EudraCT Interim Clinical Trial Results: Primary Endpoint (Safety)

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 dose limiting toxicities (DLTs) that occurred during the trial has been extracted from the approved Clinical Study Report (Version 1.0, dated 20 December 2016):

Primary endpoint: Safety

The aim of the trial was to evaluate the safety and tolerability of AT9283 (given by intravenous infusion) by characterising the DLTs and determining the maximum tolerated dose (MTD) in children and adolescents with relapsed and refractory solid tumours. The DLT in this trial was defined according to the National Cancer Institute Common Terminology Criteria for Adverse Events Version 3.0.

Six DLTs were reported in six out of 33 patients (18.1%) during the trial. All patients who experienced a DLT recovered from it sufficiently to permit their continued administration with AT9283 at a reduced dose level.

Dose Limiting Toxicities:

Dose Level (mg/m^2)	CTCAE Grade and Term
11.5	Grade 3 febrile neutropenia
18.5	Grade 3 suspected bacterial infection
23.0	Grade 4 neutropenia
23.0	Grade 3 febrile neutropenia
18.5*	Grade 4 neutropenia
14.5*	Grade 4 neutropenia

Abbreviation: CTCAE=Common Terminology Criteria for Adverse Events.
* Patients were undergoing screening at the time the DLT was identified in the second patient treated at 23.0 mg/m^2.

The MTD was established as 18.5 mg/m^2, with a total of seven patients receiving AT9283 at this dose level, of which two experienced a DLT.