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GOVERNMENT NOTICES

COMMONWEALTH OF AUSTRALIA

Department of Health
Therapeutic Goods Administration

THERAPEUTIC GOODS ACT 1989

DESIGNATION OF ECULIZUMAB (rmc) (SOLIRIS) 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 Eculizumab (rmc) (SOLIRIS) as an orphan drug on 18 January 2017 for the prevention of delayed graft function (DGF) after solid organ transplantation.

The dose form of Eculizumab (rmc) (SOLIRIS) for this indication is solution for IV infusion.

The sponsor of Eculizumab (rmc) (SOLIRIS) is Alexion Pharmaceuticals Australasia.

(Signed by)

Dr Anthony Gill

Delegate of the Secretary

18 January 2017

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