Rollover An Open Label, Multi-center, Phase IV Rollover Protocol for Patients Who Have Completed a Global Novartis or Incyte Sponsored Ruxolitinib (INC424) or Ruxolitinib and Panobinostat (LBH589) Combination Study and Are Judged by the Investigator to Benefit From Continued Treatment

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Main Information

Primary registry identifying number
LBCTR2020011380

Protocol number
CINC424A2X01B

MOH registration number
10517/ص

Study registered at the country of origin
Yes

Study registered at the country of origin: Specify

Type of registration
Retrospective

Type of registration: Justify
This trial was previously submitted prior to LBCTR

Date of registration in national regulatory agency
19/11/2015

Primary sponsor
Novartis Pharmaceuticals

Primary sponsor: Country of origin
Novartis Pharmaceuticals

Date of registration in primary registry
15/12/2020

Date of registration in national regulatory agency
19/11/2015

Public title
Rollover An Open Label, Multi-center, Phase IV Rollover Protocol for Patients Who Have Completed a Global Novartis or Incyte Sponsored Ruxolitinib (INC424) or Ruxolitinib and Panobinostat (LBH589) Combination Study and Are Judged by the Investigator to Benefit From Continued Treatment

Acronym

Scientific title
An open label, multi-center, Phase IV roll-over protocol for patients who have completed a prior global Novartis or Incyte sponsored ruxolitinib (INC424) study and are judged by the investigator to benefit from continued treatment

Acronym

Brief summary of the study: English

This roll-over protocol allows patients who are still receiving clinical benefit to continue to be treated from multiple protocols in one program spanning multiple indications during the completion of the parent study/(ies). The population for the roll-over study should be consistent with the population defined in the program parent study/(ies). The primary eligibility criteria for a patient to enter the roll-over protocol is the participation and completion of a Novartis GDD&GMA/Incyte study with ruxolitinib monotherapy or combination of ruxolitinib and panobinostat. Efficacy parameters would not be measured; however safety data and an evaluation of clinical benefit will be collected.

Patients who have completed a prior study with ruxolitinib monotherapy or combination of ruxolitinib and panobinostat and who are assessed by the Investigator to continue to benefit from ongoing treatment will be eligible.

Brief summary of the study: Arabic

بروتوكول ممدّد مفتوح اللصاقة، متعدد المراكز، في المرحلة الرابعة للمرضى الذين أتمّوا دراسة مسبقة شاملة برعاية نوفارتيس أو إنسايت حول ويستفيدون برأي الباحث من استمرار العلاج (INC424) روكسوليتينيب

Health conditions/problem studied: Specify

Splenomegaly

Interventions: Specify

INC424/ruxolitinib/Jakavi

Key inclusion and exclusion criteria: Inclusion criteria

Inclusion Criteria:
1.Patient is currently enrolled in a Novartis GDD or GMA-sponsored or Incyte-sponsored clinical study (where Incyte can delegate the sponsorship to a preferred CRO, if applicable) that is approved to enroll into this rollover study, is receiving either ruxolitinib or combination of ruxolitinib and panobinostat and fulfilled all of the requirements of the parent protocol.
2.Patient is currently benefiting from the treatment with ruxolitinib monotherapy or combination of ruxolitinib and panobinostat, as determined by the investigator
3.Patient has demonstrated compliance, as assessed by the investigator, with the parent study protocol requirements
4.Willingness and ability to comply with scheduled visits, treatment plans and any other study procedures
5.Patient currently has no evidence of progressive disease, as determined by the investigator, following previous treatment with ruxolitinib or combination of ruxolitinib and panobinostat
6.Written informed consent obtained prior to enrolling in roll-over study and receiving study medication. If consent cannot be expressed in writing, it must be formally documented and witnessed, ideally via an independent trusted witness.

