



Clinical trial results:

An Phase II trial aiming to evaluate the clinical interest of ABEMACICLIB monotherapy in patients with locally advanced/metastatic head and neck cancer after failure of platinum and cetuximab or anti-EGFR-based therapy and harboring an homozygous deletion of CDKN2A, and/or an amplification of CCND1 and/or of CDK6

Summary

EudraCT number	2016-004537-25
Trial protocol	FR
Global end of trial date	15 April 2022

Results information

Result version number	v1 (current)
This version publication date	30 October 2025
First version publication date	30 October 2025

Trial information

Trial identification

Sponsor protocol code	ET16-116
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Centre Léon Bérard
Sponsor organisation address	28 Rue Laënnec, Lyon, France,
Public contact	DRCI - Phases précoces, CENTRE LEON BERARD, 33 (0)426556824, gwenaelle.garin@lyon.unicancer.fr
Scientific contact	DRCI - Phases précoces, CENTRE LEON BERARD, 33 (0)426556824, gwenaelle.garin@lyon.unicancer.fr

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	20 January 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	15 April 2022
Global end of trial reached?	Yes
Global end of trial date	15 April 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To determine the clinical activity of ABEMACICLIB as measured by the 8-week non-progression rate (Complete response [CR] + Partial Response [PR] + Stable disease [SD] after 8 weeks of treatment according to RECIST v1.1) in adult patients with locally advanced or metastatic head and neck cancer progressive under platin and cetuximab or anti-EGFR-based chemotherapy.

Protection of trial subjects:

Study treatments will continue to be administrated as long as patient experiences evidence clinical benefit in the opinion of the investigator, or experiences an unacceptable toxicity or symptomatic deterioration attributed to disease progression as determined by the investigator after an integrated assessment of radiographic data and clinical status or withdrawal of consent.

The investigator will have to inform the patient of the study treatment, the objectives and the design of the study, as well as the biological samples collection, provide the patient information leaflet / Informed consent form, answer to any questions that the patient may have and ensure that she understands the potential risks and benefits of participating in the study before signing the informed consent form.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	05 February 2018
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy
Long term follow-up duration	66 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	France: 26
Worldwide total number of subjects	26
EEA total number of subjects	26

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)	26
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Patients were recruited at the time of enrolment at the participating sites. The declared investigator, after having identified a potential candidate for the study, informed her orally of the terms of the study and provide her with : an information note, An informed consent form that has been dated and signed by the patient and the investigator.

Pre-assignment

Screening details:

None study-related procedure can be started before ICF was signed and dated by both the patient (and impartial witness, if applicable) and the investigator - Checked the eligibility criteria list and perform the exams. The screening period is divided into 2 stages: Molecular pre-screening and clinical screening

Period 1

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

Arms

Arm title	ABEMACICLIB
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Arm description:

The molecular pre-screening step will allow to defined HPV tumor status as well as molecular status CDKN2A CCND1 CDK6 and CDK4. Following this centralized molecular screening, only patients with HPV negative status and with tumor harboring CDKN2A homozygous deletion and/or CCND1 amplification and/or CDK6 and/or CDK4 amplification could initiate abemaciclib at time of documented radiological progression. Patients will be treated with ABEMACICLIB, 200 mg QH12/day with 2 doses of 200 mg 12-hour apart (QH12). A cycle is defined as an interval of 28 days. For each 28-day cycle, a total of 56 doses of study drug will be dispensed.

Arm type	Experimental
Investigational medicinal product name	Abemaciclib
Investigational medicinal product code	LY2835219
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Patients will receive Abemaciclib 400 mg, daily (200 mg in the morning, 200 mg in the evening) per os. A cycle is defined as an interval of xx days.

Number of subjects in period 1	ABEMACICLIB
Started	26
Completed	26

Baseline characteristics

Reporting groups

Reporting group title	Overall study period
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Reporting group description: -

Reporting group values	Overall study period	Total	
Number of subjects	26	26	
Age categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	26	26	
From 65-84 years	0	0	
85 years and over	0	0	
Age continuous			
Units: years			
median	59.0		
full range (min-max)	42.0 to 78.0	-	
Gender categorical			
Units: Subjects			
Female	3	3	
Male	23	23	

End points

End points reporting groups

Reporting group title	ABEMACICLIB
Reporting group description:	
The molecular pre-screening step will allow to defined HPV tumor status as well as molecular status CDKN2A CCND1 CDK6 and CDK4. Following this centralized molecular screening, only patients with HPV negative status and with tumor harboring CDKN2A homozygous deletion and/or CCND1 amplification and/or CDK6 and/or CDK4 amplification could initiate abemaciclib at time of documented radiological progressionPatients will be treated with ABEMACICLIB, 200 mg QH12/day with 2 doses of 200 mg 12-hour apart (QH12). A cycle is defined as an interval of 28 days. For each 28-day cycle, a total of 56 doses of study drug will be dispensed.	

