Immunotherapy Following Chemotherapy Offers Extended Survival to Patients with Advanced Urothelial Cancer

*Scroll down to view the press briefing presentation*
For immediate release
May 28, 2020

ASCO Perspective

“In patients with advanced urothelial cancer, recurrence frequently happens following initial treatment with chemotherapy. This study shows the largest survival benefit seen to date in advanced urothelial cancer. When used as a maintenance therapy, avelumab significantly extended the period of time until recurrence,” said ASCO President Howard A. Burris III, MD, FACP, FASCO.

ALEXANDRIA, Va. — Treatment with avelumab combined with best supportive care following chemotherapy significantly extended overall survival compared with best supportive care alone in patients with advanced urothelial cancer in the JAVELIN Bladder 100 trial. The results of this study will be presented as part of the virtual scientific program of the 2020 American Society of Clinical Oncology (ASCO) Annual Meeting.

Study at a Glance

<table>
<thead>
<tr>
<th>Focus</th>
<th>Avelumab as maintenance therapy in patients with unresectable locally advanced or metastatic urothelial cancer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Population</td>
<td>700 patients with disease that had responded to chemotherapy</td>
</tr>
<tr>
<td>Findings</td>
<td>Avelumab improved overall survival by 7.1 months over best supportive care</td>
</tr>
</tbody>
</table>
Significance

Supports the use of avelumab as a maintenance treatment following initial chemotherapy

The study results represent the largest survival benefit seen to-date in advanced urothelial cancer in the maintenance setting. Bladder cancer is a top-10 cause of cancer deaths in the United States. While avelumab has already been shown to be effective in metastatic disease, this study reports the first data demonstrating efficacy of front-line treatment in the period following initial chemotherapy.

“The maintenance setting is an attractive time for using a checkpoint inhibitor. Patients have gone through chemotherapy and the disease is under control,” said lead author Thomas Powles, MD, a professor of genitourinary oncology and Director of Barts Cancer Centre in London. “But instead of waiting for disease to progress after chemotherapy — which it will quickly do in patients with advanced urothelial cancer — adding avelumab significantly improves survival.”

When combined with best supportive care, avelumab treatment resulted in a median overall survival of 21.4 months compared with 14.3 months for best supportive care alone.

The researchers also examined response in the group of patients with tumors that were positive for programmed death-ligand 1 (PD-L1). Avelumab plus best supportive care significantly prolonged overall survival in this group of patients, with median overall survival not yet established. Median overall survival was 17.1 months for patients who received best supportive care alone.

In addition, in all patients and in those with PD-L1+ tumors, progression-free survival was better with avelumab and best supportive care vs best supportive care alone.
Adverse events of grade 3 or higher occurred in 47.4% of patients who received avelumab plus best supportive care vs 25.2% in those who received best supportive care alone. The most common grade 3 or higher adverse events were urinary tract infection, anemia, hematuria, fatigue, and back pain.

### About the Study
Patients included in this randomized, phase III trial had unresectable locally advanced or metastatic urothelial carcinoma, with no disease progression following chemotherapy (which was either gemcitabine with either cisplatin or carboplatin). The trial included 700 patients, 350 were randomized to receive maintenance avelumab along with best supportive care, and 350 to best supportive care alone. Patients were followed for a median of more than 19 months. Just over half (51%) had tumors that were positive for PD-L1.

Avelumab is a checkpoint inhibitor immunotherapy that works by blocking a protein on the surface of cancer cells, in this case PD-L1. This protein helps cancer cells evade the body’s immune system, and when avelumab blocks it, the immune system can better identify and target the cancer cells.

“In urothelial cancer, patients have high PD-L1 expression and high tumor mutational burden. Response rates associated with immune therapy are pretty high,” said Dr. Powles. “This means that checkpoint inhibitors can work quite well in urothelial cancer.”

### Next Steps
Patients in the control group have been allowed to crossover to the avelumab group. The researchers plan to follow patients to see how long response is maintained.

### Funding
The study was funded by Pfizer (Merck KgA).
For your readers
Understanding Immunotherapy
Bladder Cancer

View the disclosures for the 2020 Cancer Communications Committee:

View the disclosures for Dr. Burris: https://coi.asco.org/share/UK4-3LNB/Howard%20Burris

Media Contact: Rachel Cagan
rachel.cagan@asco.org
mediateam@asco.org

For Patient Inquiries:
571-483-1780
contactus@cancer.net

ATTRIBUTION TO THE AMERICAN SOCIETY OF CLINICAL ONCOLOGY ANNUAL MEETING IS REQUESTED IN ALL COVERAGE.

View the abstract

Watch the 5-minute author presentation
About ASCO:
 Founded in 1964, the American Society of Clinical Oncology, Inc. (ASCO®) is committed to making a world of difference in cancer care. As the world's leading organization of its kind, ASCO represents nearly 45,000 oncology professionals who care for people living with cancer. Through research, education, and promotion of the highest-quality patient care, ASCO works to conquer cancer and create a world where cancer is prevented or cured, and every survivor is healthy. Conquer Cancer,® the ASCO Foundation, supports the Society by funding groundbreaking research and education across cancer's full continuum. Learn more at www.ASCO.org, explore patient education resources at www.Cancer.Net, and follow us on Facebook, Twitter, LinkedIn, Instagram, and YouTube.