Prevymis® (letermovir) – New indication

- On June 6, 2023, Merck announced the FDA approval of Prevymis (letermovir), for prophylaxis of cytomegalovirus (CMV) disease in adult kidney transplant recipients at high risk (Donor CMV seropositive/Recipient CMV seronegative [D+/R-]).
- Prevymis is also approved for the prophylaxis of CMV infection and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant.
- The approval of Prevymis for the new indication was based on a randomized, double-blind, active comparator-controlled non-inferiority study in 589 adult kidney transplant recipients at high risk. Patients were randomized to receive either Prevymis or valganciclovir. The primary endpoint was the incidence of CMV disease (CMV end-organ disease or CMV syndrome) through week 52 post-transplant.
    - CMV disease through week 52 occurred in 10% of patients with Prevymis vs. 12% with valganciclovir (treatment difference -1.4, 95% CI: -6.5, 3.8). Based on a non-inferiority margin of 10%, Prevymis was non-inferior to valganciclovir.
- The most common adverse reaction (≥ 10% of patients and at a frequency greater than valganciclovir) with Prevymis use for kidney transplant patients was diarrhea.
- The recommended dosage of Prevymis is 480 mg administered orally or intravenously once daily. For kidney transplant patients, Prevymis should be initiated between day 0 and day 7 post-transplant and continue through day 200 posttransplant.
- Refer to the Prevymis drug label for complete dosing information.