Safety Study of CC-93538 in Adult and Adolescent Participants With Eosinophilic Esophagitis

CLINICALTRIALS.GOV IDENTIFIER	RECRUITMENT STATUS	FIRST POSTED	LAST UPDATE POSTED
NCT04991935	RECRUITING	AUGUST 5, 2021	MAY 12, 2022

STUDY DESCRIPTION

Brief Summary

This study is an open-label, uncontrolled study design to evaluate the longer-term safety profile as well as durability of response of administration of a single dose level of CC-93538. The study will enroll participants who participated in the CC-93538-EE-001 study.

Condition or Disease: Eosinophilic Esophagitis

Intervention/treatment: Drug: CC-93538

Phase: Phase 3

DETAILED DESCRIPTION

N/A

STUDY DESIGN

Study Type: Interventional

Estimated Enrollment : 259 participants

Intervention Model : Single Group Assignment

Masking: None (Open Label) ()

Primary Purpose: Treatment

Official Title: Safety Study of CC-93538 in Adult and Adolescent Participants With Eosinophilic Esophagitis

Actual Study Start Date: September 2021

Estimated Primary Completion Date: August 2026

Estimated Study Completion Date: August 2026

ARMS AND INTERVENTIONS

Arm	Intervention/treatment
Experimental: Administration of CC-93538 Participants are administered CC-93538 dose subcutaneously once weekly	Drug: CC-93538 CC-93538

OUTCOME MEASURES

Primary Outcome Measures: 1. Incidence of Adverse Events (AEs) [Time Frame: For a minimum of 28 months]
An AE is any noxious, unintended, or untoward medical occurrence that may appear or worsen in a participant during the course of a study. It may be a new intercurrent illness, a worsening concomitant illness, an injury, or any concomitant impairment of the participant's health, including laboratory test values regardless of etiology. Any worsening (i.e., any clinically significant adverse change in the frequency or intensity of a preexisting condition) should be considered an AE.

Secondary Outcome Measures: 1. Immunogenicity of CC-93538 assessed through the incidence of anti-drug antibodies [Time Frame: For a minimum of 28 months]
This includes neutralizing antibodies when warranted.

ELIGIBILITY CRITERIA

Ages Eligible for Study: 12 to 75 Years (Child, Adult, Older Adult)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:
Previously participated in prior clinical study CC-93538-EE-001 and either:
completed both the Induction and Maintenance phases; or completed the Induction Phase, however, did not qualify for the Maintenance Phase, including having a severe eosinophilic esophagitis (EoE) flare requiring endoscopic intervention or rescue therapy. Demonstrated compliance with required investigational product dosing during the prior study. Did not permanently discontinue investigational product in the prior study and/or did not experience any clinically significant adverse events related to Investigational Product that would preclude further dosing. Females of childbearing potential must have a negative pregnancy test prior to the first dose of open-label CC-93538 and agree to practice a highly effective method of contraception (as defined in the prior study) until 5 months after the last dose of open-label CC-93538.
Exclusion Criteria:
Clinical or endoscopic evidence of other diseases or conditions that may affect or confound the histologic, endoscopic, or clinical symptom evaluation for this study. Active Helicobacter pylori infection or esophageal varices. Evidence of immunosuppression, or of having received systemic immunosuppressive or immunomodulating drugs within 5 drug half-lives prior to open-label extension study (OLE) Day 1. Use of these agents is prohibited during the study. Treatment with oral or sublingual immunotherapy within 6 months of OLE Day 1. Use of these agents is prohibited during the study. Received an investigational product, other than that administered in CC-93538-EE-001, within 5 half-lives prior to OLE Day 1 (includes investigational product received during an interventional trial for COVID-19). Those vaccinated with an investigational COVID-19 vaccine during CC-93538-EE-001 are not eligible, unless allowed following a discussion with the Clinical Trial Physician. Received a live attenuated vaccine within one month prior to OLE Day 1; or anticipates the need for a live attenuated vaccine at any time throughout the course of this study. Any disease that would affect the conduct of the protocol or interpretation of the study results, or would put a patient at risk by participating in the study (e.g. colitis, celiac disease, Mendelian disorder associated with EoE, severe uncontrolled asthma, infection causing eosinophilia, hypereosinophilic syndrome, or cardiovascular condition, or neurologic or psychiatric illness that could compromise the participant's ability to accurately document symptoms of EoE; newly diagnosed malignancy, lymphoproliferative disease, or clinically significant laboratory abnormality). Active or ongoing infections including parasitic/helminthic infections, viral hepatitis, tuberculosis, or HIV. Has had idiopathic anaphylaxis or major immunologic reaction to an immunoglobulin-G containing agent; or any known hypersensitivity to any ingredient in CC-93538. Females who are pregnant or lactating.

