Keytruda® (pembrolizumab) – Accelerated approval to full approval

- On December 16, 2022, the FDA approved Merck's Keytruda (pembrolizumab), for an alternate dosing regimen of 400 mg every six weeks for all approved adult solid tumor indications.
    - The alternate dosing regimen was previously approved under accelerated approval in 2020. This converts the accelerated approval to full approval.
    - Two indications, adult classical Hodgkin lymphoma and adult primary mediastinal large B cell lymphoma, for the alternate dosing regimen continue to be approved under accelerated approval.
- The approval of Keytruda for the full approval alternate dosing regimen was based on an analysis of overall response rate, duration of response, and safety from Cohort B of the KEYNOTE-555 trial, a phase 1 randomized trial of Keytruda to evaluate bioavailability of the dosing regimen.
    - There are no clinically significant exposure-response relationships for efficacy or safety at pembrolizumab dosages of 200 mg or 2 mg/kg every 3 weeks and 400 mg every 6 weeks in patients with solid tumors based on observed data in adult patients with melanoma.