2000 Galloping Hill Road
Kenilworth, NJ 07033 U.S.A.

July 25, 2019

## IMPORTANT PRESCRIBING INFORMATION

**Subject: Important Updated Information for PREVYMIS™ (letermovir) Injection: Notice of *New* Requirement to Administer Through a 0.2 Micron Polyethersulfone (PES) In-Line Filter [Lot #'s: S018972, S018973, S018974, S018975, S018976, S018977, S018978, S018979, S018980]**

Dear Health Care Provider:

The purpose of this letter is to inform you of important updated information requiring the administration of PREVYMIS™ (letermovir) Injection 20 mg/mL, for Intravenous Use, with a 0.2 micron Polyethersulfone (PES) in-line filter. This new requirement to use a sterile 0.2 micron PES in-line filter is intended to prevent the possible administration of product-related particulate matter observed in vials of the batches of the product identified in this letter. The presence of visible particulate matter is a characteristic of new commercial supplies of PREVYMIS injection. Administration through a sterile 0.2 micron PES in-line filter has no impact on the dosage of PREVYMIS injection.

PREVYMIS is indicated for prophylaxis of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT). PREVYMIS may be administered orally, with PREVYMIS 240 mg or 480 mg tablets, or intravenously, with PREVYMIS injection. PREVYMIS injection should be administered only to adult CMV-seropositive recipients [R+] of an allogeneic HSCT who are not able to take oral therapy or who are not able to absorb medicines in the gastrointestinal (GI) tract.

### PREPARATION AND ADMINISTRATION OF INTRAVENOUS SOLUTION

**ATTENTION:**

- For the listed batches, PREVYMIS injection MUST be administered through a sterile 0.2 micron polyethersulfone (PES) filter. If you observe **extraneous matter other than a few small translucent or white particles** in the vial/solution either before or after reconstitution, you should discard the vial/solution and do not administer it to the patient.
- Please ensure that your staff and any provider in your institution who may be involved in the reconstitution and administration of PREVYMIS receives a copy of this letter.
- Directions for diluting PREVYMIS are not changed.
- PREVYMIS must be diluted prior to intravenous (IV) use according to the instructions in the US Prescribing Information (USPI). The following items highlight important new information for healthcare professionals for administration of new commercial supplies.

**New Instructions for Preparation and Administration:**

- Inspect the vial contents for discoloration and particulate matter prior to dilution. PREVYMIS injection is a clear and colorless solution and may contain a few product-related small translucent or white particles.
- **Do not use the vial if the solution is discolored, cloudy, or contains extraneous matter other than a few small translucent or white particles.**

- **Do not use PREVYMIS (letermovir) injection with IV bags and infusion set materials containing the plasticizer Diethylhexyl phthalate (DEHP).** Use only with IV bags and infusion set materials that are DEHP-free or phthalate-free.
- Once diluted, the solution of PREVYMIS is clear, and ranges from colorless to yellow. Variations of color within this range do not affect the quality of the product.
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration.
- **Discard the diluted solution if the solution is discolored, cloudy or contains extraneous matter other than a few small translucent or white particles.**
- **The diluted solution must be administered through a sterile 0.2 micron PES in-line filter.**
- **Do not administer diluted solution through a filter other than a sterile 0.2 micron PES in-line filter.**

This letter is not intended as a complete description of the benefits and risks related to the use of PREVYMIS. Please refer to the enclosed full prescribing information.

**Reporting Product Quality Issues or Adverse Events:**

Heath care providers should report product quality problems and all suspected adverse events associated with the use of PREVYMIS to Merck at 1-877-888-4231.

Adverse events or quality problems experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting Program either online, by regular mail, or by fax:

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular mail or Fax: download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178 (1-800-332-0178)

If you require further information, please contact the Merck National Service Center at 1-800-672-6372.

Sincerely,
Merck Professional Services

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