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Global registry for long-term follow-up of patients participating in clinical trials with Posoleucel (ALVR105)

Submission date
08/06/2022

Recruitment status
Recruiting

Registration date
21/09/2022

Overall study status
Ongoing

Last Edited
03/11/2023

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Posoleucel (or ALVR105) is a research medicine that contains T-cells made from healthy human donors to defend patients against specific viruses. The purpose of this registry study is to follow up with children and adult patients who were enrolled in Posoleucel clinical trials, in order to obtain long-term safety, effectiveness, and healthcare utilization information after treatment with Posoleucel or placebo. Recording patient health information over time can help to supplement the original study results and improve the care of patients in the future.

Who can participate?
Patients who previously participated in an Allovir-sponsored PSL clinical trial,

What does the study involve?
Analysis of registry data.

What are the possible benefits and risks of participating?
No registry specific procedures will be performed, thus there are no increased risks related to participation other than potential loss of confidentiality. The Sponsor is dedicated to maintaining confidentiality and privacy of patients. The Investigator is responsible for maintaining confidentiality throughout the registry study.
All data used in the analysis and reporting of this evaluation will be without identifiable reference to the patient. The Sponsor, Institution and all Registry Personnel will comply with applicable data protection and privacy laws, including all applicable General Data Protection Requirements (GDPR).

Where is the study run from?
ICON Clinical Research Ltd (Poland)

When is the study starting and how long is it expected to run for?
June 2022 to October 2027

Who is funding the study?
AlloVir, Inc. (USA)

Who is the main contact?
Dr Renuka Palanicawandar, renuka.palanicawandar@nhs.net

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
2022-000763-45

IRAS number
1005578

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
P-105-401, IRAS 1005578, CPMS 51835

Study information

Scientific Title
Global registry for long-term follow-up of posoleucel

Study objectives
1. To evaluate the long-term safety of Posoleucel (PSL).
2. To evaluate the long-term effectiveness of PSL.
3. To evaluate rates of overall mortality and non-relapse mortality.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/08/2022, Yorkshire & The Humber - Sheffield Research Ethics Committee (HS Blood and Transplant Blood Donor Centre Holland Drive, Newcastle upon Tyne Tyne and Wear, NE2 4NQ, United Kingdom; +44 (0)207 104 8388; sheffield.rec@hra.nhs.uk), ref: 22/YH/0139

Study design
Observational registry study

Primary study design
Observational

Secondary study design
Longitudinal study

Study setting(s)
Hospital, Other

Study type(s)
Safety

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Adenovirus (AdV), BK virus (BKV), John Cunningham virus (JCV), human herpesvirus 6 (HHV- 6), Epstein-Barr virus (EBV), and cytomegalovirus (CMV) infections and/or disease in patients at high risk for these viruses following allogeneic hematopoietic cell transplant (HCT) or solid organ transplant (SOT).

Interventions
Participants will be enrolled at sites participating in Allovir-Sponsored PSL clinical trials (Protocol Number AVM-003-HC, Protocol Number P-105-202, Protocol Number P-105-303) and will be followed for 4 years following their first dose of PSL or placebo in the parent study. Registry data will be entered at enrolment and then at 1 year, 2 years, 3 years, and 4 years after the first dose of PSL or placebo.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Posoleucel

Primary outcome measure
Incidence of adverse drug reactions (ADRs) related to PSL at enrolment visit and follow up measured using patient records

Secondary outcome measures
Measured using patient records:
1. Incidence of clinical infection with viruses targeted by PSL at enrolment visit and follow up
2. Overall mortality at follow up
3. Non-relapse mortality (defined as death without recurrent or progressive disease after transplantation) at follow up

Overall study start date
01/06/2022

Completion date
18/10/2027

Eligibility

Key inclusion criteria
1. Participation in an Allovir-sponsored PSL clinical trial, regardless of treatment assignment (PSL or placebo) and completion status
(completion, early discontinuation).
2. Patient received at least one infusion of PSL or placebo.
3. Patient is willing and able to provide written informed consent to participate in the registry, or a parent or legal guardian is willing and able to provide written informed consent and the potential paediatric participant is able to provide assent in a manner approved by the Institutional Review Board/Independent Ethics Committee and local regulations.

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
500

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
10/01/2022

Date of final enrolment
01/10/2027

Locations

Countries of recruitment
Belgium

Canada

England

France

Italy

Korea, South

Spain

Sweden

Türkiye

United Kingdom

United States of America

Study participating centre
Bristol Haematology and Oncology Centre
22 Horfield Rd
Bristol
United Kingdom
BS2 8ED

Study participating centre
University College London Hospital
University College London Hospitals NHS Foundation Trust
Department of Womens Health
250 Euston Road
London

United Kingdom
NW1 2PG

Study participating centre
Queen Elizabeth University Hospital
1345 Govan Road
Glasgow
United Kingdom
G51 4TF

Study participating centre
Queen Elizabeth Hospital
Queen Elizabeth Medical Centre
Edgbaston
Birmingham
United Kingdom
B15 2TH

Study participating centre
St. Mary's Hospital
Imperial College Healthcare NHS Trust
Praed Street
London
United Kingdom
W2 1NY

Study participating centre
Royal Hospital for Sick Children (Glasgow)
1345 Govan Road
Glasgow
United Kingdom
G51 4TF

Study participating centre
Birmingham Childrens Hospital (ladywood)
Ladywood Middleway
Ladywood
Birmingham
United Kingdom
B16 8ET

Study participating centre
Kings College Hospital
King's College Hospital NHS Foundation Trust
Denmark Hill
London
United Kingdom
SE5 9RS

Study participating centre
Bristol Royal Hospital for Children
Paul O'Gorman Building
Upper Maudlin Street
St Michael's Hill
Bristol
United Kingdom
BS2 8BJ

Study participating centre
Sheffield Children's NHS Foundation Trust
Western Bank
Sheffield
United Kingdom
S10 2TH

Study participating centre
Royal Manchester Childrens Hospital
Hospital Road
Pendlebury
Swinton
Manchester
United Kingdom
M27 4HA

Study participating centre
Hammersmith Hospitals NHS Trust
Hammersmith Hospital
Du Cane Road
London
United Kingdom
W12 0HS

Study participating centre
Great Ormond Street Hospital for Children
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WC1N 3JH

Study participating centre
Nottingham University Hospitals NHS Trust - City Campus
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Nottingham
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Royal Marsden Hospital
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Sutton
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SM2 5PT

Study participating centre
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Sponsor information

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Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
AlloVir, Inc

Results and Publications

Publication and dissemination plan
Peer reviewed scientific journals
Internal report
Conference presentation
Publication on website
Other publication
Submission to regulatory authorities
Sharing of results will take place with other researchers. We want to maximise and respect the contributions of participants. Participants will also be able to contact their study doctor if wanting to learn about the results of the study.

Intention to publish date
18/10/2028

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No