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 NCT # and Site #.

Locations

United States, Alabama	AES - DRS - Simon Williamson Clinic, PC - Birmingham	Birmingham
United States, Alabama	Gastro Care PC - CAR	Tuscaloosa
United States, Arizona	Phoenix Childrens Hospital	Phoenix
United States, Arizona	AES - DRS - Central Phoenix Medical Clinic, LLC	Phoenix
United States, Arizona	Mayo Clinic Scottsdale	Scottsdale
United States, Arizona	Del Sol Research Management	Tucson
United States, Arizona	MetroHealth Medical Center	Tucson
United States, California	OM Research	Lancaster
United States, California	OM Research	Lancaster
United States, California	Gastrointestinal Biosciences	Los Angeles
United States, California	UCSF Benioff Children's Hospital Oakland	Oakland
United States, California	Palmtree Clinical Research	Palm Springs
United States, California	Alliance Clinical Research, LLC	Poway
United States, California	SDG Clinical Research, Inc.	San Diego
United States, California	Precision Research Institute, LLC	San Diego
United States, Colorado	Childrens Hospital Colorado	Aurora
United States, Colorado	Peak Gastroenterology Associates	Colorado Springs
United States, Colorado	Rocky Mountain Pediatric Gastroenterology	Denver
United States, Colorado	Western States Clinical Research Inc	Wheat Ridge
United States, Connecticut	Connecticut Clinical Research Foundation	Bristol
United States, Connecticut	University of Connecticut	Farmington
United States, Connecticut	Medical Research Center of Connecticut LLC	Hamden
United States, District of Columbia	Children's National Medical Center	Washington
United States, Florida	Gastro Florida	Clearwater
United States, Florida	Nature Coast Clinical Research LLC	Inverness
United States, Florida	Nature Coast Clinical Research LLC	Inverness

United States, Florida	ENCORE Borland-Groover Clinical Research	Jacksonville
United States, Florida	ENCORE Borland-Groover Clinical Research	Jacksonville
United States, Florida	Homestead Associates in Research Inc	Miami
United States, Florida	A Plus Research Inc	Miami
United States, Florida	Med-Care Research	North Miami Beach
United States, Florida	AES - DRS - Synexus Clinical Research US, Inc. - Orlando	Orlando
United States, Florida	Arnold Palmer Hospital For Children	Orlando
United States, Florida	Gastroenterology Consultants of Central Florida - CAR	Orlando
United States, Florida	Advanced Medical Research Center	Port Orange
United States, Florida	US Associates in Research Inc	Sweetwater
United States, Georgia	Emory University	Atlanta
United States, Georgia	Gastroenterology Associates Of Central Georgia LLC	Macon
United States, Idaho	Grand Teton Research Group PLLC	Idaho Falls
United States, Illinois	Northwestern University Feinberg School of Medicine	Chicago
United States, Illinois	University of Chicago	Chicago
United States, Indiana	Indiana University	Indianapolis
United States, Indiana	Gastroenterology Health Partners PLLC	New Albany
United States, Iowa	Iowa Digestive Disease Center	Clive
United States, Iowa	University of Iowa Hospitals and Clinics	Iowa City
United States, Kansas	University of Kansas Medical Center	Kansas City
United States, Kentucky	Tri-State Gastroentrology Associates	Florence
United States, Kentucky	University of Louisville	Louisville
United States, Louisiana	Gastroenterology Associates LLC	Baton Rouge
United States, Louisiana	Clinical Trials Management LLC	Metairie
United States, Louisiana	Clinical Trials Management LLC	Metairie
United States, Louisiana	Ochsner Children's Health Center	New Orleans
United States, Maryland	Johns Hopkins University	Baltimore
United States, Maryland	Digestive Disease Associates, PA	Catonsville
United States, Maryland	Woodholme Gastroenterology Associates	Glen Burnie
United States, Maryland	Meritus Medical Center	Hagerstown
United States, Massachusetts	Tufts - New England Medical Center	Boston
United States, Massachusetts	Massachusetts General Hospital / Dana-Farber Cancer Institute	Boston
United States, Massachusetts	Boston Children's Hospital	Boston
United States, Massachusetts	Brigham and Women's Hospital	Boston
United States, Massachusetts	Greater Boston Gastroenterology PC	Framingham
United States, Massachusetts	FC Research LLC	South Dartmouth
United States, Massachusetts	Baystate Medical Center	Springfield
United States, Massachusetts	UMASS Memorial Hospital	Worcester
United States, Michigan	Troy Gastroenterology	Troy
United States, Michigan	Gastroenterology Associates of Western Michigan PLC	Wyoming
United States, Minnesota	Minnesota Gastroenterology	Plymouth
United States, Minnesota	Mayo Clinic	Rochester
United States, Mississippi	GI Associates and Endoscopy Center-GI Clinical Research Department	Flowood
United States, Missouri	Mid America Gastrointestinal Consultants	Kansas City
United States, Missouri	Washington University Siteman Cancer Center	Saint Louis

