Clinical trial results:
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

Summary

EudraCT number	2014-001208-23
Trial protocol	GB
Global end of trial date	30 June 2025

Results information

Result version number	v1 (current)
This version publication date	04 April 2026
First version publication date	04 April 2026
Summary attachment (see zip file)	FURVA BJC Reports (FURVA manuscript published.pdf)

Trial information

Trial identification

Sponsor protocol code	2014/VCC/0013

Additional study identifiers

ISRCTN number	ISRCTN13663157
ClinicalTrials.gov id (NCT number)	NCT02530411
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Velindre NHS Trust
Sponsor organisation address	Unit 2 Charnwood Court, Cardiff, United Kingdom, CF15 7QZ
Public contact	Angela Casbard, Centre for Trials Research, Cardiff University, 44 29 2068 7500, FURVA@cardiff.ac.uk
Scientific contact	Angela Casbard, Centre for Trials Research, Cardiff University, 44 29 2068 7500, FURVA@cardiff.ac.uk

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	18 February 2020
Is this the analysis of the primary completion data?	Yes
Primary completion date	18 February 2020
Global end of trial reached?	Yes
Global end of trial date	30 June 2025
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To establish whether the combination of vandetanib and fulvestrant will improve clinical outcome in patients with endocrine resistant advanced breast cancer (RECIST v1.1).

Protection of trial subjects:

The IDMC reviewed the data at two safety reviews after 20 and 40 participants received at least 1 cycle of treatment.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 January 2015
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 165
Worldwide total number of subjects	165
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	81
From 65 to 84 years	82
85 years and over	2

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Before any trial related procedures are undertaken, the patient's written informed consent must be obtained. The patient should be given a minimum of 24 hours after initial invitation to participate before being asked to sign the consent form.

Screening logs should be completed for every patient considered for the trial.

Period 1

Period 1 title	Main (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Fulverstrant plus vandetanib

Arm description: -

Arm type	Experimental
Investigational medicinal product name	Vandetanib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Patients received oral vandetanib/placebo tablets once a day by mouth for the duration of the trial, until IMP treatment is discontinued. The starting dose was 300 or 200 mg dependent on renal impairment status.

Arm title	Fulvestrant plus placebo

Arm description: -

Arm type	Placebo
Investigational medicinal product name	vandetanib placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Patients will receive oral vandetanib/placebo tablets once a day by mouth for the duration of the trial, until IMP treatment is discontinued.

Number of subjects in period 1	Fulverstrant plus vandetanib	Fulvestrant plus placebo
Started	80	85
Completed	80	85

Baseline characteristics

Reporting groups	
Reporting group title	Fulverstrant plus vandetanib
Reporting group description: -	
Reporting group title	Fulvestrant plus placebo
Reporting group description: -	

Reporting group values	Fulverstrant plus vandetanib	Fulvestrant plus placebo	Total
Number of subjects	80	85	165
Age categorical Units: Subjects			
Adults (18-64 years)	40	41	81
From 65-84 years	38	44	82
85 years and over	2	0	2
Gender categorical Units: Subjects			
Female	80	85	165
Male	0	0	0

End points

End points reporting groups

Reporting group title	Fulverstrant plus vandetanib
Reporting group description: -	
Reporting group title	Fulvestrant plus placebo
Reporting group description: -	

Primary: Progression Free Survival

End point title	Progression Free Survival[1]
End point description:	
Progression-free survival (PFS - time to event) based on Response Evaluation Criteria in Solid Tumours (RECIST) v1.1	
End point type	Primary
End point timeframe:	
Time to event	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Progression-free survival (PFS - time to event) based on Response Evaluation Criteria in Solid Tumours (RECIST) v1.1.

End point values	Fulverstrant plus vandetanib	Fulvestrant plus placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	80	85		
Units: Number				
median (confidence interval 95%)				
PFS mean	5.5 (3.6 to 8.9)	5.5 (3.5 to 8.1)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information[1]	
Timeframe for reporting adverse events:	
At baseline, during treatment, at the end of treatment, at the end of study	
Adverse event reporting additional description:	
Full report of AEs and SAEs is in the publication.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	0

Frequency threshold for reporting non-serious adverse events: 5 %

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.
Justification: Full list of AEs and SAEs can be found in the paper.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
09 December 2016	Revision of Protocol V2.0 09/12/2016 to V3.0 09/12/2016 with more clarification about eligibility criteria, trial assessments, IMP management, prohibited medications, and translational research; Revision of PIS/Content Form V1.0 16/10 2016 to V2.0 09/12/2016 to reflect changes to the protocol; Revision of Participant Diary Card V1.0 to V2.0 07/12/2016 and Follow up Patient diary card (weeks 25-60) V1.0 121114 to V2.0 07/12/2016; Revision of Investigator Brochure (IB) for the IMP Vandetanib: Ed. 15 18/12/2013 to be used for DSUR reporting period 15/01/2015 to 14/01/2017; updated IB Ed. 16 dated 21/01/2015 and Ed. 17 dated 02/02/2016; Updated IBs for nIMP Fulvestrant Ed.17 dated 02/06/2014 and Ed.18 dated 18/08/2015; Notification of the divestment of the IMP (Vandetanib) from AstraZeneca to Genzyme

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

No limitations

Notes:

Online references

http://www.ncbi.nlm.nih.gov/pubmed/39516358