Primary: Primary End Point

End point title	Primary End Point ^[1]
End point description:	
End point type	Primary
End point timeframe:	
The primary endpoint is the progression-free rate (CR, PR, SD as per RECIST 1.1) after 8 weeks of treatment (PFR8w), assessed by central review.	

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: The non-progression rate will be analyzed using central read tumor assessments and summarized by a proportion together with its 95% confidence interval.

At the time of analysis, if at least 7 successes are observed among the 23 evaluable patients, the treatment will be considered as interesting for further investigation in this indication. With alpha 0.05 and 85% power, 23 patients are needed to test $H_0: p \leq p_0$ vs $1: p \geq p_1$ in a one-sided test.

End point values	ABEMACICLIB			
Subject group type	Reporting group			
Number of subjects analysed	24 ^[2]			
Units: Patients				
Patients in failure	17			
Patients in success	7			

Notes:

[2] - Among the 26 treated patients, 2 patients were considered non-evaluable for primary endpoint

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

The investigator collects (spontaneous patient report or questioning) and immediately notifies the sponsor of all SAEs, in a written report, whether or not they are deemed to be attributable to research and which occur during the study

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
Dictionary version	25.0

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: At the time of the analysis, 22 patients (84.6%) had presented at least one treatment-related AE and 11 patients (42.3%) had presented at least one grade ≥ 3 treatment-related AE according to NCI-CTCAE V5.0; 13 patients (50%) had presented AEs leading to dose reduction or temporary discontinuation of treatment and 5 patients (19.2%) had presented AEs leading to treatment permanent discontinuation.

Most common treatment-related AEs : anemia 26.9%, diarrhea 53.8%, vomiting 34.6%, fatigue 46.2%.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
20 February 2018	New edition of the abemaciclib Investigator Brochure (ed. 09/15/2017) impacting participant safety, SRIs, and the protocol (without impacting the study's benefit/risk balance). Clarification of an inclusion criterion (I4). Addition of a non-inclusion criterion. Updated the list of investigators.
31 May 2018	Modification of an inclusion criterion (I12)
16 October 2018	Changes to the study's planned schedule : Total study duration: initially 24 months, extended by 18 months Inclusion period: initially 12 months, extended by 18 months Treatment and follow-up period: unchanged
16 April 2019	Update of study documents following the General Data Protection Regulation (GDPR); Update of the list of investigators (Declaration of 5 investigators in a research location already declared + Declaration of a new research location)
07 January 2020	Updated and added recommendations for the management of the following adverse events (AEs) in patients receiving abemaciclib: - Grade 3 increased blood alanine aminotransferase associated with increased bilirubin, - Pneumonitis/interstitial lung disease. Updated AEs related to abemaciclib (addition of a new expected AE: interstitial lung disease/pneumonia). Updated recommendations for concomitant medications to be administered with caution in patients receiving abemaciclib.
01 April 2020	Update of the Investigator Brochure (IB) for abemaciclib, the substantial modifications of which (recommendations for the management of elevated transaminases, etc.) have been integrated into the protocol (V8.1 of 12/31/2019) of amendment 5-MSA3, following the intermediate letter from the ANSM of December 13, 2019.
07 July 2020	Changes related to the pandemic (Covid-19): patient monitoring and dispensing procedures for abemaciclib in patients with controlled disease after 6 months of treatment and no major safety issues. In addition, the procedure for reporting any Covid-19 diagnosis, documented via a specific form, is specified. Changes to the provisional study schedule : Total study duration: previous version 42 months, 24-month extension Inclusion period: previous version 12 months, 24-month extension Treatment and follow-up period: unchanged
12 May 2021	Updated three eligibility criteria in line with the new recommendations issued by Lilly in January 2021; Updated recommendations to be followed by investigators in line with the new edition of the abemaciclib BI and the new recommendations issued by Lilly in January 2021 in the event of adverse events; Clarified concomitant treatments to be administered with caution.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported