



Long-Term Follow-up Protocol for Participants Treated With Gene-Modified T Cells

CLINICALTRIALS.GOV IDENTIFIER
NCT03435796

RECRUITMENT STATUS
RECRUITING

FIRST POSTED
FEBRUARY 19, 2018

LAST UPDATE POSTED
AUGUST 2, 2022

STUDY DESCRIPTION

Brief Summary

This is a prospective study for the long-term follow-up (LTFU) of safety and efficacy for all pediatric and adult participants exposed to Gene-modified (GM) T cell therapy participating in a previous Celgene sponsored or Celgene alliance partner sponsored study. Participants who received at least one GM T cell infusion will be asked to enroll in this LTFU protocol upon either premature discontinuation from, or completion of the prior parent treatment protocol.

Condition or Disease: Neoplasms

Intervention/treatment: Genetic: Gene-modified (GM) T cell therapy

Phase: Phase 2/Phase 3

DETAILED DESCRIPTION

N/A

STUDY DESIGN

Study Type:	Interventional	Actual Study Start Date:	June 2018
Estimated Enrollment :	191 participants	Estimated Primary Completion Date:	November 2036
Intervention Model :	Single Group Assignment	Estimated Study Completion Date:	November 2036
Masking:	None (Open Label) ()		
Primary Purpose:	Other		
Official Title:	Long-Term Follow-up Protocol for Participants Treated With Gene-Modified T Cells		

ARMS AND INTERVENTIONS

Arm	Intervention/treatment
Other: Participants exposed to Gene-modified (GM) T cell therapy	Genetic: Gene-modified (GM) T cell therapy No investigational product will be administered

OUTCOME MEASURES

Primary Outcome Measures: 1. Incidence of delayed Adverse Events (AEs) [Time Frame: Up to 15 years from last gene-modified (GM) T cell infusion]

2. Persistence of GM T cells [Time Frame: Up to 15 years from last GM T cell infusion]

3. Analysis of vector integration sites [Time Frame: Up to 15 years from last GM T cell infusion]

4. Incidence of replication-competent lentiviruses [Time Frame: Up to 15 years from last GM T cell infusion]

5. Physical growth as assessed by physical examination (pediatric participants only) [Time Frame: Up to 15 years from last GM T cells infusion or until Tanner Stage 5 is reached]

6. Incidence of sexual maturation as assessed by the Tanner staging system (pediatric participants only) [Time Frame: Up to 15 years from last GM T cells infusion or until Tanner Stage 5]

7. Disease status of the primary malignancy [Time Frame: Up to 15 years from last GM T cell infusion]

8. Disease Progression: Number of participants who continue to be responders, who have progressed, and who have relapsed will be reported. [Time Frame: Up to 15 years from last GM T cells infusion]

9. Disease Relapse: Number of participants who continue to be responders, who have progressed, and who have relapsed will be reported. [Time Frame: Up to 15 years from last GM T cells infusion]

10. Overall Survival defined as the time from the first dose of investigational product or from the randomization date to the date of death or the date the participant is last known to be alive. [Time Frame: Up to 15 years from last GM T cells infusion]

Secondary Outcome Measures: 1. Health-related quality of life (HRQoL): Measurement of HRQoL changes as assessed using instruments administered in the parent treatment protocol [Time Frame: Up to approximately 5 years from last GM T cell infusion]

ELIGIBILITY CRITERIA

Ages Eligible for Study: (Child, Adult, Older Adult)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

Received at least one gene-modified (GM) T-cell infusion in a previous Celgene sponsored or Celgene alliance partner-sponsored study, and have discontinued, or completed the post-treatment follow-up period in the parent treatment protocol, as applicable. Must understand and voluntarily sign an Informed Consent Form/Informed Assent Form prior to any study-related assessments/procedures being conducted.

Exclusion Criteria:

Not Applicable

Other protocol-defined inclusion/exclusion criteria apply

CONTACTS AND LOCATIONS**Contacts**

Contact: BMS Study Connect Contact Center www.BMSStudyConnect.com 855-907-3286 Clinical.Trials@bms.com

Contact: First line of the email MUST contain the NCT# and Site #.

