



EudraCT Interim Clinical Trial Results: Secondary Endpoint (Tumour Response)

EudraCT number	2008-005542-23
Protocol number	CR0708-11
Protocol title	A CCLG/Cancer Research UK Phase I trial of AT9283 (a selective inhibitor of aurora kinases) given for 72 hours every 21 days via intravenous infusion in children and adolescents with relapsed and refractory solid tumours
Sponsor	Cancer Research UK 407 St John Street, London, United Kingdom, EC1V 4AD
End of Trial date	Not applicable

For the purpose of posting interim clinical trial results for the Cancer Research UK clinical trial CR0708-11 to the European Clinical Trials Database (EudraCT), the following table summarising the results of tumour marker assessments from the trial has been extracted from the approved Clinical Study Report (Version 1.0, dated 20 December 2016):

Secondary endpoint: Tumour Response

One of the secondary objectives of the trial was to assess the preliminary evidence of activity of AT9283 by using objective tumour measurements in relapsed/refractory patients with solid tumours (including central nervous system tumours).

Two patients had disease specific biological markers measured during the trial. The paired results of each tumour marker pre- and post-treatment are shown in the table below. The neuroblastoma patient, who had *MYCN* non-amplified disease, showed a 55% decrease in serum catecholamines homovanillic acid (HVA) whilst achieving a best tumour response of no response. In contrast, the other patient, who had transitional cell carcinoma of the liver, showed an increasing level of alpha-fetoprotein throughout the two cycles of AT9283, whilst achieving a best tumour response of progressive disease following radiological assessment of disease at the end of Cycle 2.

Paired Tumour Marker Results:

Primary Disease	Tumour Marker (units)	Pre-treatment	Cycle 1	Cycle 2	Cycle 4
Neuroblastoma (right suprarenal)	HVA (mmol/mol)	10.7	-	5.4	4.8
	Dopamine (mmol/mol)	3.7	-	1.1	0.7
	Urine noradrenaline/creatinine (mmol/mol)	0.15	-	0.07	0.02
	Urine HMMA creatinine (mmol/mol)	4.9	-	3.2	2.5
	Urine creatinine (mmol/mol)	4.7	-	6.9	6.6
Transitional cell carcinoma (liver)	Alpha-fetoprotein (Ku/L)	33282	42635 (Day 1) 50541 (Day 8)	70030 (Day 1) 98351 (Day 14)	-

Abbreviations: HMMA=4-hydroxy-3-methoxymandelic acid; HVA=homovanillic acid; Ku=kilo unit.