REPUBLIC OF LEBANON Lebanon Clinical Trials Registry

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

24/08/2025 04:42:24

Main Information	
Primary registry identifying number	Protocol number
LBCTR2020011380	CINC424A2X01B
MOH registration number	
ص/10517	
Study registered at the country of origin	Study registered at the country of origin: Specify
Yes	
Type of registration	Type of registration: Justify
Retrospective	This trial was previously submitted prior to LBCTR
Date of registration in national regulatory agency 19/11/2015	
Primary sponsor	Primary sponsor: Country of origin
Novartis Pharmaceuticals	Novartis Pharmaceuticals
Date of registration in primary registry	Date of registration in national regulatory agency
15/12/2020	19/11/2015
Public title	Acronym
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	
Scientific title	Acronym
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	
Brief summary of the study: English	

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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 بر عاية نوفارتيس أو إنسايت حول ويستغيدون 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: Age minimum

18

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

Trial scope

Type of intervention: Specify type N/A

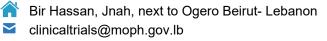
Trial scope: Specify scope

Key inclusion and exclusion criteria: Specify gender

Key inclusion and exclusion criteria: Age maximum

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Therapy	N/A	
Study design: Allocation	Study design: Masking	
N/A: Single arm study	Open (masking not used)	
Study design: Control	Study phase	
Active	4	
Study design: Purpose Treatment	Study design: Specify purpose	9
Study design: Assignment	Study design: Specify assignn	nent
Single		
IMP has market authorization Yes, Lebanon and Worldwide	IMP has market authorization: countries worldwide	Specify
Name of IMP Jakavi	Year of authorization 2015	Month of authorization 4
	2010	-
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	Study model: Explain model	
N/A	N/A	
Study model: Specify model		
N/A		
Time perspective	Time perspective: Explain time	e perspective
N/A	N/A	
Time perspective: Specify perspective		
N/A		
Target follow-up duration	Target follow-up duration: Unit	t
		-
Number of groups/cohorts		
Biospecimen retention	Biospecimen description	
None retained		



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	Not applicable
Target sample size	Actual enrollment target size
7	4
Date of first enrollment: Type	Date of first enrollment: Date
Actual	28/01/2016
Date of study closure: Type	Date of study closure: Date
Actual	22/10/2020
Recruitment status	Recruitment status: Specify
Complete	Completed for Lebanon, ongoing globally
Date of completion	
11/02/2016	
IPD sharing statement plan	IPD sharing statement description
No	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

Contac	ontact 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
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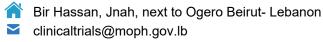
Centers/Hospitals Involved in the Study			
Center/Hospital name	Name of principles investigator	Principles investigator speciality	Ethical approval
American University of Beirut Medical Center	Prof. Ali Taher	Hematology Oncology	Approved

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