Key inclusion and exclusion criteria: Gender

Both

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age minimum

18

Key inclusion and exclusion criteria: Age maximum

99

Key inclusion and exclusion criteria: Exclusion criteria

Exclusion Criteria:
1.Patient has been permanently discontinued from study treatment in the parent study due to any reason.
2.Patient's indication is currently approved and reimbursed in the local country
3.Patient has participated in a combination trial (other than the specified panobinostat and ruxolitinib combination trial) where ruxolitinib was dispensed in combination with another study medication and the patient is still receiving combination therapy.
4.Pregnant or nursing (lactating) women, where pregnancy is defined as the state of a female after conception and until termination of gestation, confirmed by a positive hCG lab test.
5.Women of child-bearing potential, unless they are using highly effective methods of contraception throughout the study duration inclusive of the 30-day safety follow up.
6.Female patients between ≥ 12 and < 18 years of age and of childbearing potential who do not agree to abstinence or, if sexually active, do not agree to the use of highly effective contraception as defined below, throughout the study and for up to 30 days after stopping treatment.

Type of study

Interventional

Type of intervention

Pharmaceutical

Type of intervention: Specify type

N/A

Trial scope

Trial scope: Specify scope

Therapy

N/A

Study design: Allocation
N/A: Single arm study

Study design: Masking
Open (masking not used)

Study design: Control
Active

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
countries worldwide

Name of IMP
Jakavi

Year of authorization
2015

Month of authorization
4

Type of IMP
Others

Pharmaceutical class
JAK inhibitor

Therapeutic indication
To evaluate clinical benefit as assessed by the investigator

Therapeutic benefit
To evaluate clinical benefit as assessed by the investigator

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

Not applicable

Target sample size
7

Actual enrollment target size
4

Date of first enrollment: Type
Actual

Date of first enrollment: Date
28/01/2016

Date of study closure: Type
Actual

Date of study closure: Date
22/10/2020

Recruitment status
Complete

Recruitment status: Specify
Completed for Lebanon, ongoing globally

Date of completion
11/02/2016

IPD sharing statement plan
No

IPD sharing statement description
Not provided

Additional data URL
https://clinicaltrials.gov/ct2/show/record/NCT02386800

Admin comments

Trial status
Approved

Secondary Identifying Numbers

Full name of issuing authority	Secondary identifying number
ClinicalTrials.gov	NCT02386800

Sources of Monetary or Material Support

Name
Novartis Pharmaceuticals

Secondary Sponsors

Name
NA

Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Ali Taher	Beirut	Lebanon	01350000 ext 7908	ataher@aub.edu.lb	American University of Beirut Medical Center
Scientific	Hind Kairallah	Sinelfil	Lebanon	+961 1 512002 Ext. 271	Hind.khairallah@fattal.com.lb	Khalil Fattal et Fils s.a.l.

Centers/Hospitals Involved in the Study

Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
American University of Beirut Medical Center	Prof. Ali Taher	Hematology Oncology	Approved

Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
American University of Beirut Medical Center	04/06/2015	Fuad Ziyadeh	fz05@aub.edu.lb	00961350000 ext 5445

Countries of Recruitment

Name
Lebanon
Australia
Belgium
Bulgaria
Chile
China
Germany
Greece
Hungary
Italy
Republic of Korea
Mexico
Portugal
Russian Federation
South Africa
Spain
Sweden
Thailand
Turkey

Health Conditions or Problems Studied

Condition	Code	Keyword
Splenomegaly	Splenomegaly, not elsewhere classified (R16.1)	Splenomegaly

Interventions

Intervention	Description	Keyword
ICF, Physical Examination, IMP administration	ICF, Physical Examination, IMP administration	ICF, Physical Examination, IMP administration

Primary Outcomes

Name	Time Points	Measure
Number of Participants with Adverse Events as a Measure of Safety and Tolerability [Time Frame: through study completion estimated to be approximately 10 years]	through study completion	Adverse Events

Key Secondary Outcomes

Name	Time Points	Measure
1.To evaluate clinical benefit as assessed by the investigator	approximately 10 years	clinical benefit as assessed by the investigator

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