2/show/NCT02603432)

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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