CANCER RI

SUMMARY FINAL CLINICAL STUDY REPORT

A Cancer Research UK randomised Phase II trial of ATN-224 (copper binding agent) in combination with exemestane versus exemestane alone in post-menopausal women with recurrent or advanced, oestrogen and/or progesterone receptor positive breast cancer

EudraCT Number: 2007-005752-16

Sponsor Protocol Number: CR0207-22

The study was sponsored and managed by Cancer Research UK

Cancer Research UK
61 Lincoln's Inn Fields
London WC2A 3PX

Study Initiation Date:	05 September 2008 (date first patient consented)
Date of Early Termination:	28 October 2008 (date of decision to terminate the study)
Report Date:	23 October 2009

Chief Investigator: [redacted] Churchill Hospital, Oxford

This study was performed in accordance with the principles of Good Clinical Practice.

Report Title: A Cancer Research UK randomised Phase II trial of ATN-224 (copper binding agent) in combination with exemestane versus exemestane alone in post-menopausal women with recurrent or advanced, oestrogen and/or progesterone receptor positive breast cancer

This summary report has been approved by:

Signature Date

[redacted]

Chief Investigator

Churchill Hospital, Oxford.

Report Title: A Cancer Research UK randomised Phase II trial of ATN-224 (copper binding agent) in combination with exemestane versus exemestane alone in post-menopausal women with recurrent or advanced, oestrogen and/or progesterone receptor positive breast cancer

This summary report has been approved by:

Signature Date

[redacted]

Head of Clinical Operations

Cancer Research UK (DDO)

Report Title: A Cancer Research UK randomised Phase II trial of ATN-224 (copper binding agent) in combination with exemestane versus exemestane alone in post-menopausal women with recurrent or advanced, oestrogen and/or progesterone receptor positive breast cancer

This summary report has been approved by:

Signature Date

[redacted]

Clinical Study Manager

Cancer Research UK (DDO)

Final Summary Report

Title:

A Cancer Research UK randomised Phase II trial of ATN-224 (copper binding agent) in combination with exemestane versus exemestane alone in post-menopausal women with recurrent or advanced, oestrogen and/or progesterone receptor positive breast cancer.

Investigators:

Chief Investigator: [redacted] Churchill Hospital, Oxford.

Ten sites were included in the protocol. Of these, only [redacted] recruited a patient. This was the only patient recruited to this study.

Study centres:

[redacted] Churchill Hospital, Oxford

[redacted] UCLH, London

[redacted] Western General Hospital, Edinburgh

The above three sites were the only sites to receive ATN-224, the investigational medicinal product (IMP). Since the study was closed prematurely, the sites were instructed to destroy the IMP.

A further seven centres were stated in the protocol however none of these sites received any IMP prior to early study closure. These additional sites were Bristol Haematology and Oncology Centre, Southampton General Hospital, Velindre Hospital, Ninewells Hospital, Weston Park Hospital, St James University Hospital and Leicester Royal Infirmary.

Study period:

One patient was recruited before early study termination. The study period details for this patient are as follows:

Date patient on study:	22 September 2008 (first dose)
Recruitment terminated:	28 October 2008
Date patient completed (off study):	11 November 2008

The patient was randomised to the standard arm (exemestane) and given the patient number: [redacted].

Reason for study termination:

Following a project review meeting on 28 October 2008, the decision was taken to prematurely terminate the study. The reasons for study termination are listed below.

- Lack of positive data from the ATN-224 studies conducted in the USA.
- Cessation of the development of ATN-224 due to withdrawal of funding by Attentuon (the company who supplied the IMP for this study) hence uncertainty in the continued supply of ATN-224 for the study.

Oxfordshire Main REC was notified of the end of study on 10 November 2008.

MHRA was notified of the end of study on 11 November 2008.

Regulatory status:

This study was conducted under a clinical trial authorisation (CTA). CTA number: 21106/0223/001. The study was sponsored and monitored by Cancer Research UK, Drug Development Office (DDO). The study was managed and conducted in accordance with the principles of Good Clinical Practice and with Cancer Research UK DDO's Standard Operating Procedures.

Summary of Patient [redacted]

This patient was randomised on 19 September 2008 to the standard arm of exemestane only.

Date of the first dose was 22 September 2008.

[redacted]

- [redacted]
- [redacted]

[redacted]

- [redacted]

[redacted]

- [redacted]

The patient was informed about the premature termination of the study on 09 November 2008.

[redacted] The patient subsequently came off study.

Basic demographic data was collected for this patient but no additional toxicity data was retrieved from the site.