Prevymis® (letermovir) – Expanded indication, new dosage formulation

- On August 30, 2024, the FDA approved Merck's Prevymis (letermovir), for the prophylaxis of cytomegalovirus (CMV) infection and disease in adult and pediatric patients 6 months of age and older and weighing at least 6 kg who are CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT), and for prophylaxis of CMV disease in adult and pediatric patients 12 years of age and older and weighing at least 40 kg who are kidney transplant recipients at high risk (donor CMV seropositive/recipient CMV seronegative [D+/R-]).
    - Prevymis was previously approved for these indications for adult patients only.
- Prevymis was also approved as 20 mg or 120 mg per packet oral pellets. Previously, Prevymis was available as oral tablets and intravenous injection.
- The approval of Prevymis for the expanded indication of allogeneic HSCT patients was based on an open-label, single-arm study. Patients received Prevymis daily either orally or intravenously for CMV prophylaxis within 28 days post-HSCT through week 14 post-HSCT. The efficacy analyses population consisted of 56 patients who received at least one dose of Prevymis and had no detectable CMV DNA at baseline.
    - The proportion of subjects who failed CMV prophylaxis through week 24 post-HSCT was 25% (14 of the 56 subjects). Six subjects had initiation of pre-emptive therapy based on CMV viremia and 8 subjects discontinued from the study before week 24. None of the subjects had CMV end-organ disease.
- The approval of Prevymis for prophylaxis of CMV disease in high-risk [D+/R-] kidney transplant recipients 12 years of age and older and weighing at least 40 kg is supported by evidence from an adequate and well-controlled study in adults and safety data from pediatric HSCT recipients.
- The most common adverse reactions with Prevymis use in pediatric patients were similar to adults.
- The recommended dose of Prevymis for the treatment of adult and pediatric patients 12 years of age and older who are HSCT or kidney transplant recipients is 480 mg administered orally or intravenously once daily.
    - Refer to the Prevymis drug label for additional administration instructions.
- The recommended dose of Prevymis for the treatment of pediatric patients 6 months to less than 12 years of age or 12 years of age and older and weighing less than 30 kg who are HSCT recipients are based on weight and may be given orally or intravenously.
    - Refer to the Prevymis drug label for detailed dosage information and additional administration instructions.
- Merck's launch plans for Prevymis oral pellets are pending.