

Trial title	A signal seeking window trial of AZD8931 in patients with resectable non-small cell lung cancer
R&D PIN	2011PO004
EudraCT reference	2011-001518-33
REC Reference	Unknown
Sponsor	Manchester University NHS Foundation Trust
Chief Investigator	Dr Paul Taylor

The above referenced single-centre, single-arm, open label, phase II Clinical Trial of an Investigational Medicinal Product (CTIMP) was in the setup process at University Hospital of South Manchester NHS Foundation Trust (now known as Manchester University NHS Foundation Trust) until 04/12/2012.

The primary objective of the trial was to determine whether a 40mg twice daily dose of AZD8931 administered for 10-14 days (up to 18 days if surgery rescheduled) resulted in suppression of cancer cell growth by looking at changes in a marker called Ki67 which represents proliferation of tumour cells before and after treatment with AZD8931.

The secondary endpoints were:

- Tolerability and safety of ADZ8931 up to 40 days post-operatively
- Complete resection rate
- Changes in expression of pharmacodynamic biomarkers of EGFR pathway activation as determined by immunohistochemistry.
- Tumour mutation status
- Changes in levels of circulating cell death biomarkers
- Changes in levels of circulating HER family ligands before, during and after AZD8931 exposure
- Plasma levels of AZD8931 at day 3, 8 and the day before and immediately prior to surgery

The trial aimed to recruit 20 adult participants.

The trial was prematurely withdrawn by the Sponsor on 4th December 2012 before it had begun due to the fact that AstraZeneca UK Ltd, who supplied the IMP, halted development of the Investigational Medicinal Product (IMP). As such, no participants were recruited to the trial.

Name: Paul Taylor

Date: 05 December
2012

Signature: 