



## Clinical trial results:

**Phase II, open label, single arm study to investigate anti-tumor effect of ixabepilone in patients with locally recurrent metastatic breast cancer (mBC) selected by the ixabepilone Drug Response Prediction (DRP) after failure of an anthracycline and a taxane**

### Summary

EudraCT number	2020-004610-35
Trial protocol	FI PL NL
Global end of trial date	29 August 2024

### Results information

Result version number	v1 (current)
This version publication date	25 December 2024
First version publication date	25 December 2024

### Trial information

#### Trial identification

Sponsor protocol code	AL-2001
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#### Additional study identifiers

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

Notes:

### Sponsors

Sponsor organisation name	Allarity Therapeutics Europe ApS
Sponsor organisation address	Venlighedsvej 1, Hørsholm, Denmark, 2970
Public contact	Jeremy Graff , Allarity Therapeutics Europe ApS, +45 31 20 75 39, jgraff@allarity.com
Scientific contact	Jeremy Graff , Allarity Therapeutics Europe ApS, +45 31 20 75 39, jgraff@allarity.com

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	27 September 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	29 August 2024
Global end of trial reached?	Yes
Global end of trial date	29 August 2024
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

The main objective of the trial was to evaluate the clinical benefit rate (CBR) of ixabepilone.

Protection of trial subjects:

The trial was conducted in accordance with the Declaration of Helsinki, adopted by the 18th World Medical Association (WMA) General Assembly, Helsinki, Finland, June 1964, and subsequent amendments and International Council for Harmonisation (ICH) guideline for Good Clinical Practice E6 (R2) (European Medicine Agency (EMA)/ Committee for medical Products for Human Use (CHMP/ICH/135/1995), including archiving of essential documents and the EU Clinical Trial Directive (CTD) 2001/20/EC.

Background therapy:

None

Evidence for comparator:

None

Actual start date of recruitment	01 March 2021
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

## Population of trial subjects

### Subjects enrolled per country

Country: Number of subjects enrolled	Netherlands: 1
Country: Number of subjects enrolled	Poland: 3
Country: Number of subjects enrolled	United Kingdom: 3
Country: Number of subjects enrolled	Belgium: 6
Worldwide total number of subjects	13
EEA total number of subjects	10

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)	6
From 65 to 84 years	7
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details:

Patients were screened at 4 sites in Belgium, 1 site in Netherlands, 1 site in Finland, 4 sites in Poland, 1 sites in Germany and 7 sites in the UK.

### Pre-assignment

Screening details:

Patents were screened using a companion diagnostic IVDR , a drug response prediction. Patients above a score of 33% was enrolled into the study for treatment.

### Period 1

Period 1 title	Treatment period (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Blinding implementation details:

This was an open study

### Arms

Arm title	Ixabepilone
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Arm description:

Ixabepilone 40 mg/m2 infused intravenously every 3 weeks

Arm type	Experimental
Investigational medicinal product name	Ixabepilone
Investigational medicinal product code	Ixabepilone
Other name	
Pharmaceutical forms	Concentrate for solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Dose 40mg/m2 every 3 weeks

<b>Number of subjects in period 1</b>	Ixabepilone
Started	13
Completed	13

## Baseline characteristics

### Reporting groups

Reporting group title	Treatment period
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Reporting group description: -

Reporting group values	Treatment period	Total	
Number of subjects	13	13	
Age categorical			
Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		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)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous			
Units: years			
arithmetic mean	59		
standard deviation	± 8.7	-	
Gender categorical			
Units: Subjects			
Female	13	13	
Male	0	0	

## End points

### End points reporting groups

Reporting group title	Ixabepilone
Reporting group description: Ixabepilone 40 mg/m <sup>2</sup> infused intravenously every 3 weeks	

### Primary: Primary endpoint

End point title	Primary endpoint <sup>[1]</sup>
End point description: Clinical benefit rate was defined as the proportion of patients having a complete response, partial response or stable disease for 24 weeks.	
End point type	Primary
End point timeframe: Baseline to 24 weeks.	
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: Not applicable	

End point values	Ixabepilone			
Subject group type	Reporting group			
Number of subjects analysed	13			
Units: Clinical benefit rate				
Complete Response	0			
Partial Response	2			
Stable Disease	0			
Progressive disease	10			

### Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

AEs were reported from first dose until progression of disease or end for treatment for other reasons.

