Padcev Improves Overall Survival in People With Bladder Cancer

The 30% improvement in survival has brought a Phase III trial to an early halt.

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Padcev (enfortumab vedotin) improved overall survival in comparison with chemotherapy in a Phase III clinical trial for people with locally advanced or metastatic urothelial cancer who had previously been treated with platinum-based chemotherapy and immunotherapy, according to a company announcement.

Urothelial cancer involves the bladder in 90% of cases, but it can also occur in other parts of the urinary tract. The standard initial treatment is platinum-based chemotherapy, but those who are unable to use cisplatin have poor outcomes. Moreover, some 80% of people do not respond to checkpoint inhibitor immunotherapy after platinum-based therapy has failed as a first-line treatment for advanced disease.

Padcev, an antibody-drug conjugate from Astellas Pharma and Seattle Genetics, consists of an antibody that targets nectin-4, a protein found in high levels on most urothelial cancer cells. The antibody carries a chemotherapy drug (monomethyl auristantin E) that disrupts cellular structures known as microtubules and prevents cell division.

Padcev was granted accelerated approval based on findings from the Phase II EV-201 trial (NCT03219333), which enrolled people with locally advanced or metastatic urothelial cancer who had previously received immunotherapy or platinum-based chemotherapy.

Follow-up data presented recently at the ESMO Virtual Congress 2020 showed overall survival rates of 50% at 12 months and 34% at 18 months. The median overall survival time was 12.4 months.

The current findings are from the EV-301 trial (NCT03474107). It is a global, multicenter randomized trial designed to evaluate Padcev versus chemotherapy in around 600 patients with locally advanced or metastatic urothelial cancer who had previously been treated with a PD-1 or PD-L1checkpoint inhibitor and platinum-based chemotherapy. The primary endpoint was overall survival; secondary endpoints were progression-free survival, duration of response and overall response rate. Safety, tolerability and quality of life were also monitored.

In this trial, participants in the experimental treatment group were given Padcev on days 1, 8 and 15 over a 28-day cycle. People in the chemotherapy group were given either docetaxel, vinflunine or paclitaxel on day 1 of a 21-day cycle.

The clinical trial found that Padcev significantly improved overall survival, with a 30% drop in the risk of death. Padcev also significantly improved progression-free survival, with a 39% drop in risk of disease progression or death.

Treatment was generally safe and well tolerated. Adverse events were consistent with those previously seen in earlier studies of Padcev, including rash, hyperglycemia, decreased neutrophil count, fatigue, anemia and decreased appetite.

Based on these interim results, an independent review panel recommended that the trial be stopped ahead of schedule. The companies now plan to submit these data to the Food and Drug Administration to secure a full approval of Padcev for advanced urothelial cancer.

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