Drug demonstrates poor efficacy in advanced bladder cancer

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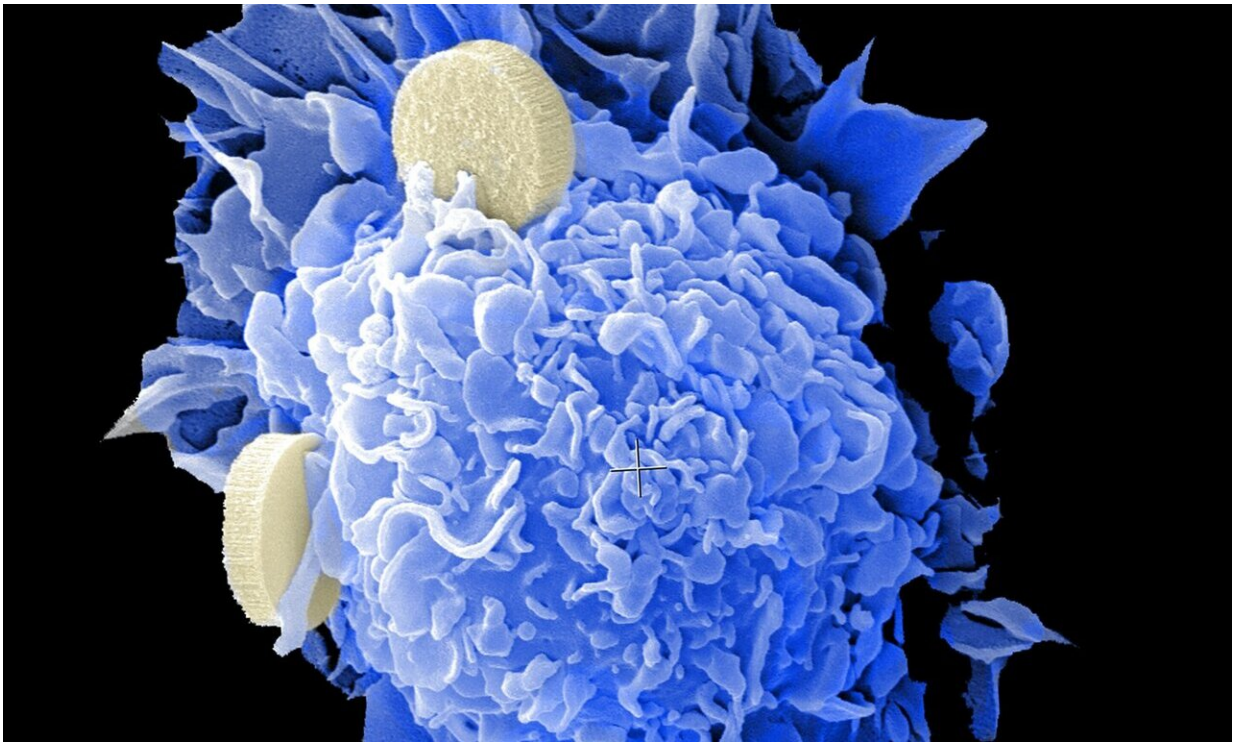

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An FDA-approved monoclonal antibody drug used to treat advanced bladder cancer demonstrated poor efficacy in a recent clinical trial published in *The Lancet Oncology*.

Muscle invasive urothelial carcinoma (MIUC), the most common type of

bladder cancer, is characterized by cancerous urothelial cells that line the inside of the bladder and urinary tract wall. The cancer is aggressive and can spread despite the use of available treatments.

The current standard of care for patients with MIUC is a combination of surgery and cisplatin-based neoadjuvant chemotherapy. However, almost half of patients are ineligible for this treatment due to inherent frailty, comorbidities or impaired kidney function. Coupled with the cancer's high recurrence rate, developing novel therapies for this patient population continues to remain high priority.

"Despite progress to date, MIUC continues be a high-risk disease despite curative intent therapy. It's therefore very critical to continue to investigate new agents and combination therapy to further enhance the chance for a cure," said Maha Hussain, MBChB, the Genevieve E. Teuton Professor of Medicine in the Division of Hematology and Oncology, and a study steering committee member and co-author of the clinical trial.

For the current clinical trial, Hussain and collaborators evaluated the efficacy of atezolizumab, a monoclonal antibody cancer drug approved by the Food and Drug Administration, in treating patients with advanced MIUC.

"The safety profile for atezolizumab was consistent with that observed in prior studies in the advanced setting, with no new safety concerns," said Hussain, who is also a member of the Robert H. Lurie Comprehensive Cancer Center of Northwestern University.

Investigators enrolled 800 adult patients with MIUC from 24 different countries who had surgery, either a radical cystectomy or a nephroureterectomy with lymph node dissection.

Patients were then randomized to receive 1,200 milligrams of atezolizumab intravenously every three weeks for one year or be kept under observation without additional treatment after surgery.

Overall, the atezolizumab group did not show significant improvement in disease-free survival compared to the observation group—average disease-free survival was 19.4 months for the atezolizumab group compared to 16.6 months for the observation group.

Additionally, serious adverse events occurred in 31 percent of patients who received atezolizumab compared to 18 percent of patients in the observation group.

"Atezolizumab was generally tolerable, with no new safety signals; however, higher frequencies of adverse events leading to discontinuation were reported than in metastatic urothelial carcinoma studies. These data do not support the use of atezolizumab in the setting evaluated in IMvigor010 at this time," the authors wrote.

More information: Joaquim Bellmunt et al. Adjuvant atezolizumab versus observation in muscle-invasive urothelial carcinoma (IMvigor010): a multicentre, open-label, randomised, phase 3 trial, *The Lancet Oncology* (2021). DOI: 10.1016/S1470-2045(21)00004-8

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