Locations

United States, Alabama	University of Alabama Birmingham	Birmingham
United States, Alabama	University of Alabama Birmingham	Birmingham
United States, Arizona	Banner MD Anderson Cancer Center	Gilbert
United States, Arizona	Mayo Clinic Phoenix	Phoenix
United States, Arizona	Arizona Cancer Center	Scottsdale
United States, California	City of Hope	Duarte
United States, California	University of California San Diego Moores Cancer Center	La Jolla
United States, California	Cedars-Sinai Medical Center	Los Angeles
United States, California	Sutter Hematology and Oncology	Sacramento
United States, California	University of California, San Francisco- California	San Francisco
United States, California	UCLA Medical Centre-Santa Monica	Santa Monica
United States, California	Stanford Cancer Center	Stanford
United States, Colorado	University of Colorado Cancer Center	Aurora
United States, Colorado	Colorado Blood Cancer Institute	Denver
United States, Connecticut	Yale Cancer Center	New Haven
United States, District of Columbia	Lombardi Cancer Center - Georgetown University Hospital	Washington
United States, Florida	The Mayo Clinic - Jacksonville, Davis-E	Jacksonville
United States, Florida	The Mayo Clinic - Jacksonville, Davis-E	Jacksonville
United States, Florida	Baptist Cancer Center	Miami
United States, Florida	Florida Hospital Transplant Institute	Orlando
United States, Florida	H. Lee Moffitt Cancer Center and Research Institute University of South Florida	Tampa
United States, Georgia	Winship Cancer Institute of Emory University	Atlanta
United States, Georgia	Northside Hospital, Inc	Atlanta
United States, Illinois	Northwestern Memorial Hospital	Chicago
United States, Illinois	University of Chicago Medical Center	Chicago
United States, Illinois	Loyola University Medical Center	Maywood
United States, Illinois	Illinois Cancer Specialists	Niles
United States, Indiana	IN Univ Simon Cancer Center	Indianapolis
United States, Indiana	IN Univ Simon Cancer Center	Indianapolis
United States, Indiana	Franciscan St. Francis Health - Indiana Blood and Marrow Transplantation (IBMT)	Indianapolis
United States, Kansas	Kansas University Medical Center	Westwood
United States, Kansas	Cancer Center of Kansas	Wichita
United States, Kentucky	University of Kentucky	Lexington
United States, Kentucky	Norton Cancer Institute Louisville Oncology	Louisville
United States, Maryland	University of Maryland - Greenebaum Comprehensive Cancer Center	Baltimore

United States, Maryland	Sidney Kimmel Comp Cancer Center at Johns Hopkins	Baltimore
United States, Maryland	National Cancer Institute	Bethesda
United States, Massachusetts	Massachusetts General Hospital / Dana-Farber Cancer Institute	Boston
United States, Massachusetts	Massachusetts General Hospital / Dana-Farber Cancer Institute	Boston
United States, Massachusetts	Dana-Farber/Mass General Brigham Cancer Care, Inc	Boston
United States, Michigan	University of Michigan Comprehensive Cancer Center	Ann Arbor
United States, Michigan	Karmanos Cancer Center Wayne State University	Detroit
United States, Michigan	Providence Cancer Institute	Southfield
United States, Minnesota	University of Minnesota	Minneapolis
United States, Minnesota	Mayo Clinic	Rochester
United States, Missouri	Siteman Cancer Center	Saint Louis
United States, Nebraska	University of Nebraska Medical Center	Omaha
United States, New Jersey	Regional Cancer Care Associates LLC	East Brunswick
United States, New Jersey	Hackensack University Medical Center	Hackensack
United States, New Jersey	Morristown Memorial Hosp	Morristown
United States, New Jersey	Rutgers Cancer Institute of New Jersey	New Brunswick
United States, New York	New York Oncology Hematology P.C.	Albany
United States, New York	Roswell Park Cancer Institute	Buffalo
United States, New York	NYU Langone Laura and Isaac Perlmutter Cancer Center	New York
United States, New York	Weill Cornell Medicine / New York Presbyterian Hospital	New York
United States, New York	Icahn School of Medicine at Mount Sinai	New York
United States, New York	Columbia University Medical Center/New York-Presbyterian Hospital	New York
United States, New York	Memorial Sloan Kettering Cancer Center	New York
United States, New York	University of Rochester James P. Wilmot Cancer Center	Rochester
United States, North Carolina	Levine Cancer Institute	Charlotte
United States, North Carolina	Duke University Medical Center	Durham
United States, Ohio	Oncology Hematology Care, Inc.	Cincinnati
United States, Ohio	University Hospitals of Cleveland	Cleveland
United States, Ohio	Cleveland Clinic Foundation	Cleveland
United States, Oklahoma	University of Oklahoma Peggy and Charles Stephenson Cancer Center	Oklahoma City
United States, Oregon	Willamette Valley Cancer Institute	Eugene
United States, Oregon	Providence Portland Medical Center	Portland
United States, Oregon	Oregon Health and Science University OHSU	Portland
United States, Pennsylvania	The Children's Hospital of Philadelphia	Philadelphia
United States, Pennsylvania	University of Pennsylvania Perelman Center for Advanced Medicine	Philadelphia
United States, Pennsylvania	Thomas Jefferson University	Philadelphia
United States, Pennsylvania	Fox Chase Cancer Center	Philadelphia
United States, Pennsylvania	UPMC Cancer Pavillion	Pittsburgh
United States, South Carolina	Hematology and Oncology Associates of SC, LLC	Greenville
United States, South Dakota	Avera Cancer Institute	Sioux Falls
United States, Tennessee	Sarah Cannon Research Inst	Nashville
United States, Texas	Texas Oncology	Dallas
United States, Texas	Texas Oncology - Baylor Charles A. Sammons Cancer Center	Dallas
United States, Texas	UT Southwestern Medical Center	Dallas
United States, Texas	University of Texas- MD Anderson	Houston

