Immunotherapy Trial in Advanced Bladder Cancer Shows Promise

"Potentially practice-changing" data show patients with advanced urothelial carcinoma survive longer with immune-boosting drug after chemo.

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Immunotherapy Trial in Advanced Bladder and Other Urinary Tract Cancers Shows 'Exciting' Results

At the annual meeting of the American Society of Clinical Oncology May 29-31, researchers presented the interim results of a large randomized clinical trial of the immunotherapy drug avelumab for patients with advanced urothelial cancer.

The findings from the JAVELIN Bladder 100 study are "very exciting — and really, in my humble opinion, potentially practice-changing," said Petros Grivas, MD, PhD, of Fred Hutchinson Cancer Research Center, who is the co-leader of this global, industry-sponsored trial.

Urothelial cancer, or carcinoma, most commonly manifests as bladder cancer but can also affect other parts of the urinary tract. The data from this trial shows that patients who received the immune-boosting drug after chemotherapy lived longer than those who didn't. The median overall survival — the length of time patients lived after trial enrollment — was about 21 months in those who received the drug versus about 14 months in those who didn't. ("Median" means half the patients in each group survived longer than that amount of time and half survived less.)

In this video created by Fred Hutch's clinical care partner, Seattle Cancer Care Alliance, Grivas describes the results and their significance for patients with these cancers. Watch the video or read the transcript below.

See more highlights of Fred Hutch research at ASCO.

We've edited the below video transcript slightly for readability.

Hello, I'm Petros Grivas. I'm a medical oncologist at Seattle Cancer Care Alliance, an associate professor at the University of Washington and an associate member of Fred Hutchinson Cancer Research Center.

Today, we're going to discuss the very exciting — and really, in my humble opinion, potentially practice-changing — data that were presented at the ASCO 2020 virtual meeting in the plenary session, regarding the JAVELIN Bladder 100 trial. In the front-line setting of advanced urothelial cancer, the trial is evaluating the role of switch maintenance avelumab, an anti-PDL1 agent [a type of immune checkpoint inhibitor, a category of immunotherapy], plus best supportive care, compared to best supportive care alone. ["Switch" means that patients switch from chemotherapy to immunotherapy.]

What does the data show?

The results of this trial that are being presented at the ASCO plenary session show that switch maintenance avelumab prolonged life compared to best supportive care alone in this front-line maintenance setting. This means that patients who completed initial chemotherapy … if they had no [cancer] progression, they could be randomized to avelumab [plus best supportive care] versus best supportive care alone. And those who were randomized to avelumab plus best supportive care — the immunotherapy part — lived longer compared to those who just received best supportive care alone.

So this data, in my humble opinion, should change the way we treat this disease. It's practice-changing. Because instead of waiting until progression happens after the completion of front-line chemotherapy, with the new data, if there's no progression, we're going to hit it back to back with immunotherapy after the completion of chemotherapy. … And this seems to be prolonging life, based on the data so far.

What is metastatic urothelial cancer?

Metastatic urothelial cancer, as a term, can cause some confusion. So, metastatic means "spread." The cancer originates, usually, in the bladder, or other parts of the urinary tract — such as the internal parts of the kidney, what we call the kidney pelvis; or the ureters, which are the "urine pipes," as I call them, that connect the kidneys with the bladder; or the urethra, which is distal to the bladder and how urination takes place. Any of those areas can give rise to what we call urothelial cancer. And "urothelial" means that the cancer originates in the internal lining of those urinary tract systems [the urothelium]. … The most common location, as I mentioned, is the urinary bladder. And when it's spread out it's metastatic.

What do this trial's results mean for this cancer?

This [metastatic cancer] is a very challenging condition, and usually there is no cure for it. But over the last five to six years, we have seen data on immunotherapy that has actually prolonged life compared to what we had before that, just chemotherapy alone. And just for context, I can say there are other drugs that are being approved by the FDA — antibody-drug conjugates, targeted therapies — that all together, I think, can move the needle forward.

Overall, I would say it has been very hard to have a clinical trial that actually prolongs overall survival — leads to longer life. In the last 15, 20 years, probably I can think of two trials that actually led to the prolongation of overall survival with immunotherapy [in metastatic urothelial

cancer]. So despite the very, very promising role of immunotherapy, only two Phase 3 clinical trials [in this disease setting] have led to statistically significant — with statistical rigor — improvement in overall survival, as a primary endpoint of the trial.

Just think how difficult it is to move the needle forward with metastatic urothelial cancer.

Pfizer funded this study as part of an alliance between Pfizer and Merck KGaA, Darmstadt, Germany.

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