

Tecentriq (atezolizumab) Injection Clinical Update

Clinical Update: FDA Approves Genentech's Tecentriq in Combination with Avastin for People With Hepatocellular Carcinoma.

FDA approval date: May 29, 2020

Tecentriq is a monoclonal antibody designed to bind with a protein called PD-L1. Tecentriq is designed to bind to PD-L1 expressed on tumor cells and tumor-infiltrating immune cells, blocking its interactions with both PD-1 and B7.1 receptors. By inhibiting PD-L1, Tecentriq may enable the re-activation of T cells. Tecentriq may also affect normal cells.

Avastin is a prescription-only medicine that is a solution for intravenous infusion. It is a biologic antibody designed to specifically bind to a protein called VEGF that plays an important role throughout the lifecycle of the tumor to develop and maintain blood vessels, a process known as angiogenesis. Avastin is designed to interfere with the tumor blood supply by directly binding to the VEGF protein to prevent interactions with receptors on blood vessel cells. The tumor blood supply is thought to be critical to a tumor's ability to grow and spread in the body (metastasize).

According to the American Cancer Society, it is estimated that more than 42,000 Americans will be diagnosed with liver cancer in 2020. Liver cancer incidence has more than tripled since 1980. HCC accounts for approximately 75% of all liver cancer cases in the United States. HCC develops predominantly in people with cirrhosis due to chronic hepatitis (B and C) or alcohol consumption, and typically presents at an advanced stage where there are limited treatment options.

The approval was based on results from the Phase III IMbrave150 study, which demonstrated that Tecentriq in combination with Avastin reduced the risk of death (overall survival; OS) by 42% (hazard ratio [HR]=0.58; 95% CI: 0.42-0.79; p=0.0006) and reduced the risk of disease worsening or death (progression-free survival; PFS) by 41% (HR=0.59; 95% CI: 0.47-0.76; p<0.0001), compared with sorafenib. IMbrave150 is the first Phase III cancer immunotherapy study to show an improvement in OS and PFS in people with unresectable or metastatic HCC compared with sorafenib. Serious adverse reactions (Grade 3-4) occurred in 38% of people in the Tecentriq and Avastin arm. The most frequent serious adverse reactions ($\geq 2\%$) were bleeding in the gastrointestinal tract, infections and fever.

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