



# Open-label, Multicenter, Single Arm, Phase II Study Assessing Treatment Patient Preference for New Deferasirox Formulation (Film-coated Tablet) Compared to the Reference Deferasirox Dispersible Tablet Formulation

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## Main Information

### Primary registry identifying number

LBCTR2019020189

### Protocol number

CICL670FIC05

### MOH registration number

29858/2018

### Study registered at the country of origin

Yes

### Study registered at the country of origin: Specify

### Type of registration

Retrospective

### Type of registration: Justify

LCTR was already initiated, original file was previously submitted by paper

### Date of registration in national regulatory agency

13/07/2018

### Primary sponsor

Novartis Pharma Services Inc.

### Primary sponsor: Country of origin

Novartis Pharmaceuticals

### Date of registration in primary registry

04/01/2021

### Date of registration in national regulatory agency

13/07/2018

### Public title

Open-label, Multicenter, Single Arm, Phase II Study Assessing Treatment Patient Preference for New Deferasirox Formulation (Film-coated Tablet) Compared to the Reference Deferasirox Dispersible Tablet Formulation

### Acronym

JUPITER

### Scientific title

Open-label, Multicenter, Single Arm, Phase II Study Assessing Treatment Patient Preference for New Deferasirox Formulation (Film-coated Tablet) Compared to the Reference Deferasirox Dispersible Tablet Formulation

### Acronym

### Brief summary of the study: English

Study to evaluate patient preference of deferasirox FCT or deferasirox DT in patient with transfusion - dependent thalassemia or non-transfusion -dependent thalassemia as measured by preference questionnaire at Week 48

### Brief summary of the study: Arabic

دراسة مفتوحة اللصاق، متعددة المراكز، وحيدة المجموعة، في المرحلة الثانية لتقييم الأفضلية العلاجية للمريض لصيغة ديفيرازيروكس الجديدة (قرص مغلف بطبقة رقيقة) مقارنة بصيغة ديفيرازيروكس المرجعية من قرص قابل للتفتت

### Health conditions/problem studied: Specify

- Transfusion-dependent Thalassemia
- Non-transfusion-dependent Thalassemia

### Interventions: Specify

Deferasirox (Tablet & Dispersible)



**Key inclusion and exclusion criteria: Inclusion criteria**

1. Prior to any screening procedures are performed, written informed consent/assent must be provided.
2. Male and female patient aged  $\geq 2$  years
3. Exjade naïve patient or chelated naïve patient or treated by other chelators for at least 6 months, such as: a. Deferiprone/ DFP b. Deferoxamine /DFO c. Combination (DFO + DFP)
4. Subject is willing to discontinue current iron chelation therapy at least 7 days prior to the first day and for the duration of the study
5. Patients with transfusion-dependent thalassemia (independent of underlying condition) with transfusional iron overload as shown by: -a serum ferritin level of  $> 1000$  ng/ml at screening and if available, LIC  $> 3$  mg Fe/g dw until 6 months prior to screening
6. Patients with non-transfusion-dependent thalassemia with iron overload as shown by: -a serum ferritin level of  $\geq 800$  ng/ml at screening and if available, LIC  $\geq 5$  mg Fe/g dw until 6 months prior to screening

**Key inclusion and exclusion criteria: Gender**

Both

**Key inclusion and exclusion criteria: Specify gender****Key inclusion and exclusion criteria: Age minimum**

2

**Key inclusion and exclusion criteria: Age maximum**

99

**Key inclusion and exclusion criteria: Exclusion criteria**

1. Male and female patient aged  $< 2$  years
2. Written consent/assent from patients/parents/legal representative is not obtained
3. Creatinine clearance below the contraindication limit in the locally approved prescribing information.
4. Serum creatinine level  $> 1.5 \times$  ULN (upper limit of normal)
5. AST (SGOT) /ALT (SGPT)  $> 5 \times$  ULN, unless if LIC confirmed as  $< 10$  mg Fe/dw within 6 months prior to screening visit.
6. Significant proteinuria as indicated by a urinary protein/creatinine ratio  $> 0.5$  mg/mg in a non-first void urine sample.
7. Patients with significant impaired gastrointestinal (GI) function or GI disease that may significantly alter the absorption of oral deferasirox (e.g. ulcerative diseases, uncontrolled nausea, vomiting, diarrhea, malabsorption syndrome, or small bowel resection).
8. Clinical or laboratory evidence of active Hepatitis B or Hepatitis C (HBsAg in the absence of HBsAb OR HCV Ab positive with HCV RNA positive).
9. Patients with psychiatric or addictive disorders which prevent them from giving their informed consent or undergoing any of the treatment options or patients unwilling or unable to comply with the protocol (including use of electronic devices for ePRO).
10. Patients with a known history of HIV seropositivity (Elisa or Western blot).
11. History of malignancy of any organ system, treated or untreated, within the past 5 years whether or not there is evidence of local recurrence or metastases, with the exception of localized basal cell carcinoma of the skin.
12. Patients participating in another clinical trial or receiving an investigational drug.
13. History of hypersensitivity to any of the study drug or excipients.
14. Significant medical condition interfering with the ability to partake in this study (e.g. systemic uncontrolled hypertension, unstable cardiac disease not controlled by standard medical therapy, systemic disease (cardiovascular, renal, hepatic, etc.).
15. Women of child-bearing potential, defined as all women physiologically capable of becoming pregnant, unless they are using effective methods of contraception during dosing of study treatment
16. Women are considered post-menopausal and not of child bearing potential if they have had 12 months of natural (spontaneous) amenorrhea with an appropriate clinical profile (e.g. age appropriate, history of vasomotor symptoms) or have had surgical bilateral oophorectomy (with or without hysterectomy) or tubal ligation at least six weeks ago. In the case of oophorectomy alone, only when the reproductive status of the woman has been confirmed by follow up hormone level assessment is she considered not of child bearing potential.
17. Sexually active males unless they use a condom during intercourse while taking drug and for 28 days after stopping study medication and should not father a child in this period. A condom is required to be used also by vasectomized men in order to prevent delivery of the drug via seminal fluid.

**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**

N/A: Single arm study

**Study design: Masking**

Open (masking not used)

**Study design: Control**

Active

**Study phase**

2

**Study design: Purpose**

Treatment

**Study design: Specify purpose**

N/A

## Study design: Assignment

Other

## IMP has market authorization

Yes, Worldwide

## Name of IMP

Deferasirox (ICL670)

## Type of IMP

Others

## Pharmaceutical class

Non-chiral, Tridentate ligand iron chelator

## Therapeutic indication

Male or female with transfusion-dependent thalassemia or non-transfusion-dependent thalassemia requiring chelation therapy due to iron overload will be included in this study.

## Therapeutic benefit

Symptomatic treatment of Thalassemia

## Study model

N/A

## Study model: Specify model

N/A

## Time perspective

N/A

## Time perspective: Specify perspective

N/A

## Target follow-up duration

## Number of groups/cohorts

## Biospecimen retention

None retained

## Target sample size

10

## Study design: Specify assignment

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## IMP has market authorization: Specify

Albania, Argentina, Canada, United states, United Arab Emirates, Ukraine, Turkey, Switzerland, Saudi Arabia, Oman, Mexico , Malasia

## Year of authorization

2017

## Month of authorization

10

## Study model: Explain model

N/A

## Time perspective: Explain time perspective

N/A

## Target follow-up duration: Unit

## Biospecimen description

Local lab samples are done at local lab, no samples are retained or shipped outside Lebanon.

## Actual enrollment target size

5

<b>Date of first enrollment: Type</b> Actual	<b>Date of first enrollment: Date</b> 18/10/2018
<b>Date of study closure: Type</b> Actual	<b>Date of study closure: Date</b> 30/06/2021
<b>Recruitment status</b> Complete	<b>Recruitment status: Specify</b>
<b>Date of completion</b> 28/02/2019	
<b>IPD sharing statement plan</b> Yes	<b>IPD sharing statement description</b> There is a plan to share IPD , however not mentioned yet on clinical trials.gov
<b>Additional data URL</b> <a href="https://clinicaltrials.gov/ct2/show/record/NCT02993224?id=CICL670FIC05&amp;rank=1">https://clinicaltrials.gov/ct2/show/record/NCT02993224?id=CICL670FIC05&amp;rank=1</a>	
<b>Admin comments</b>	
<b>Trial status</b> Approved	

Secondary Identifying Numbers	
Full name of issuing authority	Secondary identifying number
National Institute of Health (clinicaltrials.gov)	NCT02993224

Sources of Monetary or Material Support
Name
Novartis Pharma Services Inc.

Secondary Sponsors
Name
NA



## Contact for Public/Scientific Queries

Contact type	Contact full name	Address	Country	Telephone	Email	Affiliation
Public	Ali Taher	Baabda	Lebanon	009613755 669	ataher@aub.edu.lb	Chronic Care Center
Scientific	Hind Khairallah	Beirut	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
Chronic Care Center	Dr Ali Taher	Hematology	Approved

## Ethics Review

Ethics approval obtained	Approval date	Contact name	Contact email	Contact phone
Chronic Care Center	15/05/2018	Michele Abi saad	cccmass@chroniccare.org.lb	+961 3 664 310
American University of Beirut Medical Center	07/11/2017	Fuad Ziyadeh	fz05@aub.edu.lb	+9611350000#5445

## Countries of Recruitment

Name
Egypt
Lebanon
Saudi Arabia
Thailand
Turkey
Viet Nam
Algeria
Morocco



## Health Conditions or Problems Studied

Condition	Code	Keyword
Thalassemia	Thalassaemia, unspecified (D56.9)	Thalassemia

## Interventions

Intervention	Description	Keyword
Audiometry, ECG, Chest X ray, Lab test	Audiometry, ECG, Chest X ray, Lab test	ICF, Lab, Audiometry, IMP administration

## Primary Outcomes

Name	Time Points	Measure
Percentage of patient preference for deferasirox FCT vs deferasirox DT	Week 48	week 48

## Key Secondary Outcomes

Name	Time Points	Measure
Percentage of patient preference for deferasirox FCT vs deferasirox DT vs previous previous iron chelation	Week 28	Week 28
Percentage of patient preference for deferasirox DT vs previous iron chelation	Week 4 and week 24	Week 4 and week 24
Percentage of reasons for preference of deferasirox FCT vs. deferasirox DT	Week 28 and week 48	Week 28 and week 48
Pill counts to assess drug compliance for deferasirox DT vs FCT	Baseline to wk 24, wk 25 to wk 48	Baseline to wk 24, wk 25 to wk 48



## 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