United States, Nebraska	University of Nebraska Medical Center	Omaha
United States, Nevada	Advanced Research Institute - Reno	Reno
United States, New Hampshire	Dartmouth Hitchcock Medical Center	Lebanon
United States, New Jersey	Atlantic Research Center LLC	Ocean City
United States, New Mexico	New Mexico Clinical Research and Osteoporosis Center	Albuquerque
United States, New York	Long Island Gastrointestinal Research Group LLP	Great Neck
United States, New York	Drug Trials America	Hartsdale
United States, New York	NYU Langone Medical Center	New York
United States, New York	Dr. Jeffrey Crespin, MD - New York - CAR	New York
United States, New York	Icahn School of Medicine at Mount Sinai	New York
United States, New York	Rochester Gastroenterology: Devgun Surinder MD	Rochester
United States, New York	Hill Medical Center	Syracuse
United States, New York	Syracuse VA Medical Center	Syracuse
United States, North Carolina	University of North Carolina at Chapel Hill	Chapel Hill
United States, North Carolina	Clinical Research of Charlotte	Charlotte
United States, North Carolina	Duke University Medical Center	Durham
United States, North Carolina	Medication Management LLC	Greensboro
United States, North Carolina	Atlantic Medical Group - Kinston - CAR	Kinston
United States, Ohio	Dayton Gastroenterology, Inc	Beavercreek
United States, Ohio	Consultants for Clinical Research	Cincinnati
United States, Ohio	Cincinnati Children's Hospital Medical Center	Cincinnati
United States, Ohio	University of Cincinnati Medical Center	Cincinnati
United States, Ohio	Cleveland Clinic Foundation	Cleveland
United States, Ohio	The Cleveland Clinic Foundation	Cleveland
United States, Ohio	AES - DRS - Synexus Clinical Research US, Inc. - Columbus	Columbus
United States, Ohio	Optimed Research Ltd	Columbus
United States, Ohio	Optimed Research Ltd	Columbus
United States, Oregon	Velocity Clinical Research - Grants Pass - ERN - PPDS	Medford
United States, Pennsylvania	Penn State Health Milton S. Hershey Medical Center	Hershey
United States, Pennsylvania	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	Glenn S Freed, DO - CAR	Pottsville
United States, Rhode Island	University Gastroenterology	Providence
United States, South Carolina	AES - DRS - Synexus Clinical Research US, Inc. - Anderson	Anderson
United States, South Carolina	Prisma Health - Upstate	Greenville
United States, Tennessee	ClinSearch LLC	Chattanooga
United States, Tennessee	Vanderbilt University	Nashville
United States, Texas	Texas Digestive Disease Consultants Dallas	Cedar Park
United States, Texas	AES - DRS - Synexus Clinical Research US, Inc. - Dallas	Dallas
United States, Texas	Childrens Medical Center	Dallas
United States, Texas	Brooke Army Medical Center Francis Street Medical Center	Fort Sam Houston
United States, Texas	Cook Childrens Medical Center	Fort Worth
United States, Texas	Houston Endoscopy and Research Center	Houston
United States, Texas	Digestive Health Associates of Texas (DHAT)	Rockwell