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	24
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### Reporting groups

Reporting group title	All subjects
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Reporting group description: -

Serious adverse events	All subjects		
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 12 (33.33%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Nervous system disorders			
Tremor			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
Neutropenia			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
General physical health deterioration			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		

Asthenia			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		

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

<b>Non-serious adverse events</b>	All subjects		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 12 (100.00%)		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	2 / 12 (16.67%)		
occurrences (all)	3		
Fatigue			
subjects affected / exposed	7 / 12 (58.33%)		
occurrences (all)	17		
General physical health deterioration			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	4		
Mucosal inflammation			
subjects affected / exposed	2 / 12 (16.67%)		
occurrences (all)	2		
Oedema peripheral			
subjects affected / exposed	2 / 12 (16.67%)		
occurrences (all)	2		
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		



Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Dyspnoea			
subjects affected / exposed	2 / 12 (16.67%)		
occurrences (all)	6		
Epistaxis			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	2		
Hydrothorax			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Hypoventilation			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Hypoxia			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	2		
Interstitial lung disease			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Nasal congestion			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Productive cough			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Pulmonary embolism			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Rhinorrhoea			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Psychiatric disorders			

Insomnia subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 2		
Mood altered subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 2		
Investigations Platelet count decreased subjects affected / exposed occurrences (all)	2 / 12 (16.67%) 3		
Weight decreased subjects affected / exposed occurrences (all)	2 / 12 (16.67%) 3		
Cardiac disorders Sinus tachycardia subjects affected / exposed occurrences (all)	2 / 12 (16.67%) 2		
Nervous system disorders Balance disorder subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1		
Dizziness subjects affected / exposed occurrences (all)	2 / 12 (16.67%) 2		
Dysgeusia subjects affected / exposed occurrences (all)	2 / 12 (16.67%) 2		
Headache subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1		
Neuralgia subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 2		
Neuropathy peripheral subjects affected / exposed occurrences (all)	7 / 12 (58.33%) 18		
Polyneuropathy			

subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Tremor			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	2		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 12 (25.00%)		
occurrences (all)	15		
Leukopenia			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Neutropenia			
subjects affected / exposed	7 / 12 (58.33%)		
occurrences (all)	18		
Thrombocytopenia			
subjects affected / exposed	3 / 12 (25.00%)		
occurrences (all)	5		
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	2 / 12 (16.67%)		
occurrences (all)	2		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	3 / 12 (25.00%)		
occurrences (all)	3		
Abdominal pain upper			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Anal hypoaesthesia			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Constipation			
subjects affected / exposed	3 / 12 (25.00%)		
occurrences (all)	4		
Diarrhoea			

subjects affected / exposed	5 / 12 (41.67%)		
occurrences (all)	9		
Dry mouth			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Dyspepsia			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Gastrointestinal pain			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Nausea			
subjects affected / exposed	5 / 12 (41.67%)		
occurrences (all)	9		
Proctalgia			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Stomatitis			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Toothache			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Vomiting			
subjects affected / exposed	5 / 12 (41.67%)		
occurrences (all)	5		
Hepatobiliary disorders			
Hepatic failure			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		
Hepatic pain			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		

Skin and subcutaneous tissue disorders	Alopecia			
	subjects affected / exposed	6 / 12 (50.00%)		
	occurrences (all)	8		
	Dry skin			
	subjects affected / exposed	1 / 12 (8.33%)		
	occurrences (all)	1		
	Erythema			
	subjects affected / exposed	1 / 12 (8.33%)		
	occurrences (all)	1		
Endocrine disorders	Nail discolouration			
	subjects affected / exposed	1 / 12 (8.33%)		
	occurrences (all)	1		
	Plantar erythema			
	subjects affected / exposed	2 / 12 (16.67%)		
	occurrences (all)	2		
	Pruritus			
	subjects affected / exposed	1 / 12 (8.33%)		
	occurrences (all)	1		
Musculoskeletal and connective tissue disorders	Rash			
	subjects affected / exposed	1 / 12 (8.33%)		
	occurrences (all)	1		
	cushi			
	subjects affected / exposed	1 / 12 (8.33%)		
	occurrences (all)	1		
	Arthralgia			
	subjects affected / exposed	2 / 12 (16.67%)		
	occurrences (all)	3		
Musculoskeletal and connective tissue disorders	Back pain			
	subjects affected / exposed	2 / 12 (16.67%)		
	occurrences (all)	2		
	Flank pain			
	subjects affected / exposed	2 / 12 (16.67%)		
	occurrences (all)	2		

Muscular weakness subjects affected / exposed occurrences (all)	4 / 12 (33.33%) 6		
Musculoskeletal pain subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 3		
Myalgia subjects affected / exposed occurrences (all)	3 / 12 (25.00%) 5		
Tendon pain subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1		
Infections and infestations			
Cystitis subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 2		
Oral candidiasis subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1		
Pneumonia subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1		
Sinusitis subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1		
Staphylococcal sepsis subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1		
Urinary tract infection subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1		
Metabolism and nutrition disorders			
Diabetes mellitus subjects affected / exposed occurrences (all)	1 / 12 (8.33%) 1		
Decreased appetite			

subjects affected / exposed	6 / 12 (50.00%)		
occurrences (all)	8		
Hypercalcaemia			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	2		
Hyperkalaemia			
subjects affected / exposed	1 / 12 (8.33%)		
occurrences (all)	1		

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
18 November 2021	Changes to inclusion/exclusions criteria, screening period was increased form 4-6 weeks.
23 February 2022	Sponsor change of name, archival tissue can be used for DRP analysis.
28 December 2022	Inclusion cut off for DRP was changed from 67% to 33%
10 October 2023	Inclusion/exclusion criteria were updated, recommendation for use of contraceptives and concomitant medications were changed,

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported