EudraCT Interim Clinical Trial Results: Secondary Endpoint (Pharmacokinetics)

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 pharmacokinetic data from the trial has been extracted from the approved Clinical Study Report (Version 1.0, dated 20 December 2016):

Secondary endpoint: Pharmacokinetics

One of the secondary objectives of the trial was to determine the pharmacokinetics of AT9283 when administered as a 72 hour intravenous infusion in children and adolescents with solid tumours.

Summary Pharmacokinetic Data by Dose Level for AT9283:

Mean ±SD (standard deviation), except for Cmax (range) and for the two patients treated at 23 mg/m^2/day, where values for both patients are given.

Dose level mg/m^2/day	Number of patients	Cmax (ng/ml)	AUC (ng/ml.h)	Half-life (h)	Cl (l/h)	Vss (l)
7	5	7.0 – 19.0	639 ± 383	5.7 ± 0.4	39.7 ± 23.6	328±180
9	5	14.7 – 68.2	1817 ± 1246	4.9 ± 1.5	20.4 ± 7.7	158±74
11.5	6	14.5 - 68.8	2102 ± 1074	5.1 ± 1.2	22.3 ± 15.1	157±122
14.5	7	14.8 – 60.6	2267 ± 938	5.2 ± 2.0	21.0 ± 6.8	114±73
18.5	7	17.3 – 80.9	1946 ± 799	5.6 ± 1.5	37.8 ± 16.4	224±79
23.0	2	63.1, 89.0	3436, 5305	4.0, 18.7	20.9, 19.6	256, 363

Abbreviations: AUC=area under the plasma concentration time curve; Cl=clearance; Cmax=maximum concentration; Vss=volume of distribution at steady state.