United States, Texas	SAM Clinical Research Center	San Antonio
United States, Texas	Baylor Scott and White Health	Temple
United States, Texas	Texas Oncology, P.A. - Tyler	Tyler
United States, Utah	University of Utah - Huntsman Cancer Institute	Salt Lake City
United States, Utah	Intermountain Healthcare - LDS Hospital	Salt Lake City
United States, Virginia	University of Virginia Health System	Charlottesville
United States, Virginia	Virginia Oncology Associates	Norfolk
United States, Virginia	Virginia Commonwealth University	Richmond
United States, Washington	Swedish Cancer Institute	Seattle
United States, Washington	Seattle Children's Hospital	Seattle
United States, Washington	Fred Hutchinson Cancer Research Center	Seattle
United States, Washington	Northwest Medical Specialties PLLC	Tacoma
United States, Wisconsin	University Of Wisconsin	Madison
United States, Wisconsin	University Of Wisconsin	Madison
United States, Wisconsin	Froedtert Hospital BMT Medical College of Wisconsin	Milwaukee
United States, Wisconsin	Froedtert Hospital BMT Medical College of Wisconsin	Milwaukee
Austria	Allgemeines Krankenhaus (AKH) Wien - Medizinische Universität Wien	Wien
Belgium	Local Institution - 05351	Gent
Belgium	UZ Gent	Gent
Belgium	University Hospital Leuven	Leuven
Canada, Alberta	University of Calgary	Calgary
Canada, British Columbia	Vancouver General Hospital	Vancouver
Canada, Ontario	Juravinski Cancer Centre	Hamilton
Canada, Ontario	Princess Margaret Cancer Centre	Toronto
Canada, Quebec	CIUSSS de l'Est-de-l'Île-de-Montreal	Montreal
Finland	Helsinki University Central Hospital (HUCH)	Helsinki
France	CHRU de Lille France	Lille Cedex
France	Institute for Pediatric Hematology - Oncology, Leon Berard Cancer Center	Lyon
France	Institut Paoli-Calmettes	Marseille Cedex 9
France	Hopitaux de La Timone	Marseille Cedex 9
France	CHU Montpellier - Hôpital Saint Eloi	Montpellier CEDEX 5
France	CHU Hotel Dieu	Nantes Cedex 01
France	Hopital Saint Louis	Paris
France	Hospital Saint Louis	Paris
France	Hopital Robert Debre	Paris
France	Centre Hospitalier Lyon-Sud	Pierre-Benite CEDEX
France	CHU La Miletrie	Poitiers Cedex
France	Institut Universitaire du Cancer de Toulouse - Oncopole	Toulouse CEDEX 9
France	Gustave Roussy	Villejuif
Germany	Robert-Rössle-Klinik im HELIOS Klinikum Berlin-Buch Klinik für Hämatologie, Onkologie u. Tumormedizin	Berlin
Germany	Charité -Universitätsmedizin Berlin	Berlin
Germany	Universitätsklinikum Carl Gustav Carus an der TU Dresden	Dresden
Germany	Hematology Oncology and clinical immunology / Heinrich-Heine-University	Düsseldorf
Germany	Medizinische Klinik II ZIM, Hämatologie Onkologie Uniklinik Frankfurt	Frankfurt

