## 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