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Phase I study of S 78454 in combination with radiotherapy in patients with solid tumour

Submission date	Recruitment status	[_] Prospectively registered
08/07/2013	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/08/2013	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
22/02/2019	Cancer	

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
CL1-78454-004

Study information

Scientific Title
Phase I dose-escalation study of oral administration of the Pan-Histone Deacetylase (HDAC) inhibitor S 78454 in combination with standard hypofractionated radiotherapy in patients with advanced solid tumour

Study objectives

To establish the safety profile and the recommended Phase II dose of S 78454 in combination with radiotherapy

Ethics approval required
Old ethics approval format

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

Study design
International multicentric non-randomised open-label dose escalation Phase I study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Solid tumours

Interventions
Capsules containing 20 mg of S 78454 administered orally. Treatment duration is at the discretion of the investigator.

Intervention Type
Drug

Phase
Phase I

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

Primary outcome(s)
Dose-limiting toxicity (DLT) and maximum tolerated dose (MTD) at the end of cycle measured by adverse events monitoring

Key secondary outcome(s))
1. Safety profile at each visit measured by adverse events monitoring
2. Tumour response evaluation at baseline and at the final visit measured by imaging and blood tests
3. Tumour perfusion measurements only for schedule 1 using functional imaging
4. Exploration of changes in biological markers (optional part in schedule 1) using biopsies

Completion date
07/08/2015

Eligibility

Key inclusion criteria
1. Solid tumour, with measurable or evaluable disease, requiring a course of hypofractionated radiotherapy
2. Ability to swallow oral capsule(s) without difficulty
3. Eastern Cooperative Oncology Group (ECOG) performance status less than or equal to 2
4. Estimated life expectancy of more than 20 weeks
5. Adequate haematological, renal and hepatic functions

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Allogenic bone marrow transplant
2. Major surgery within previous 4 weeks
3. Chemotherapy within previous 3 weeks (6 weeks in case of nitrosoureas)
4. Previous radiotherapy on the same area
5. Cumulative radiation therapy involving more than 25% of the total bone marrow
6. Immunotherapy or hormonotherapy within previous 2 weeks, except stable luteinizing hormone-releasing hormone (LHRH) agonist therapy for prostate cancer, stable oral glucocorticoid and mineralocorticoid replacement for adrenal insufficiency, stable mitotane for adrenal carcinoma, or oral contraceptives
7. Concurrent therapeutic anticoagulation by Vitamin K antagonists
8. Patients treated by valproic acid
9. Risk factors for, or use of medications known to prolong QTc interval and that may be associated with Torsades de Pointes.

Date of first enrolment
02/09/2010

Date of final enrolment
04/02/2015

Locations

Countries of recruitment
France

Italy

Study participating centre

Institut de Cancérologie Gustave Roussy
Villejuif
France
94 805

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	24/12/2016		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes