

Clinical Development

EGF816 (Nazartinib)

CEGF816X2101 / NCT02108964

A Phase I/II, multicenter, open-label study of EGFRmut–TKI EGF816 administered orally in adult patients with EGFRmut solid malignancies

Statistical Analysis Plan (SAP) for close-out CSR

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16-May- 2023	Prior to DBL	Creation of final version	N/A - First version	NA

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1 Introduction

This statistical analysis plan (SAP) describes all planned analyses for the close-out clinical study report (CSR) of study CEGF816X2101, a phase I/II, multicenter, open-label study of EGFRmut-TKI EGF816 administered orally in adult patients with EGFRmut solid malignancies.

The close-out CSR will present the results of cumulative study data which are collected up to the LPLV date. The outputs planned for the close-out CSR will be a subset of the primary analysis outputs that need to be updated after the data cut-off date for the primary analysis. The list of outputs are specified in Section 2.

The statistical methods for the analyses in the final CSR, including data analysis general information, analysis of baseline characteristics, treatments and analysis supporting primary, secondary and exploratory objectives, will remain unchanged from that documented in the SAP for the primary analysis.

At the time of the finalization of the SAP, the following versions of study documents referred to are in place:

- [CEGF816X2101 SAP CSR 1 amendment3](dated 14-Jun-2018)
- [CEGF816X2101 TFL CSR addendum 1 0] (date 18-Oct-2018)

2 Planned tables, figures, and listings

The table below provides the list of outputs that need to be generated, with additional guidelines added under 'Programming notes'.

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1.3b preferred term and maximum grade - Phase II (Safety set) Serious adverse events by system organ class, preferred term and maximum grade - Phase II (Safety set) Table 14.3.1- 1.4a	Table 14.3.1-		Table 14.3.1-	•	
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Table 14.3.1- 1.4b organ class, preferred term and maximum grade - Phase II (Safety set) Table 14.3.1- Adverse events Table 14.3.1- Adverse events Table 14.3.1- Adverse events Adverse events					
Table 14.3.1- 1.4b preferred term and maximum grade - Phase II (Safety set) Table 14.3.1- Adverse events Table 14.3.1- Adverse events Adverse events Table 14.3.1- Adverse events		2 2			
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Table 14 3 1- Adverse events Table 14 3 1- Adverse events				(Safety set)	
Table 14 3 1		/		Adverse events	
L leading to Leading to treatment. L					
1.6a treatment 1.6a discontinuation, by		leading to		leading to treatment	

	T 10 10 10 10	1	1 1	
	discontinuation, by system organ class, preferred term and maximum grade - Phase I (Safety set)		system organ class, preferred term and maximum grade - Phase I (Safety set)	
Table 14.3.1- 1.6b	Adverse events leading to treatment discontinuation, by system organ class, preferred term and maximum grade - Phase II (Safety set)	Table 14.3.1- 1.6b	Adverse events leading to treatment discontinuation, by system organ class, preferred term and maximum grade - Phase II (Safety set)	
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Table 14.3.1- 1.10b	Overview of adverse events of special interest - Phase II (Safety set)	Table 14.3.1- 1.10b	Overview of adverse events of special interest - Phase II (Safety set)	
Table 14.3.1-1.17a	All deaths, by system organ class and preferred term - Phase I (Safety set)	Table 14.3.1- 1.17a	All deaths, by system organ class and preferred term - Phase I (Safety set)	
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Table 14.3.1-1.19	Non-serious adverse events (threshold = 5%) by system organ class and preferred term for all subjects (Safety set)	Table 14.3.1-1.19	Non-serious adverse events (threshold = 5%) by system organ class and preferred term for all subjects (Safety set)	
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		T	T =	
	Tumor assessments		Tumor assessments	
Listing 14.2-1.1b	and responses per	Listing 14.2-1.1b	and responses per	
	BIRC – Phase II		BIRC – Phase II Full	
	Full analysis set		analysis set	
	Progression-free		Progression-free	
Listing 14.2-1.2b	survival per BIRC	Listing 14.2-1.2b	survival per BIRC –	
21341119 1 112 1 12 1	– Phase II Full	2104119 1 1120	Phase II Full analysis	
	analysis set		set	
	Time to response		Time to response and	
	and duration of		duration of response	
Listing 14.2-1.3b	response per BIRC	Listing 14.2-1.3b	per BIRC – Phase II	
	– Phase II Full		Full analysis set	
	analysis set		,	
	Tumor assessments		Tumor assessments	
-	and response per		and response per	
Listing 14.2-2.1a	investigator	Listing 14.2-2.1a	investigator	
	assessment – Phase		assessment – Phase I	
	I Full analysis set		Full analysis set	
	Tumor assessments		Tumor assessments	
T: /: 140011	and response per	T: 4: 140011	and response per	
Listing 14.2-2.1b	investigator	Listing 14.2-2.1b	investigator	
	assessment – Phase		assessment – Phase II	
	II Full analysis set		Full analysis set	
	Progression-free		Progression-free	
T: /: 14000	survival per	1 14000	survival per	
Listing 14.2-2.2a	investigator	Listing 14.2-2.2a	investigator	
	assessment – Phase		assessment – Phase I	
	I Full analysis set		Full analysis set	
	Progression-free		Progression-free	
Listing 14 2 2 2h	survival per investigator	Listing 14.2.2.2h	survival per investigator	
Listing 14.2-2.2b	assessment – Phase	Listing 14.2-2.2b	assessment – Phase II	
	II Full analysis set		Full analysis set	
	Time to response		Tull allalysis set	
	and duration of		Time to response and	
	response per		duration of response	
Listing 14.2-2.3a	investigator	Listing 14.2-2.3a	per investigator	
	assessment – Phase		assessment – Phase I	
	I Full analysis set		Full analysis set	
	Time to response			
	and duration of		Time to response and	
	response per		duration of response	
Listing 14.2-2.3b	investigator	Listing 14.2-2.3b	per investigator	
	assessment – Phase		assessment – Phase II	
	II Full analysis set		Full analysis set	
T	Overall survival –	T1.1 11.0 0.1	Overall survival –	
Listing 14.2-2.6a	Phase I Safety set	Listing 14.2-2.6a	Phase I Safety set	
T 1 1 1 1 1 2 2 2 2	Overall survival –	T 11000	Overall survival –	
Listing 14.2-2.6b	Phase II Safety set	Listing 14.2-2.6b	Phase II Safety set	
Listing 14.3.2-	Deaths - Phase I	Listing 14.3.2-	Deaths - Phase I	
1.1a	(Safety set)	1.1a	(Safety set)	
Listing 14.3.2-	Deaths - Phase II	Listing 14.3.2-	Deaths - Phase II	
1.1b	(Safety set)	1.1b	(Safety set)	

	1	1		
Listing 14.3.2-	Serious adverse	Listing 14.3.2-	Serious adverse	
2.1a	events - Phase I	2.1a	events - Phase I	
2.1a	(Safety set)	2.1a	(Safety set)	
	Serious adverse		Serious adverse	
Listing 14.3.2-	events - Phase II	Listing 14.3.2-	events - Phase II	
2.1b	(Safety set)	2.1b	(Safety set)	
T 1 1 1 1 0 0	Serious adverse	T	Serious adverse	
Listing 14.3.2-	events with fatal	Listing 14.3.2-	events with fatal	
2.2a	outcome - Phase I	2.2a	outcome - Phase I	
	(Safety set)		(Safety set)	
	Serious adverse		Serious adverse	
Listing 14.3.2-	events with fatal	Listing 14.3.2-	events with fatal	
2.2b	outcome - Phase II	2.2b	outcome - Phase II	
	(Safety set)		(Safety set)	
	Adverse events		Adverse events	
Listing 14.3.2-	leading to	Listing 14.3.2-	leading to	
3.1a	discontinuation -	3.1a	discontinuation -	
3.14		3.1a		
	Phase I (Safety set)		Phase I (Safety set)	
	Adverse events		Adverse events	
Listing 14.3.2-	leading to	Listing 14.3.2-	leading to	
3.1b	discontinuation -	3.1b	discontinuation -	
3.10	Phase II (Safety	3.10		
	set)		Phase II (Safety set)	
	Adverse events		Adverse events	
	leading to dose		leading to dose	
Listing 14.3.2-	adjustment and/or	Listing 14.3.2-	adjustment and/or	
4.1a		4.1a	interruption - Phase I	
	interruption -			
	Phase I (Safety set)		(Safety set)	
	Adverse events		Adverse events	
	leading to dose		leading to dose	
Listing 14.3.2-	adjustment and/or	Listing 14.3.2-	adjustment and/or	
4.1b	interruption -	4.1b	interruption - Phase	
	Phase II (Safety			
	set)		II (Safety set)	
	Adverse events of		Adverse events of	
Listing 14.3.2-	special interest -	Listing 14.3.2-	special interest -	
5.1a	Phase I (Safety set)	5.1a	Phase I (Safety set)	
	` •		Thase I (Salety set)	
T '-4' 14 2 2	Adverse events of	T '-4' 14 2 2	Adverse events of	
Listing 14.3.2-	special interest -	Listing 14.3.2-	special interest -	
5.1b	Phase II (Safety	5.1b	Phase II (Safety set)	
	set)		` ' '	
Listing 16.2.1-	Subject disposition	Listing 16.2.1-	Subject disposition -	
_	- Phase I (Full	_	Phase I (Full analysis	
1.1a	analysis set)	1.1a	set)	
	Subject disposition		Subject disposition -	
Listing 16.2.1-	- Phase II (Full	Listing 16.2.1-	Phase II (Full	
1.1b	analysis set)	1.1b	analysis set)	
	Informed consent		Informed consent	
Listing 16.2.1-		Listing 16.2.1-		
1.3	(All screened	1.3	(All screened	
	subjects)		subjects)	
Listing 16.2.2-	Protocol deviations	Listing 16.2.2-	Protocol deviations -	
1.1a	- Phase I (Full		Phase I (Full analysis	
1.1a	analysis set)	1.1a	set)	
	. ,	1	/	