United States, Texas	Southern Star Research Institute LLC	San Antonio
United States, Texas	Texas Digestive Disease Consultants - Southlake	Southlake
United States, Texas	Tyler Research Institute, LLC	Tyler
United States, Utah	Intermountain Clinical Research	Draper
United States, Utah	Ogden Clinic Gastrenterology - CAR	Ogden
United States, Utah	Advanced Research Institute-South Ogden	Ogden
United States, Utah	University of Utah Primary Children's Medical Center	Salt Lake City
United States, Utah	University of Utah School of Medicine	Salt Lake City
United States, Vermont	University of Vermont Medical Center Gastro	Burlington
United States, Virginia	Emeritas Research Group	Leesburg
United States, Virginia	Blue Ridge Medical Research	Lynchburg
United States, Virginia	McGuire Veterans Affairs Medical Center	Richmond
United States, Virginia	Carilion Clinic	Roanoke
United States, Washington	Velocity Clinical Research - Spokane - ERN - PPDS	Spokane
United States, Washington	Vancouver Clinic Inc PS	Vancouver
United States, Wisconsin	University of Wisconsin	Madison
United States, Wisconsin	Aurora Saint Lukes Medical Center	Milwaukee
United States, Wisconsin	Medical College of Wisconsin	Milwaukee
United States, Wyoming	Gastroenterology Associates, PC - Casper - CAR	Casper
Argentina	Hospital Italiano de Buenos Aires	Buenos Aires
Argentina	Gedyt	BuenosAires
Argentina	Centro de Investigaciones Medica Mar del Plata	Mar Del Plata
Argentina	Instituto CER S.A.	Quilmes
Argentina	Investigaciones En Patologias Respiratorias	San Miguel de Tucumán
Australia, New South Wales	Concord Repatriation General Hospital	Concord
Australia, New South Wales	Liverpool Hospital	Liverpool
Australia, New South Wales	The Childrens Hospital at Westmead	Westmead
Australia, Queensland	Coastal Digestive Health	Maroorchydore
Australia, Queensland	Coral Sea Clinical Research Institute	North Mackay
Australia, Queensland	Mater Adult Hospital	South Brisbane
Australia, Queensland	Princess Alexandra Hospital	Woolloongabba
Australia, South Australia	Royal Adelaide Hospital	Adelaide
Australia, South Australia	Lyell McEwin Hospital	Elizabeth Vale
Australia, Victoria	Monash Health, Monash Medical Centre	Clayton
Australia, Victoria	Footscray Hospital	Footscray
Australia, Victoria	The Alfred Hospital	Melbourne
Australia, Western Australia	Fiona Stanley Hospital	Murdoch
Australia	St Vincents Hospital Melbourne	Fitzroy
Australia	St John of God Midland Hospital	Western Australia
Austria	Krankenhaus der Barmherzigen Brüder Eisenstadt	Burgenland
Austria	LKH-Universitätsklinikum Klinikum Graz	Graz
Austria	Hospital of Barmherzige Schwestern Linz	Linz
Austria	Medizinische Universitat Wien	Vienna
Belgium	UZ Brussel	Brussels
Belgium	AZ Groeninge	Kortrijk

Belgium	UZ Leuven	Leuven
Belgium	AZ Sint-Lucas Brugge	West-Vlaanderen
Canada, Alberta	University of Calgary	Calgary
Canada, Alberta	University of Alberta	Edmonton
Canada, Alberta	South Edmonton Gastroenterology	Edmonton
Canada, British Columbia	GI Research Institute	Vancouver
Canada, British Columbia	PerCuro Clinical Research LTD	Victoria
Canada, Ontario	Ottawa Allergy Research Corporation	Ottawa
Canada, Ontario	Toronto Western Hospital	Toronto
Canada, Ontario	Toronto Digestive Disease Associates Inc	Vaughan
Germany	Staedisches Klinikum Brandenburg	Brandenburg an der Havel
Germany	AES - DRS - Synexus Frankfurt Research Centre	Frankfurt am Main
Germany	Klinikum Garmisch-Partenkirchen Gmbh	Garmisch-Partenkirchen
Germany	Facharztzentrum Eppendorf	Hamburg
Germany	Universitatsklinikum Leipzig	Leipzig
Germany	EUGASTRO GmbH	Leipzig
Germany	Gastroenterologische Gemeinschaftspraxis Mainz	Mainz
Germany	Klinikum rechts der Isar der Technischen Universitaet Muenchen	Munchen
Germany	Praxis Prof. Herbert Kellner	München
Israel	Rambam Medical Center	Haifa
Israel	Edith Wolfson Medical Center	Holon
Israel	Shaare Zedek Medical Center	Jerusalem
Israel	Hadassah Medical Center	Jerusalem
Israel	Tel-Aviv Sourasky Medical Center	Tel-Aviv
Israel	Shamir Medical Center - Assaf Harofeh	Zerifin
Italy	Ospedale Policlinico San Martino	Genova
Italy	Fondazione IRCCS Ca Granda Ospedale Maggiore Policlinico	Milano
Italy	AOU dell'Università degli Studi della Campania Luigi Vanvitelli	Napoli
Italy	Azienda Ospedaliera di Padova	Padova
Italy	Azienda Ospedaliera Universitaria Pisana	Pisa
Italy	Azienda Policlinico Umberto I	Rome
Japan	Akita University Hospital	Akita-shi
Japan	Nippon Medical School Hospital	Bunkyo-ku
Japan	Tokai University Hospital	Isehara City, Kanagawa
Japan	Kobe University Hospital	Kobe
Japan	Local Institution - 597	Kobe
Japan	Gunma University Hospital	Maebashi
Japan	Daido Clinic	Nagoya
Japan	Nagoya City University Hospital	Nagoya
Japan	Niigata University Medical and Dental Hospital	Niigata-shi
Japan	Hyogo College of Medicine Hospital	Nishinomiya
Japan	Kawasaki Medical School Hospital	Okayama-Shi
Japan	Osaka City University Hospital	Osaka
Japan	Gunma Children's Medical Center	Shibukawa
Japan	Center Hospital of the National Center for Global Health and Medicine	Shinjuku-Ku