Germany	Universitaetsklinikum Hamburg-Eppendorf	Hamburg
Germany	Universitaetsklinikum Heidelberg	Heidelberg
Germany	Klinikum der Universitaet zu Koeln	Koeln
Germany	Universitaetsklinikum Muenster	Muenster
Germany	LMU Klinikum der Universität	München
Germany	Universitaetsklinikum Tuebingen	Tuebingen
Germany	University Hospital of Ulm	Ulm
Germany	Local Institution - 03501	Würzburg
Germany	Universitaetsklinikum Wurzburg Medizinische Klinik und Poliklinik II	Würzburg
Italy	Ospedali Riuniti di Ancona	Ancona
Italy	Azienda Ospedaliero Universitaria Di Bologna Policlinico Sorsola Malpighi	Bologna
Italy	Fondazione IRCCS Istituto Nazionale dei Tumori	Milan
Italy	Fondazione Monza e Brianza per il Bambino e la sua Mamma (MBBM)	Monza
Italy	Istituto Nazionale Per Lo Studio E La Cura Dei Tumori Fondazione Giovanni Pascale	Napoli
Italy	Universita La Sapienza	Roma
Italy	Ospedale Pediatrico Bambino Gesù	Rome
Italy	Istituto Clinico Humanitas	Rozzano (MI)
Italy	Azienda Ospedaliera Citta della Salute e della Scienza di Torino	Torino
Italy	Azienda Sanitaria Ospedaliera San Giovanni Battista Molinette	Turin
Japan	Tokyo Metropolitan Cancer and Infectious Diseases Center Komagome Hospital	Bunkyo-ku
Japan	National Cancer Center Hospital	Chuo-ku
Japan	Kyushu University Hospital	Fukuoka
Japan	Tokai University Hospital	Isehara City, Kanagawa
Japan	Toranomon Hospital	Minato-ku
Japan	Local Institution - 13203	Osaka
Japan	Osaka City University Hospital	Osaka
Japan	Hokkaido University Hospital	Sapporo, Hokkaidô
Japan	Japan Red Cross Medical Center	Shibuya-ku
Japan	Jichi Medical University Hospital	Shimotsuke
Japan	Tokyo Women's Medical University Hospital	Shinjuku City
Netherlands	Vrije Universiteit Medisch Centrum (VUMC)	Amsterdam
Netherlands	Erasmus Medical Center - Daniel den Hoed	Rotterdam
Netherlands	Princess Maxima Center for Pediatric Oncology	Utrecht
Norway	Oslo Universitetssykehus	Oslo
Spain	Hospital Universitario Vall D hebron	Barcelona
Spain	Hospital Universitari Germans Trias i Pujol ICO Badalona	Barcelona
Spain	Institut Clinic de Nefrologia i Urologia - Hospital Clinic i Provincial de Barcelona	Barcelona
Spain	Hospital San Joan de Deu Barcelona	Esplugues de Llobregat
Spain	Hospital Infantil Universitario Nino Jesus	Madrid
Spain	Hospital 12 de Octubre	Madrid
Spain	Clinica Universidad de Navarra	Pamplona
Spain	Universitario de Salamanca - Hospital Clinico	Salamanca
Spain	Hospital Virgen del Rocio	Sevilla
Sweden	Karolinska University Hospital Huddinge	Stockholm
Switzerland	Inselspital Bern	Bern

United Kingdom	The Leeds Teaching Hospitals NHS Trust - St James's University Hospital	Leeds
United Kingdom	Kings College Hospital	London
United Kingdom	UCL Cancer Institute	London
United Kingdom	Christie Hospital NHS Trust	Manchester Withington
United Kingdom	Somers Cancer Research Building	Shirley Southampton

Sponsors and Collaborators

Celgene

Investigator

Study Director : Bristol-Myers Squibb Bristol-Myers Squibb

MORE INFORMATION

Responsible Party : Celgene
ClinicalTrials.gov Identifier : NCT03435796
Other Study ID Numbers : GC-LTFU-001, U1111-1206-8250, 2017-001465-24
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Studies a U.S. FDA-regulated Drug Product: Yes
Studies a U.S. FDA-regulated Device Product: No
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Gene-Modified T Cells CAR T Cell*