	T			
Listing 16.2.2- 1.1b	Protocol deviations - Phase II (Full	Listing 16.2.2- 1.1b	Protocol deviations - Phase II (Full	
Listing 16.2.4- 1.3a	analysis set) Relevant medical history and current medical conditions - Phase I (Full analysis set)	Listing 16.2.4- 1.3a	analysis set) Relevant medical history and current medical conditions - Phase I (Full analysis set)	
Listing 16.2.4- 1.3b	Relevant medical history and current medical conditions - Phase II (Full analysis set)	Listing 16.2.4- 1.3b	Relevant medical history and current medical conditions - Phase II (Full analysis set)	
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Listing 16.2.4- 1.7b	Antineoplastic therapies since discontinuation of study drug - Surgery - Phase II (Full analysis set)	Listing 16.2.4- 1.7b	Antineoplastic therapies since discontinuation of study drug - Surgery - Phase II (Full analysis set)	
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Listing 16.2.4- 1.8b	Antineoplastic therapies since discontinuation of study drug - Radiotherapy - Phase II (Full analysis set)	Listing 16.2.4- 1.8b	Antineoplastic therapies since discontinuation of study drug - Radiotherapy - Phase II (Full analysis set)	
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Listing 16.2.8- 1.5b	Biochemistry - liver - Phase II (Safety set)	Listing 16.2.8- 1.5b	Biochemistry - liver - Phase II (Safety set)	

Listing 16.2.8- 1.6a	Biochemistry - renal - Phase I (Safety set)	Listing 16.2.8- 1.6a	Biochemistry - renal - Phase I (Safety set)	
Listing 16.2.8- 1.6b	Biochemistry - renal - Phase II (Safety set)	Listing 16.2.8- 1.6b	Biochemistry - renal - Phase II (Safety set)	
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Listing 16.2.8- 1.9b	Urinary parameters: urinalysis (microscopic analysis) - Phase II (Safety set)	Listing 16.2.8- 1.9b	Urinary parameters: urinalysis (microscopic analysis) - Phase II (Safety set)	
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Listing 16.2.8- 1.10b	Subjects with worst post-baseline Total bilirubin > 2xULN and AT > 3xULN values - Phase II (Safety set)	Listing 16.2.8- 1.10b	Subjects with worst post-baseline Total bilirubin > 2xULN and AT > 3xULN values - Phase II (Safety set)	
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	Phase II (Safety set)		laboratory values - Phase II (Safety set)	
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Listing 16.2.9- 1.2b	Vital signs - Phase II Safety set	Listing 16.2.9- 1.2b	Vital signs - Phase II Safety set	
Listing 16.2.9- 2.1a	Notable ECG values - Phase I Safety set	Listing 16.2.9- 2.1a	Notable ECG values - Phase I Safety set	
Listing 16.2.9- 2.1b	Notable ECG values - Phase II Safety set	Listing 16.2.9- 2.1b	Notable ECG values - Phase II Safety set	
Listing 16.2.9- 2.2a	ECG values - Phase I Safety set	Listing 16.2.9- 2.2a	ECG values - Phase I Safety set	
Listing 16.2.9- 2.2b	ECG values - Phase II Safety set	Listing 16.2.9- 2.2b	ECG values - Phase II Safety set	
Listing 16.2.9- 3.1a	Pregnancy test results - Phase I Safety set	Listing 16.2.9- 3.1a	Pregnancy test results - Phase I Safety set	
Listing 16.2.9- 3.1b	Pregnancy test results - Phase II Safety set	Listing 16.2.9- 3.1b	Pregnancy test results - Phase II Safety set	
Listing 16.2.9-5.1a	Hepatitis screen and monitoring - Phase I Safety set	Listing 16.2.9- 5.1a	Hepatitis screen and monitoring - Phase I Safety set	Please change column title "Hepatitis screen" to "Hepatitis assessment"
Listing 16.2.9- 5.1b	Hepatitis screen and monitoring - Phase II Safety set	Listing 16.2.9- 5.1b	Hepatitis screen and monitoring - Phase II Safety set	