



# 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 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  $\geq 12$  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	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**