Results from the JAVELIN Bladder 100 study investigating avelumab in people with advanced urothelial cancer in Japan

Medical terms pronunciations

Avelumab <a-VEL-yoo-mab> Ureter <YER-eh-ter> Urothelial <yoo-roh-THEE-lee-al>
Metastatic <meh-tuh-STAT-k> Urethra <yoo-REE-thruh>

What did this study look at?

- Urothelial cancer can affect the bladder or other parts of the urinary tract, such as the urethra, ureters, and the part of the kidney that collects urine (called the renal pelvis).
  - Urothelial cancer is called advanced when it has spread beyond the urinary tract into nearby tissues (also known as locally advanced cancer) or other parts of the body (also 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 improve with chemotherapy, in most people the cancer either comes back or keeps growing.
  - If a person’s cancer stops growing or shrinks with first-line chemotherapy, they may receive a different treatment after they have finished chemotherapy. This is called maintenance treatment and aims to help people live longer and stop their cancer from getting worse or coming back.
  - People may also receive additional treatments to help manage their symptoms. This is called best supportive care, and includes antibiotics, pain relief, and treatment to help get enough nutrition.
- In this study, called the JAVELIN Bladder 100 trial, researchers wanted to find out if avelumab maintenance treatment could help people with advanced urothelial cancer live longer.
  - This study included people from multiple countries around the world.
- Avelumab is a type of medicine called immunotherapy that is given as an infusion into a vein every 2 weeks.
  - Avelumab attaches to a protein called PD-L1, which is found on the surface of cancer cells.
  - PD-L1 hides cancer cells from the immune system (the body’s own defense cells). This stops the immune system from finding and killing the cancer cells.
  - When avelumab attaches to PD-L1, it can stop PD-L1 from working. This releases the “brakes” on the immune system, which may help immune cells to destroy cancer cells.
- People taking part in the study had received first-line chemotherapy to treat their advanced cancer and their cancer had not gotten worse or had shrunk. They were put into one of two groups:
  - Group 1 was treated with avelumab maintenance treatment plus best supportive care.
  - Group 2 was treated with only best supportive care.
- Looking at all people who took part in the trial around the world, the researchers found that people who were treated with avelumab maintenance treatment plus best supportive care lived longer than people who received only best supportive care.
- This summary looks at the group of people who took part in the JAVELIN Bladder 100 trial in Japan.
  - Researchers compared the two treatment groups to look at how long people lived overall, how long it took for their cancer to get worse, and any side effects that happened during treatment.
  - Researchers also looked at people who had PD-L1 on their cancer cells, in both treatment groups, to see whether this affected a person’s response to treatment.

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Who took part in this study?

- **People in Japan with advanced urothelial cancer who received first-line chemotherapy**: 73 people
- **People in Japan whose cancer did not get worse**: 36 people received avelumab every 2 weeks (maintenance therapy) + best supportive care
- **People in Japan whose cancer did not get worse**: 37 people received only best supportive care
- **People in Japan with advanced urothelial cancer who received first-line chemotherapy**: 53% of these people had PD-L1 on their cancer cells
- **People in Japan whose cancer did not get worse**: 62% of these people had PD-L1 on their cancer cells

What were the results of the study?

This summary shows how long at least half of people lived with study treatment:

- **Avelumab + best supportive care**
  - All people who took part in the trial in Japan: 25 months
  - People whose cancer cells had PD-L1: 19 months

This summary shows how long at least half of people lived without their cancer getting worse with study treatment:

- **Avelumab + best supportive care**
  - All people who took part in the trial in Japan: 6 months
  - People whose cancer cells had PD-L1: 6 months

- **Only best supportive care**
  - All people who took part in the trial in Japan: 2 months
  - People whose cancer cells had PD-L1: 2 months

continued →
The most common side effects with avelumab + best supportive care in people from Japan were

- **Pyrexia** (fever): 28% of people, None were severe*
- **Nasopharyngitis** (cold-like symptoms): 19% of people, None were severe*
- **Anemia** (low number of red blood cells): 19% of people, None were severe*

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

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

What was the main conclusion reported by the researchers?

- This study showed that people in Japan with advanced urothelial cancer who received avelumab plus best supportive care after first-line chemotherapy lived longer than people who received only best supportive care.
  - People in Japan who received avelumab plus best supportive care also lived longer without their cancer getting worse.
- The results from Japan, including the side effects reported by people who received avelumab maintenance treatment plus best supportive care, were similar to the results from all people who took part in the trial around the world.

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:

For more information on clinical studies in general, please visit:
[https://www.clinicaltrials.gov/ct2/about-studies/learn](https://www.clinicaltrials.gov/ct2/about-studies/learn)

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