



COMMONWEALTH OF AUSTRALIA

Department of Health
Therapeutic Goods Administration

THERAPEUTIC GOODS ACT 1989

DESIGNATION OF LETERMОВIR (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