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Phase I study of S 78454 in the treatment of patients with acute myeloid leukemia, acute lymphoblastic leukemia or myelodysplastic syndrome

Submission date
04/10/2013

Recruitment status
No longer recruiting

Registration date
09/12/2013

Overall study status
Completed

Last Edited
22/01/2019

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration and not expected to be available in the future

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
CL1-78454-007

Study information

Scientific Title

Phase I dose escalation study of oral administration of S 78454 given as monotherapy in the treatment of patients with refractory or relapsed acute myeloid leukemia, acute lymphoblastic leukemia or high or intermediary-2 risk myelodysplastic syndrome

Study objectives
To establish the safety profile and the recommended Phase II dose of S 78454.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval was obtained before recruitment of the first participants

Study design
National multicentric dose escalation open Phase I study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Acute myeloid leukemia, acute lymphoblastic leukemia or myelodysplastic syndrome.

Interventions
Capsules containing 20 mg and 100 mg of S 78454 / Oral use / Treatment duration is at the discretion of the investigator

Intervention Type
Drug

Phase
Phase I

Drug/device/biological/vaccine name(s)
S 78454

Primary outcome(s)
1. DLTs and MTDs at the end of cycle 1 - methods used: blood samples, physical examination, bone marrow samples, ECG
2. Safety profile at each visit

Key secondary outcome(s))
1. Pharmacokinetic and pharmacodynamic evaluations on cycle 1 and cycle 2 by blood sample
2. Response evaluation during the study by blood samples and bone marrow samples

Completion date
30/09/2015

Eligibility

Key inclusion criteria
1. Male or female patient aged > or equal to 18
2. Ability to swallow oral capsule(s)
3. Estimated life expectancy > 8 weeks
4. ECOG performance status < or equal to 2
5. Adequate renal and hepatic functions
6. Left ventricular ejection fraction within normal limits
7. Patients with AML as defined by WHO 2008 classification, excluding acute promyelocytic leukemia
8. Patients with high or intermediary risk (IPSS int-2) myelodysplastic syndrome (MDS) as defined by WHO 2008 classification and IPSS, who have failed hypomethylating therapy (5 azacytidine)
9. Patients with histologically or cytologically confirmed B-cell ALL as defined by WHO 2008 revised classification, excluding Philadelphia chromosome-positive (Ph+) ALL (or BCR-ABL+) and B-cell ALL 3 Burkitt like, who have failed conventional or investigational therapy

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Major surgery within previous 4 weeks
2. Diagnosis of acute promyelocytic leukemia, Philadelphia chromosomepositive (Ph+) ALL (or BCR-ABL+) or B-cell ALL 3 Burkitt like
3. Patients who have not recovered from toxicity of previous antileukaemic therapy, including grade < or equal to 1 non-haematologic toxicity
4. Any previous chemotherapy for AML within at least 2 weeks (or at least 5 half-life whichever is longer), except for hydroxyureas which must be stopped within 24 hours before starting the study drug)
5. Neutrophil growth factor stimulating agent (G-CSF) within previous one week
6. Last dose of biological therapy or immunotherapy agent (therapeutic or diagnostic) less than 7 days prior to the first study drug intake
7. Any concurrent treatment with anticoagulants (curative or preventive),
8. Any radiotherapy within previous 4 weeks (except for palliative radiotherapy at localised lesions)
9. Patients with history of allogeneic stem cell transplant of less than 6 months or with active graft versus host disease requiring immune suppressive therapy
10. Patients with active disseminated intravascular coagulation (DIC) (plasma fibrinogen <1 g/L)

11. Presence of heart disorders or clinically significant heart diseases
12. Pregnant or breastfeeding women, women of child-bearing potential without effective contraception

Date of first enrolment
15/07/2012

Date of final enrolment
17/10/2014

Locations

Countries of recruitment
France

Study participating centre
Institut Paoli Calmettes
Marseille CEDEX 9
France
13273

Sponsor information

Organisation
Pharmacyclics LLC (USA)

ROR
https://ror.org/03hm8w204

Funder(s)

Funder type
Industry

Funder Name
Pharmacyclics LLC (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/01/2013	22/01/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes