## COMMONWEALTH OF AUSTRALIA

## Department of Health Therapeutic Goods Administration

## *THERAPEUTIC GOODS ACT 1989*

DESIGNATION OF Letermovir (TBA) AS AN ORPHAN DRUG

I, Dr Anthony Gill, Delegate of the Secretary for the purposes of 16J of the Therapeutic Goods Regulations 1990 (“the Regulations”), acting under subregulation 16J(2) of the Regulations, designate Letermovir (TBA) as an orphan drug on 15 March 2017 for the prevention of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT).

The dose forms of Letermovir (TBA) for this indication are film coated tablet and powder for injection.

The sponsor of Letermovir (TBA) is Merck Sharp & Dohme (Australia) Pty Limited.

(Signed By)

Dr Anthony Gill

Delegate of the Secretary

15 March 2017