ABOUT FELIX

WHO CAN TAKE PART?

SITE INFORMATION

For information on who to contact at each site, see clinicaltrials.gov, write to clinicaltrials@autolus.com or in the UK call +44 (0)203 911 4385 and in the US call xxx-xx-xxxx

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The following bullet points are a summary of the entry conditions for this trial. You may want to print this page to take to your doctor if you are unsure about any of these. They will be able to advise you.

Who can take part:

1. You have B-cell acute lymphoblastic leukaemia and your leukaemia has come back, or your treatment has stopped working (relapsed or refractory), in one of the following ways:

- your leukaemia has not gone away after 2 cycles of induction chemotherapy
- this is the first time your leukaemia has come back - if your leukaemia went away (into remission) 12 months ago or less
- you have had two or more different types of treatment (different lines of treatment) and your leukaemia has not gone away or it has come back
- you have had a stem cell transplant from a donor (allogeneic transplant) and your leukaemia did not go away, or it came back. You would need wait to have the CAR T-cells for at least 3 months after your transplant.
- you have Philadelphia chromosome positive ALL and you are unable to take a tyrosine kinase inhibitor (TKI) or a TKI is not a suitable treatment for you. If you have taken 2 different TKIs and these have not worked, you may be able to join the trial. Or if you have taken a newer 'second generation' TKI and this has not worked for you, you might be able to take part. Your doctor can explain more.

2. And you may be able to join this trial if all of the following apply:

- your B-cell leukaemia is showing CD-19 proteins on its surface (CD-19 positive) in your blood, bone marrow or cerebrospinal fluid (CSF) within 1 month of the trial team checking this study is suitable for you (screening). If you have had, or are having blinatumomab, your CD-19 test should happen after you have stopped the drug.
- you are well enough to carry out all your normal activities, apart from heavy physical work (ECOG performance status of 0 or 1)
- you have satisfactory blood test results
- your heart, kidneys, lungs and liver are working well
- you have good blood oxygen levels
- you are willing and able to use reliable contraception if you or your partner could become pregnant. Your doctor will explain more.
- you are at least 18 years old (there is no upper age limit).

The trial team will look at:

- the number of leukaemia cells left behind after treatment (minimal residual disease)
- the amount of leukaemia cells seen under the microscope from your bone marrow
- if you have any leukaemia outside of your blood and bone marrow, for example in your skin or liver. Doctors call this extramedullary disease. You might be able to take part if you have just one of these areas affected by leukaemia unless this is your central nervous system (brain or spinal cord).

*The phase 1b part of the trial has now closed.

Who can't take part:

#1. You cannot join this trial if any of these apply. You:

- have Burkitt's leukaemia/lymphoma
- have chronic myeloid leukaemia (CML) in lymphoid cell blast phase – (this can look like ALL)
- have had a central nervous system disorder which is causing symptoms such as epilepsy, muscle weakness, stroke, brain injury, or Parkinson's disease in the 3 months before you signed the consent form
- have leukaemia cells in your cerebrospinal fluid (at a level called CNS2 and CNS3) and this is causing you symptoms. If you have signed the consent form and you develop a certain amount of leukaemia in your CSF, or it is getting worse, you might not be able to take part at this time. Your doctor will tell you more.
- have an active or uncontrolled infection that is needing treatment that reaches your whole body
- have hepatitis B or active hepatitis C
- have HIV
- have HTLV-1, HTLV-2 or syphilis
- have acute graft versus host disease (GvHD). Or you have moderate to severe longer term (chronic) GvHD, and you have needed treatment to dampen your immune system including systemic steroids within the 4 weeks before signing the consent form. Your doctor can explain more about what GvHD is moderate or severe.
- have had treatment that targets CD-19 in the past, apart from blinatumomab. You might not be able to take part if you had bad side effects from blinatumomab that affected your nervous system (neurotoxicity). Your doctor can explain more.
- are pregnant or breastfeeding
- have had a live vaccine in the 4 weeks before your cells are collected to make Obe-cel

