Generic Name:
Atezolizumab
Trade Name:
Tecentriq
Company:
Roche
Notes:

Roche announced FDA approval of atezolizumab in combination with carboplatin and etoposide (chemotherapy) for first-line treatment of adults with extensive-stage small cell lung cancer (ES-SCLC).

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

Approval was based on results from a Phase III study showing that atezolizumab in combination with chemotherapy helped people live significantly longer compared with chemotherapy alone (median overall survival =12.3 vs. 10.3 mo; hazard ratio [HR] = 0.70 [95% CI 0.54?0.91]; *P* = 0.0069) in the intention-to-treat population.

The atezolizumab-based combination also significantly reduced the risk of disease worsening or death (progression-free survival [PFS]) compared with chemotherapy alone (PFS = 5.2 vs. 4.3 mo; HR = 0.77, 0.62?0.96; *P* = 0.017). Safety for the atezolizumab and chemotherapy combination appeared consistent with the known safety profile of atezolizumab.

Atezolizumab is approved in combination with bevacizumab, paclitaxel, and carboplatin (chemotherapy) for first-line treatment of adults with metastatic nonsquamous NSCLC with no EGFR or ALK genomic tumor aberrations.

It is also approved for treatment of adults with metastatic NSCLC who have disease progression during or following platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for NSCLC harboring these aberrations before receiving atezolizumab.

Medication Monitor Categories:
Supplemental Approvals