



COMMONWEALTH OF AUSTRALIA

Department of Health
Therapeutic Goods Administration

THERAPEUTIC GOODS ACT 1989

DESIGNATION OF CERITINIB (ZYKADIA) 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 Ceritinib (ZYKADIA) as an orphan drug on 1 September 2014 for the treatment of patients with non-small cell lung cancer (NSCLC) that is anaplastic lymphoma kinase (ALK)-positive.

The dose form of Ceritinib (ZYKADIA) for this indication is hard capsule.

The sponsor of Ceritinib (ZYKADIA) is Novartis Pharmaceuticals Australia Pty Ltd.

Dr Anthony Gill
Delegate of the Secretary

3 October 2014