

Wales REC 3
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13 January 2017

Mr Robert Jones
Velindre NHS Trust
Velindre Hospital
Velindre Road
Cardiff CF14 2TL

Dear Mr Jones

Study title: A randomised, double blind, placebo controlled, phase II study of fulvestrant with or without the addition of vandetanib as treatment for patients with metastatic breast cancer resistant to aromatase inhibitor therapy.

REC reference: 14/WA/1219
Protocol number: 2014/VCC/0013
EudraCT number: 2014-001208-23
Amendment number: SA7
Amendment date: 09 December 2016
IRAS project ID: 153819

The above amendment was reviewed at the meeting of the Committee held on 12 January 2017.

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Covering letter on headed paper	Signed by Dr Jo Smith, FURVA Trial Manager	13 December 2016
Investigator's brochure / IMP Dossier [IB FASLODEX]	Edition 18	18 August 2015
Investigator's brochure / IMP Dossier [IB Vandetanib ZD6474]	Edition 16, Jan 2015	
Investigator's brochure / IMP Dossier [FURVA - Genzyme update]		02 November 2015
Investigator's brochure / IMP Dossier [Vandetanib-IB]	Edition-17, Jan 2016	
Notice of Substantial Amendment (CTIMP)	SA7	09 December 2016
Other [Protocol Amendment Log_V2.0-V3.0]		09 December 2016
Other [PIS and Consent Form Amendment Log V1.0-V2.0]		09 December 2016
Other [FURVA Diary Amendment Log V1.0-V2.0]		07 December 2016

Other [FURVA Follow Up Diary Amendment Log V1.0-V2.0]		07 December 2016
Other [Caprelsa ESR Investigator Letter]		27 July 2015
Other [2015Nov02 FURVA - Genzyme update]		02 November 2015
Participant information sheet (PIS) [FURVA_PIS]	2.0 (tracked)	09 December 2016
Participant information sheet (PIS) [FURVA_PIS]	2.0 (clean)	09 December 2016
Research protocol or project proposal [FURVA_protocol]	3.0 (tracked changes)	09 December 2016
Research protocol or project proposal [FURVA_protocol]	3.0 (clean)	09 December 2016
Sample diary card/patient card [FURVA Patient Diary Card]	2.0	07 December 2016
Sample diary card/patient card [FURVA Follow Up Patient diary card (Weeks 25-60)]	2.0	07 December 2016

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Statement of compliance

This Committee is recognised by the United Kingdom Ethics Committee Authority under the Medicines for Human Use (Clinical Trials) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.

The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our Research Ethics Committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

14/WA/1219:	Please quote this number on all correspondence
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Yours sincerely

Dr. Corinne Scott
Senior Ethics Service Manager
Health and Care Research Wales

pp Dr Pete Wall
Chair

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Enclosures: List of names and professions of members who took part in the review

Copy to: Mrs Sarah Townsend, Velindre NHS Trust
Mrs Angela Cashbard

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Attendance at Committee meeting on 12 January 2017

Committee Members:

Name	Profession	Present	Notes
Dr Gail Boniface	Occupational Therapist	Yes	
Dr Paul Brown	Radiographer	Yes	
Professor Kate Bullen	Psychologist	No	
Dr Joy Darch	Academic Subject Lead Nursing	Yes	
Ms Donna Duncan	Dietitian	Yes	
Mrs Monika Hare	Vice Chair / Lay member	No	
Ms Nicola Heales	Lay Plus member	No	
Mr HAO Hughes	Pharmacist	Yes	
Dr Andrea Longman	Lay member	Yes	
Mrs Emma Mills	Clinical Research Midwife	No	
Mr William Payne	Lay Plus member	Yes	
Dr V. Bapuji Rao	Hospital consultant (Psychiatrist)	Yes	
Ms Paula Strong	Nurse	Yes	
Mrs Wendy Turkie	Retired nurse	Yes	
Dr Richard Walker	Alternate Vice Chair / Lay Plus member	Yes	
Dr Pete Wall	Chair / Clinical Physiologist	Yes	Chaired meeting
Mr Stewart Williams	Lay Plus member	No	

Also in attendance:

Name	Position (or reason for attending)
Dr Corinne Scott	Senior Ethics Service Manager
Mrs Helen Williams	REC Coordinator
Miss Joanne Love	REC Administrative Assistant