UNIVERSITY OF LEEDS

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15 August 2016
Information Processing Unit
Area 6
MHRA
151 Buckingham Palace Road
Victoria
London SW1W 9SZ

Dear Sir/Madam,

Re: Early termination of Clinical Trial
REC: 12/YH/0539 EudraCT: 2012-004537-16
Sponsor ID No/R&D No: MO11/10085
ABLE Trial – Afatinib Before Lung surgEry
An Open Label Multi-Centre Preoperative Window of Opportunity Study of Afatinib in Stage Ia to IIb Non-Small Cell Lung Cancer

On behalf of the Sponsor and Chief Investigator, Dr Clive Mulatero, I wish to submit notification of an early termination of the above clinical trial. Please find enclosed the following documentation of Notification of the end of a clinical trial of a medicine for human use to the competent authority and the ethics committee.

Yours sincerely,

S. Natch

Samantha Noutch
Clinical Trial Coordinator

Declaration of the End of Trial Form (cf. Section 4.2.1 of the *Detailed guidance on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, the notification of substantial amendments and the declaration of the end of the trial*[1])

NOTIFICATION OF THE END OF A CLINICAL TRIAL OF A MEDICINE FOR HUMAN USE TO THE COMPETENT AUTHORITY AND THE ETHICS COMMITTEE

For official use

Date of receipt :	Competent authority registration number : Ethics committee registration number:

To be filled in by the applicant

A MEMBER STATE IN WHICH THE DECLARATION IS BEING MADE : UK

B TRIAL IDENTIFICATION

B.1 EudraCT number :2012-00453-16
B.2 Sponsor's protocol code number: MO11/10085 ABLE Trial
B.3 An Open Label Multi-Centre Preoperative Window of Opportunity Study of Afatinib in Stage Ia to IIb Non-Small Cell Lung Cancer

C APPLICANT IDENTIFICATION (please tick the appropriate box)

C.1	**DECLARATION FOR THE COMPETENT AUTHORITY**
C.1.1	Sponsor
C.1.2	Legal representative of the sponsor
C.1.3	Person or organisation authorised by the sponsor to make the application. ☒
C.1.4	**Complete below**:
C.1.4.1	Organisation : University of Leeds
C.1.4.2	Name of person to contact : Samantha Noutch
C.1.4.3	Address : University of Leeds, Leeds, LS2 9JT
C.1.4.4	Telephone number : 0113 343 1477
C.1.4.5	Fax number : 0113 343 0686
C.1.4.6	E-mail: Samantha.noutch@nhs.net

C.2	**DECLARATION FOR THE ETHICS COMMITTEE**
C.2.1	Sponsor
C.2.2	Legal representative of the sponsor
C.2.3	Person or organisation authorised by the sponsor to make the application. ☒
C.2.4	Investigator in charge of the application if applicable[2]:
	• Co-ordinating investigator (for multicentre trial):
	• Principal investigator (for single centre trial):
C.2.5	**Complete below** :
C.2.5.1	Organisation: University of Leeds
C.2.5.2	Name : Samantha Noutch
C.2.5.3	Address : University of Leeds, Leeds, LS2 9JT
C.2.5.4	Telephone number : 0113 343 1477
C.2.5.5	Fax number : 0113 343 0686
C.2.5.6	E-mail : Samantha.noutch@nhs.net

D END OF TRIAL

D.1	**Date of the end of the complete trial in all countries concerned by the trial?**
D.1.1	(YYYY/MM/DD):2016/08/01

D.2	**Is it an early termination?**[3]	yes ☒ no

1 OJ, C82, 30.3.2010, p. 1; hereinafter referred to as 'detailed guidance CT-1'.
2 According to national legislation.
3 Cf. Section 4.2. of the detailed guidance CT-1.

D.2.1 If yes, give date (2016/08/09):
D.2.2 Briefly describe in an annex (free text): Last Patient follow-up visit completed on the 2016/08/09.
D.2.2.1 The justification for early termination of the trial; Low Recruitment
D.2.2.2 Number of patients still receiving treatment at time of early termination in the MS concerned by the declaration and their proposed management; None
D.2.2.3 Only 7 patients were recruited to the study, the study funder was not willing to support the analysis of only 7 samples. Unfortunately, this will result in no samples being evaluated, and hence no results for the primary, secondary or exploratory endpoints of the study. However, there should not be an implication for risk benefit of the IMP, as the IMP is already an approved medication for treatment of non-small cell lung cancer, with a well-established safety profile.

E SIGNATURE OF THE APPLICANT IN THE MEMBER STATE

E.1 I hereby confirm that/confirm on behalf of the sponsor that (delete which is not applicable):

- The above information given on this declaration is correct; and
- That the clinical trial summary report will be submitted within the applicable deadlines in accordance with the applicable guidance by the Commission.[4]

E.2 APPLICANT TO THE COMPETENT AUTHORITY (as stated in C.1) ❑

E.2.1 Date : 15 AUG 16
E.2.2 Signature : S. Noutch
E.2.3 Print name: Samantha Noutch

E.3 APPLICANT TO THE ETHICS COMMITTEE (as stated in C.2) : ❑

E.3.1 Date : 15 AUG 16
E.3.2 Signature : S. Noutch
E.3.3 Print name: Samantha Noutch

4 Section 4.3. of the detailed guidance CT-1.