Rollover Study for Patients With Sickle Cell Disease Who Have Completed a Prior Novartis-Sponsored Crizanlizumab Study

22/11/2024 05:03:20

Main Information

Primary registry identifying number
LBCTR2021104867

Protocol number
CSEG101A2401B

MOH registration number

Study registered at the country of origin
Yes

Study registered at the country of origin: Specify

Type of registration
Prospective

Type of registration: Justify
N/A

Date of registration in national regulatory agency

Primary sponsor
Novartis Pharmaceuticals

Primary sponsor: Country of origin
Novartis Pharmaceuticals

Date of registration in primary registry
16/05/2023

Date of registration in national regulatory agency

Public title
Rollover Study for Patients With Sickle Cell Disease Who Have Completed a Prior Novartis-Sponsored Crizanlizumab Study

Acronym

Scientific title
An Open-label, Multi-center, Phase IV, Rollover Study for Patients With Sickle Cell Disease Who Have Completed a Prior Novartis-Sponsored Crizanlizumab Study

Acronym

Brief summary of the study: English
This is a multi-center multi-national rollover study to allow continued access to crizanlizumab for patients with sickle cell disease (SCD) who are on crizanlizumab treatment in a Novartis-sponsored study (parent study) and are benefiting from the treatment as judged by the investigator.

Brief summary of the study: Arabic
دراسة تمديد مفتوحة التسمية، متعددة المراكز، في المرحلة الرابعة لمرضى مصابين بداء الكريات المنجليّة أنجزوا دراسة سابقة حول كريزانليزوماب برعاية نوفارتيس

Health conditions/problem studied: Specify
Sickle Cell Disease

Interventions: Specify
Drug: Crizanlizumab
Concentrate for solution for infusion for Intravenous use
Other Name: SEG101

Key inclusion and exclusion criteria: Inclusion criteria
Inclusion criteria:
1.Written informed consent/assent, according to local guidelines, signed by the adult patients. In the population under 18 years, it will be signed by the patient and/or by the parents or legal guardian prior to enrolling in the rollover study and receiving study medication

2.SCD patient currently enrolled in a Novartis-sponsored study receiving crizanlizumab and has fulfilled all the requirements in the parent study. Patient is currently benefiting from the treatment with crizanlizumab as determined by the investigator and has completed the treatment schedule as planned in the parent study
3.Patient has demonstrated compliance to the planned visit schedule in the parent study, and in the opinion of the investigator has shown willingness and ability to comply with future visit schedules

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

6

Key inclusion and exclusion criteria: Age maximum

99

Key inclusion and exclusion criteria: Exclusion criteria

1.Patient had permanently discontinued from crizanlizumab study treatment in the parent study before the parent study completion
2.Ongoing/unresolved treatment-related Grade 3 or higher AEs, and/or any ongoing AE requiring dose interruption. Patients meeting all other eligibility criteria may be enrolled once toxicities have resolved unless those toxicities were grade 4
3.Concurrent participation in any other investigational clinical trial other than the parent study or plan to participate in any other investigational clinical trial
4.Pregnant or nursing women
5.Women of childbearing potential who are unwilling to be on highly effective contraceptives during dosing and until 15 weeks after stopping treatment with crizanlizumab
6.SCD patients who do not meet parent study protocol criteria to continue with crizanlizumab

Type of study

Interventional

Type of intervention

Pharmaceutical

Type of intervention: Specify type

N/A

Trial scope

Therapy

Trial scope: Specify scope

N/A

Study design: Allocation

Single Arm Study

Study design: Masking

Open (masking not used)

Study design: Control

N/A

Study phase

4

Study design: Purpose

Treatment

Study design: Specify purpose

N/A

Study design: Assignment

Single

Study design: Specify assignment

N/A

IMP has market authorization

Yes, Lebanon and Worldwide

IMP has market authorization: Specify

Albania,Australia,Austria,Bahrain,Belgium,Brazil,Bulgaria, Lebanon,United Arab Emirates, United Kingdom, United States,South Africa,Norway, Oman, Qatar, Romania Denmark, Germany, Greece,Italy,France.

