Yescarta® (axicabtagene ciloleucel) – New indication

- On March 5, 2021, Kite, a Gilead Company, announced the FDA approval of Yescarta (axicabtagene ciloleucel), for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy.
    - This indication is approved under accelerated approval based on response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).
- Yescarta is also approved for the treatment of adult patients with relapsed or refractory large B-cell lymphoma 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 FL.
- The approval of Yescarta for the new indication was based on a single-arm, open-label study (ZUMA-5) that evaluated a single infusion of Yescarta in adult patients with relapsed or refractory FL after two of more lines of systemic therapy. Of 123 patients with FL who underwent leukapheresis, 120 received Yescarta. Of the 120 patients with FL infused with Yescarta, the 81 consecutive patients included in the primary efficacy analysis had at least 9 months of potential follow-up from date of first response. The primary endpoints were objective response rate (ORR) and duration of response (DOR).
    - In the primary efficacy population (n = 81), the ORR was 91% (95% CI: 83, 96). In all leukapheresed patients (n = 123), the ORR was 89% (95% CI: 83, 94).
    - The median DOR in the primary efficacy population was not estimable (95% CI: 20.8, not estimable).
- Yescarta carries boxed warnings for cytokine release syndrome and neurologic toxicities.
- Yescarta is a CD19-directed genetically modified autologous T cell immunotherapy. Refer to the Yescarta drug label for dosing and administration recommendations.