



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: Country of origin

Primary sponsor

Novartis Pharmaceuticals

Novartis Pharmaceuticals

Date of registration in primary registry

07/01/2020

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 اللصاق، متعدد المراكز، في المرحلة الرابعة للمرضى الذين أتموا دراسة مسبقة شاملة برعاية نوفارتيس أو إنسايت حول ويستقيدون 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

31/01/2020

Recruitment status

Recruiting

Recruitment status: Specify

Completed for Lebanon, ongoing globally

Date of completion

09/02/2021

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 | Sinefil | Lebanon | +961 1 512002 Ext. 271 | Hind.khairallah@fattal.com.lb | Khail 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