Name of IMP

Crizanlizumab

Year of authorization

2020

Month of authorization

12

Type of IMP

Others

Pharmaceutical class

anti-P-selectin

Therapeutic indication

Sickle Cell Disease

Therapeutic benefit

Not Applicable as this protocol is to provide an option for continued access to crizanlizumab for patients with Sickle Cell Disease who have completed a prior Novartis-sponsored Crizanlizumab study

Study model

N/A

Study model: Explain model

N/A

Study model: Specify model

N/A

Time perspective

N/A

Time perspective: Explain time perspective

N/A

Time perspective: Specify perspective

N/A

Target follow-up duration

Target follow-up duration: Unit

Number of groups/cohorts

Biospecimen retention

None retained

Biospecimen description

N/A

Target sample size

10

Actual enrollment target size

5

Date of first enrollment: Type

Actual

Date of first enrollment: Date

29/12/2021

Date of study closure: Type

Actual

Date of study closure: Date

17/01/2029

Recruitment status

Recruiting

Recruitment status: Specify

Date of completion

31/03/2023

IPD sharing statement plan

Yes

IPD sharing statement description

Novartis is committed to sharing with qualified external researchers, access to patient-level data and supporting clinical documents from eligible studies. These requests are reviewed and approved by an independent expert panel on the basis of scientific merit. All data provided is anonymized to respect the privacy of patients who have participated in the trial in line with applicable laws and regulations.

This trial data is currently available according to the process described on www.clinicalstudydatarequest.com.

Additional data URL

https://clinicaltrials.gov/ct2/show/record/NCT04657822?term=CSEG101A2401B&draw=2&rank=1

Admin comments

Trial status

Approved

Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
Clinicaltrials.gov	NCT04657822

Sources of Monetary or Material Support

Name
Novartis pharma services Inc.

Secondary Sponsors

Name
N/A

Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Adlette Inati	Tripoli	Lebanon	961 (0) 3 228 033	adlette.inati@lau.edu.lb	Nini Hospital
Scientific	Hind Khairallah	KFF Healthcare - Khalil Fattal et fils	Lebanon	+961 1512002 #271	Hind.Khairallah@fattal.com.lb	Khalil Fattal et Fils Sal
Public	Miguel Abboud	Beirut	Lebanon	9613534213	ma56@aub.edu.lb	American University of Beirut Medical Center

Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
Nini Hospital	Adlette Inati	Pediatric Hematology	Approved
American University of Beirut Medical Center	Miguel Abboud	Pediatric Hematology	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Nini Hospital	08/10/2021	Nabil Kabbara	Nabil.kabbara@hopitalnini.com	+961 (0) 6 431 400 ext 1062
American University of Beirut Medical Center	14/12/2021	Fuad Ziyadeh	fz05@aub.edu.lb	961 (0) 1 350 000 ext:5445

Countries of Recruitment

Name
Lebanon
Belgium

Health Conditions or Problems Studied

Condition	Code	Keyword
sickle cell disease	Sickle-cell disorders (D57)	SCD

Interventions

Intervention	Description	Keyword
Consenting, IMP administration	Consenting, IMP administration	Consenting, IMP administration

Primary Outcomes

Name	Time Points	Measure
Not Applicable as this protocol is to provide an option for continued access to crizanlizumab for patients with Sickle Cell Disease who have completed a prior Novartis-sponsored Crizanlizumab study	Not Applicable - Study Completion	Not Applicable - Study Completion

Key Secondary Outcomes

Name	Time Points	Measure
Number of participants with treatment emergent adverse events	from day of first dose of study medication to 105 days after last dose of study medication	from day of first dose of study medication to 105 days after last dose of study medication

Trial Results

Summary results

Study results globally

Date of posting of results summaries

Date of first journal publication of results

Results URL link

Baseline characteristics

Participant flow

Adverse events

Outcome measures

URL to protocol files