Oncology trial shows positive results for patients with muscle-invasive urothelial carcinoma

January 26 2024

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Patients with muscle-invasive urothelial cancer and a high risk of recurrence after surgery may have a new treatment option. The Alliance

for Clinical Trials in Oncology has announced positive results from the Phase III AMBASSADOR (A031501) trial for the adjuvant treatment of patients with localized muscle-invasive urothelial carcinoma (MIUC) and locally advanced urothelial carcinoma.

Late-breaking data from the trial are being presented during an oral abstract session at the 2024 American Society of Clinical Oncology (ASCO) Genitourinary (GU) Cancers Symposium (abstract #LBA531).

"Patients with muscle-invasive bladder cancer after radical surgery are at high risk of disease recurrence and metastases. Pembrolizumab versus observation significantly reduced the risk of disease recurrence for these patients," said Andrea B. Apolo, MD, study chair for the AMBASSADOR trial and Head of the Bladder Cancer Section of the Genitourinary Malignancies Branch and Director of the Bladder Cancer and Genitourinary Tumors Multidisciplinary Clinic in the Center for Cancer Research of the National Cancer Institute.

"This is long-awaited data in the bladder cancer community."

At a pre-specified interim analysis review, pembrolizumab, an anti-PD-1 therapy, demonstrated a statistically significant and clinically meaningful improvement in disease-free survival (DFS) versus observation in patients after surgery, meeting one of the trial's dual primary endpoints.

After a median follow-up of 22.3 months, pembrolizumab reduced the risk of DFS or death by 31% (HR=0.69 [95% confidence interval (CI), 0.55–0.87]; p=0.0013) versus observation in patients after surgery. Median DFS was 29.0 months (95% CI, 21.8–not evaluable [NE]) for pembrolizumab and 14.0 months (95% CI, 9.7–20.2) for observation, an improvement of 15 months.

These DFS results were consistent regardless of patients' PD-L1

expression status. The trial's other dual primary endpoint of overall survival (OS) did not reach statistical significance at the time of this interim analysis and will continue to be followed as data mature (HR=0.98 [95% CI, 0.76–1.26]; p=0.88). After a median follow-up of 36.9 months, median OS was 50.9 months (95% CI, 43.9–NE) for pembrolizumab versus 55.8 months (95% CI, 53.3–NE) for observation (HR=0.98 [95% CI, 0.76–1.26]; p=0.88).

The safety profile of pembrolizumab in this trial was consistent with that observed in previously reported studies, and no new safety signals were identified. Grade 3+ adverse events (side effects that are severe or medically significant but not immediately life-threatening) occurred in 48.4% of patients receiving pembrolizumab versus 31.8% of patients under observation.

17.4% of patients receiving pembrolizumab withdrew from the trial without event, versus 27.2% from the observation arm. Seventy-six patients (22%) in the observation arm subsequently received an immune checkpoint inhibitor.

AMBASSADOR (A031501) is a randomized, open-label Phase III trial evaluating pembrolizumab versus observation for the adjuvant treatment of localized MIUC and locally advanced urothelial carcinoma. The dual primary endpoints are OS and DFS, and secondary endpoints include OS and DFS in PD-L1 positive and negative patients. The trial enrolled 702 patients who were randomized to receive pembrolizumab (200 mg intravenously every three weeks for up to 18 cycles) or undergo observation.

It is estimated that approximately 82,290 people in the U.S. will be diagnosed with bladder cancer in 2023. Globally, there were approximately 573,000 new cases and 212,000 deaths from bladder cancer in 2020.

Muscle-invasive bladder cancer is bladder cancer that has spread into the deep muscle of the bladder wall, and locally advanced urothelial cancer is cancer that begins in the urothelial cells and has spread from where it started to nearby tissue or lymph nodes. Despite surgery, up to 50% of patients with bladder cancer experience recurrence within 12 months.

Provided by Alliance for Clinical Trials in Oncology

Citation: Oncology trial shows positive results for patients with muscle-invasive urothelial carcinoma (2024, January 26) retrieved 29 April 2024 from https://medicalxpress.com/news/2024-01-oncology-trial-positive-results-patients.html

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