Kymriah® (tisagenlecleucel) – New indication

- On May 28, 2022, Novartis announced the FDA approval of Kymriah (tisagenlecleucel), 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 and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).
- Kymriah is also approved for the treatment of:
    - Patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia that is refractory or in second or later relapse, and
    - 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, high grade B-cell lymphoma and DLBCL arising from FL.
- The approval of Kymriah for the new indication was based on a single-arm, open-label study (ELARA) in 98 patients with relapsed or refractory FL. Among the 98 patients, 90 were included in the primary efficacy analysis. Efficacy was established on the basis of objective response rate (ORR) and duration of response (DOR).
    - In the primary efficacy analysis, the ORR was 86% (95% CI: 76.6, 92.1).
    - The median DOR in months was not estimable (95% CI: 15.6, not estimable).
- Kymriah carries a boxed warning for cytokine release syndrome (CRS) and neurological toxicities.
    - Kymriah is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Kymriah REMS.
- The most common adverse reactions (> 20%) with Kymriah use in patients with FL were CRS, infections-pathogens unspecified, fatigue, musculoskeletal pain, headache, and diarrhea.
- Kymriah is a CD19-directed genetically modified autologous T cell immunotherapy. Refer to the Kymriah drug label for complete dosing and administration recommendations.