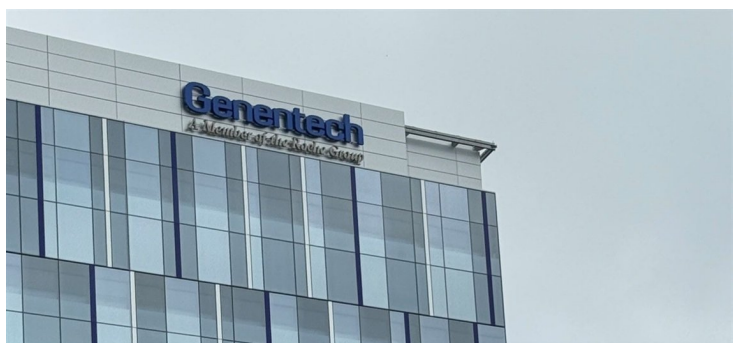


FDA Approves Genentech's Tecentriq for ctDNA-Guided Adjuvant Bladder Cancer Treatment

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The approval introduces a precision medicine approach for muscle-invasive bladder cancer patients with molecular residual disease after cystectomy.



Genentech has received US FDA approval for Tecentriq and Tecentriq Hybreza as adjuvant treatment for adults with muscle-invasive bladder cancer who have circulating tumour DNA molecular residual disease after cystectomy.

The approval introduces a ctDNA MRD-guided treatment strategy into bladder cancer care, allowing clinicians to identify patients at higher risk of recurrence after surgery and target adjuvant immunotherapy more selectively. It also provides a potential pathway to avoid unnecessary treatment in patients without molecular evidence of residual disease.

The decision was based on the Phase III IMvigor011 study, which showed that Tecentriq reduced the risk of disease recurrence or death by 36 percent and the risk of death by 41 percent in patients with detectable ctDNA MRD identified through serial testing within one year of cystectomy.

IMvigor011 is described as the first prospective Phase III study to demonstrate that a ctDNA-guided approach to adjuvant therapy can significantly improve survival in muscle-invasive bladder cancer. The study used Natera's Signatera personalised ctDNA assay to identify molecular evidence of cancer before standard imaging detection.

The FDA also authorised Signatera CDx as a companion diagnostic for Tecentriq in this indication. This connection between therapy and molecular residual disease testing is central to the approval's clinical significance, as it embeds diagnostic-guided treatment selection into the post-surgical care pathway.

Globally, more than 150,000 people are diagnosed each year with muscle-invasive bladder cancer and undergo bladder removal surgery. Nearly half experience disease recurrence after surgery, underscoring the need for better risk stratification and targeted intervention.