Clinical trial results:
Molecular-biological tumor profiling for drug treatment selection in patients with advanced and refractory carcinoma

Summary

EudraCT number	2014-005341-44
Trial protocol	AT
Global end of trial date	08 June 2018

Results information

Result version number	v1 (current)
This version publication date	14 March 2020
First version publication date	14 March 2020

Trial information

Trial identification

Sponsor protocol code	ICT

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Medical University Graz
Sponsor organisation address	Auenbruggerplatz 2, Graz, Austria, 8036
Public contact	Koordinierungszentrum f. Kli. Stud., Medical University of Graz, +43 31638578017, astrid.friedel@medunigraz.at
Scientific contact	Koordinierungszentrum f. Kli. Stud., Medical University of Graz, +43 31638578017, astrid.friedel@medunigraz.at

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	26 July 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	08 June 2018
Global end of trial reached?	Yes
Global end of trial date	08 June 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This phase II study is designed to increase the PFS of an anti-tumor drug therapy based on a molecular-biologic tumor profile in patients with proven progressed carcinoma of different origin after all evidence-based therapies 1.2-fold to the PFS of the last evidence-based drug therapy. Furthermore, the number of patients in which an anti-tumor drug therapy based on a molecular-biologic tumor profile can be defined, overall survival (OS), overall response rate (ORR) and safety will be evaluated. PFS ratio (PFS on targeted drug therapy / PFS on last evidence-based drug therapy). The PFS of the last evidence-based therapy will be assessed by predefined specialist of the Division of Clinical Oncology of the Medical University of Graz who take part in the study at the time when a patient is included in the study.

Protection of trial subjects:

tracking Adverse
Events

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	04 May 2015
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	Austria: 8
Worldwide total number of subjects	8
EEA total number of subjects	8

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	2
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

recruitmenpthase 3.7.2015-9.3.2018, 24 patients, single site

Pre-assignment

Screening details:

24 patients screened,
one patient excluded during screeningphase because of death
one patient excluded during screeningphase because of non adequate liver function
14 because of no results of molecular profiling

Pre-assignment period milestones

Number of subjects started	24[1]
Number of subjects completed	8

Pre-assignment subject non-completion reasons

Reason: Number of subjects	inclusion exclusion criteria: 15
Reason: Number of subjects	death: 1

Notes:

[1] - The number of subjects reported to have started the pre-assignment period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: Enrollment starts after Screening (pre assignment)

Period 1

Period 1 title	treatment period
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	individual treatment

Arm description: -

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

Dosage and administration details:

individual treatment

Number of subjects in period 1	individual treatment
Started	8
Completed	8

Period 2	
Period 2 title	follow up
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms	
Arm title	after progression
Arm description: -	
Arm type	No intervention
No investigational medicinal product assigned in this arm	

Number of subjects in period 2	after progression
Started	8
Completed	8

Baseline characteristics

Reporting groups	
Reporting group title	treatment period

Reporting group description: -

Reporting group values	treatment period	Total	
Number of subjects	8	8	
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)	6	6	
From 65-84 years	2	2	
85 years and over	0	0	
Gender categorical Units: Subjects			
Female	5	5	
Male	3	3	

End points

End points reporting groups

Reporting group title	individual treatment
Reporting group description: -	
Reporting group title	after progression
Reporting group description: -	

Primary: Progression-free survival (PFS)

End point title	Progression-free survival (PFS)
End point description:	
End point type	Primary
End point timeframe: 12 month	

End point values	individual treatment	after progression		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	8		
Units: patients	8	8		

Statistical analyses

Statistical analysis title	individual treatment PFS ratio

Statistical analysis description:

The null hypothesis H0: p ≤ p0, that ≤10% of this patient population would have a PFS ratio of ≥ 1.2, will be tested using a one-sided binomial test (α=5%).

Comparison groups	individual treatment v after progression
Number of subjects included in analysis	16
Analysis specification	Pre-specified
Analysis type	other[1]
P-value	= 0.05 [2]
Method	one-sided binomial test

Notes:

[1] - The null hypothesis H0: p ≤ p0, that ≤10% of this patient population would have a PFS ratio of ≥ 1.2, will be tested using a one-sided binomial test (α=5%).

[2] - The null hypothesis H0: p ≤ p0, that ≤10% of this patient population would have a PFS ratio of ≥ 1.2, will be tested using a one-sided binomial test (α=5%).

Adverse events

Adverse events information[1]

Timeframe for reporting adverse events:

until 30 days after last study medication was taken

Adverse event reporting additional description:

Events not treated as AE/SAEs:
1) Death and Progression of underlying disease is not an SAE. Signs and symptoms of tumor progression may meet a criterion of a SAE and if so, should be reported as such.
2) Elective hospitalization for treatment of underlying disease or administration of study medication/procedures is not considered as AE/SAE.

Assessment type	Systematic

Dictionary used

Dictionary name	CTCAE
Dictionary version	4

Reporting groups

Reporting group title	individual treatment

Reporting group description: -

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: Frequency of non serious AE did not exceed 5% and are therefore not reported.

Serious adverse events	individual treatment		
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 8 (62.50%)		
number of deaths (all causes)	8		
number of deaths resulting from adverse events	0		
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	1 / 8 (12.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cholestasis			
subjects affected / exposed	1 / 8 (12.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Subileus			
subjects affected / exposed	2 / 8 (25.00%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			

Pain			
subjects affected / exposed	1 / 8 (12.50%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Infection			
subjects affected / exposed	2 / 8 (25.00%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	individual treatment		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 8 (0.00%)		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
22 January 2015	Change of PI
07 July 2015	Changes in safety or integrity of trial subjects Amendment to information in the CT application form Amendment to the protocol
06 July 2016	Amendment to the protocol Amendment to other documents appended to the initial application form specify: ICD and ICD Gentetic
08 May 2018	Amendment to information in the CT application form Amendment to the protocol

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported