Blood Test Guides Post-Surgical Immunotherapy for Muscle-Invasive Bladder Cancer

Phase III trial results show periodic ctDNA screening after surgery can help guide a decision to begin adjuvant immunotherapy.

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Patients with muscle-invasive bladder cancer who test positive for circulating tumor (ct)DNA after surgery to remove the cancer benefit from immunotherapy with atezolizumab [Tecentriq] compared to placebo whereas ctDNA-negative patients may potentially be spared unnecessary treatment.

The finding is based on results from the global, randomized, Phase III IMvigor011 trial, co-led by investigators from Dana-Farber Cancer Institute, the Technical University of Munich, and Queen Mary University of London, UK.

Patients with positive ctDNA taking atezolizumab had a 36% lower risk of disease recurrence than those taking placebo, regardless of whether they were ctDNA positive immediately after surgery or if ctDNA positivity emerged during screening up to a year after surgery. Risk of death was also reduced by 41%.

The results of the IMvigor011 trial were presented today at the European Society for Medical Oncology (ESMO) Congress 2025 in Berlin, Germany, and published simultaneously in the The New England Journal of Medicine.

“By selecting patients based on ctDNA, we see a benefit not only for disease-free survival but also for overall survival with atezolizumab,” says co-principal investigator Dr. Joaquim Bellmunt, director of the bladder cancer center at Dana-Farber. “This is the first time that an adjuvant immunotherapy trial has shown a benefit for survival in selected patients based on ctDNA testing.”

Atezolizumab is an immune checkpoint inhibitor that targets a marker called PD-L1 on cancer cells, unmasking them so that immune cells can recognize them. An earlier trial called IMvigor010 and led by Bellmunt tested the use of atezolizumab in patients with muscle-invasive bladder cancer after surgery.

The study did not show a benefit across all patients, but a retrospective data analysis suggested that patients with positive ctDNA did benefit from treatment. A positive ctDNA test indicates the presence of minimal residual disease, meaning the patient has a small number of cancer cells that are undetectable using other clinical tests.

The IMvigor011 study was designed to test the hypothesis that ctDNA could be used to guide the use of immunotherapy with atezolizumab in patients with minimum residual disease.

In the trial, 800 patients who had no clinical evidence of cancer after surgery were screened using a personalized blood test (ctDNA) every 6 weeks for 9 months and up to one year. Of these, 250 ctDNA-positive patients were randomized in a 2:1 ratio to receive either atezolizumab or placebo.

Patients who remained ctDNA negative received no additional treatment. Of those patients, 89% remained disease-free and more than 90% were still living at a median follow up of 21.8 months.

“What these findings tell us is that this ctDNA test is detecting minimum residual disease and can identify patients who still have bladder cancer after surgery and might benefit from receiving atezolizumab,” said Bellmunt. “Further, it suggests that patients who are persistently ctDNA negative have a low risk of recurrence and can be spared from unnecessary treatment.”

No new side effects were identified. Based on this data, regulatory agencies will determine if standard therapy should change to link the use of atezolizumab with a ctDNA test in patients with this indication.

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