Yescarta® (axicabtagene ciloleucel) – Expanded indication

- On April 1, 2022, Gilead announced the FDA approval of Yescarta (axicabtagene ciloleucel), for the treatment of adult patients with large B-cell lymphoma (LBCL) that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy.
    - Yescarta is also approved for treatment of adult patients with relapsed or refractory large B-cell lymphoma (LBCL) after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma.
    - Yescarta is not indicated for the treatment of patients with primary central nervous system lymphoma.
- In addition to LBCL, Yescarta is also approved for the treatment of adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy.
- The approval of Yescarta for the expanded indication was based on ZUMA-7, a randomized, open-label study in adult patients with relapsed or refractory LBCL after first-line chemoimmunotherapy that included rituximab and anthracycline. In total, 359 patients were randomized to receive a single infusion of Yescarta or to receive second-line standard therapy, consisting of 2 or 3 cycles of chemoimmunotherapy followed by high-dose therapy and autologous hematopoietic stem cell transplantation. The primary endpoint was event-free survival (EFS). Secondary endpoints were objective response rate (ORR) and progression-free survival (PFS).
    - Median EFS was 8.3 months and 2.0 months for the Yescarta and standard therapy arm, respectively (stratified hazard ratio [HR] 0.40, 95% CI: 0.31, 0.51; $p < 0.0001$).
    - The ORR was 83% and 50% for the Yescarta and standard therapy arm, respectively (difference 33, 95% CI: 23, 42; $p < 0.0001$).
    - Median PFS was 14.9 months and 5.0 months for the Yescarta and standard therapy arm, respectively (stratified HR 0.56, 95% CI: 0.41, 0.76).
- Yescarta carries a boxed warning for cytokine release syndrome and neurologic toxicities.
- Refer to the Yescarta drug label for completing dosing and administration recommendations.