NOVARTIS

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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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)	
Listing 16.2.8-1.11a	Subject laboratory profile of hepatic laboratory values - Phase I (Safety set)	Listing 16.2.8-1.11a	Subject laboratory profile of hepatic laboratory values - Phase I (Safety set)	
Listing 16.2.8-1.11b	Subject laboratory profile of hepatic laboratory values -	Listing 16.2.8-1.11b	Subject laboratory profile of hepatic	

	Phase II (Safety set)		laboratory values - Phase II (Safety set)	
Listing 16.2.9-1.1a	Notable vital sign values - Phase I Safety set	Listing 16.2.9-1.1a	Notable vital sign values - Phase I Safety set	
Listing 16.2.9-1.1b	Notable vital sign values - Phase II Safety set	Listing 16.2.9-1.1b	Notable vital sign values - Phase II Safety set	
Listing 16.2.9-1.2a	Vital signs - Phase I Safety set	Listing 16.2.9-1.2a	Vital signs - Phase I Safety set	
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	