



COMMONWEALTH OF AUSTRALIA

Department of Health  
Therapeutic Goods Administration

*THERAPEUTIC GOODS ACT 1989*

**DESIGNATION OF RUXOLITINIB JAKAVI 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 Ruxolitinib JAKAVI as an orphan drug on 16 October 2014 for the treatment of patients with polycythaemia vera who are resistant to or intolerant of hydroxyurea

The dose form of Ruxolitinib JAKAVI for this indication is tablet.

The sponsor of Ruxolitinib JAKAVI is Novartis Pharmaceuticals Australia Pty Ltd

(Signed by)

Dr Anthony Gill  
Delegate of the Secretary

24 October 2014