



COMMONWEALTH OF AUSTRALIA

Department of Health  
Therapeutic Goods Administration

*THERAPEUTIC GOODS ACT 1989*

**DESIGNATION OF BLINATUMOMAB 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 Blinatumomab as an orphan drug on 20 November 2013 for the treatment of B-precursor acute lymphoblastic leukaemia .

The dose form of Blinatumomab for this indication is powder for reconstitution, injection.

The sponsor of Blinatumomab is Amgen Australia Pty Ltd.

(Signed by)

Dr Anthony Gill  
Office of Scientific Evaluation  
Delegate of the Secretary

20 November 2013