#2. You <u>might not</u> be able to take part if you have had other leukaemia treatments recently. Your doctor can explain more about the gaps in treatment needed to join this trial. The treatments include:

- steroids
- immunosuppression
- cells from a donor, such as donor lymphocyte infusions
- drugs used for GvHD
- chemotherapy and TKI's
- some monoclonal antibodies such as alemtuzumab (Campath)

United States, California

City of Hope National Medical Center
Duarte, California, United States, 93534

University of California San Diego Health (UCSD)
La Jolla, California, United States, 92093

University of California Davis (UC Davis)
Sacramento, California, United States, 95817

University of California San Francisco (UCSF)
San Francisco, California, United States, 94143

United States, Colorado

Colorado Blood Cancer Institute (CBCI)
Denver, Colorado, United States, 80218

United States, Florida

University of Miami
Miami, Florida, United States, 33136

H Lee Moffitt Cancer Center
Tampa, Florida, United States, 33612

United States, Georgia

Winship Cancer Institute of Emory University
Atlanta, Georgia, United States, 30322

United States, Illinois

University of Chicago
Chicago, Illinois, United States, 60637

United States, Kansas

University of Kansas
Kansas City, Kansas, United States, 66160

United States, Maryland

University of Maryland Medical Center
Baltimore, Maryland, United States, 21201

United States, Massachusetts

Massachusetts General Hospital
Boston, Massachusetts, United States, 02114

Dana-Farber Cancer Institute
Boston, Massachusetts, United States, 02115

United States, Minnesota

Mayo Clinic
Rochester, Minnesota, United States, 55905

United States, Missouri

Washington University School of Medicine
Saint Louis, Missouri, United States, 63110

United States, Nebraska

University of Nebraska
Omaha, Nebraska, United States, 68105

United States, New York

Memorial Sloan Kettering Cancer Center
New York, New York, United States, 10065

University of Rochester
Rochester, New York, United States, 14642

United States, Ohio

Cleveland Clinic
Cleveland, Ohio, United States, 44195

United States, Tennessee

TriStar Centennial Medical Center (SCRI)
Nashville, Tennessee, United States, 37203

United States, Texas

Baylor Scott & White Research Institute
Dallas, Texas, United States, 75246

MD Anderson Cancer Center
Houston, Texas, United States, 77030

TTI-Methodist (Texas Transplant Institute) (SCRI)
San Antonio, Texas, United States, 78229

United States, Wisconsin

The Medical College of Wisconsin
Milwaukee, Wisconsin, United States, 53226

Spain

Fundacio' Hospital Universitari Vall d'Hebron
Barcelona, Spain, 08035

Hospital Universitario Virgen del Rocío
Sevilla, Spain, 41013

Hospital Universitario La Fé
Valencia, Spain, 46026

United Kingdom

Cambridge University Hospitals NHS Foundation Trust
Cambridge, Cambridgeshire, United Kingdom, CB2 0QQ

University College London Hospitals NHS Foundation Trust
London, Greater London, United Kingdom, NW1 2PG

King's College Hospital
London, Greater London, United Kingdom, SE5 9RS

Manchester Royal Infirmary Hospital
Manchester, Greater Manchester, United Kingdom, M13 9WL

Queen Elizabeth University Hospital
Glasgow, Scotland, United Kingdom, G514TF

Freeman Hospital, The Newcastle upon Tyne Hospitals NHS Foundation Trust
Newcastle upon Tyne, Tyne And Wear, United Kingdom, NE7 7DN

University Hospitals Birmingham NHS Foundation Trust
Birmingham, West Midlands, United Kingdom, B15 2GW

University Hospitals Bristol and Weston NHS Foundation Trust (UHBW)
Bristol, United Kingdom, BS2 8ED