Japan	International University of Health and Werfare Mita Hospital	Tokyo
Japan	Local Institution - 605	Tokyo
Japan	National Center for Child Health and Development	Tokyo
Japan	Fujita Health University Hospital	Toyoake
Japan	Local Institution - 596	Toyoake
Japan	Yamagata University Hospital	Yamagata
Poland	Vitamed Galaj i Cichomski sp.j.	Bydgoszcz
Poland	AES - DRS - Synexus Polska Sp. z o.o. Oddzial w Czestochowie	Czestochowa
Poland	AES - DRS - Synexus Polska Sp. z o.o. Oddzial w Gdansku	Gdansk
Poland	AES - DRS - Synexus Polska Sp. z o.o. Oddzial w Katowicach	Katowice
Poland	AES - DRS - Synexus Polska Sp. Z o.o. Oddzial w Lodzi	Lódz
Poland	TWOJA PRZYCHODNIA Medical Centre of Szczecin LLC	Szczecin
Poland	WIP Warsaw IBD Point	Warsaw
Poland	Centrum Zdrowia MDM	Warszawa
Poland	AES - DRS - Synexus Polska Sp. z o.o. Oddzial w Warszawie	Warszawa
Poland	AES - DRS - Synexus Polska Sp. z o.o. Oddzial we Wroclawiu	Wroclaw
Poland	Akademicki Szpital Kliniczny im. Jana Mikulicza-Radeckiego	Wroclaw
Poland	Centrum Badan Klinicznych Piotr Napora Lekarze Spolka Partnerska	Wroclaw
Portugal	Centro Hospitalar de Lisboa Central - Hospital de Santo António dos Capuchos	Lisboa
Portugal	Centro Hospitalar Lisboa Central- Hospital Dona Estefânia	Lisboa
Portugal	Centro Hospitalar do Porto - Hospital de Santo António	Porto
Portugal	Centro Hospitalar de São João, E.P.E.	Porto
Spain	Hospital Clinic de Barcelona	Barcelona
Spain	Hospital Universitario Reina Sofia	Cordoba
Spain	Hospital La Princesa	Madrid
Spain	Hospital Universitario La Paz	Madrid
Spain	Hospital Costa del Sol	Marbella
Spain	Hospital Virgen del Rocio	Sevilla
Switzerland	Chuv Bh-04	Lausanne
Switzerland	Kantonsspital Liestal	Liestal
United Kingdom	Belfast Health and Social Care Trust	Belfast Northern Ireland
United Kingdom	AES - DRS - Synexus Midlands Clinical Research Centre	Birmingham
United Kingdom	Addenbrooke's Hospital	Cambridge
United Kingdom	AES - DRS - Synexus Wales Clinical Research Centre	Cardiff
United Kingdom	AES - DRS - NW Consortium Lancashire	Chorley
United Kingdom	AES - DRS - Synexus North Teesside Clinical Research Centre	Hardwick
United Kingdom	AES - DRS - Synexus Hexham Clinical Research Centre	Hexam
United Kingdom	AES - DRS - NW Consortium Merseyside	Liverpool
United Kingdom	Royal Manchester Children's Hospital	Manchester
United Kingdom	AES - DRS - NW Consortium Manchester	Manchester
United Kingdom	Southampton General Hospital	Southampton

Sponsors and Collaborators

Celgene

Investigator

Study Director :	Bristol-Myers Squibb	Bristol-Myers Squibb

MORE INFORMATION

Responsible Party :	Celgene
ClinicalTrials.gov Identifier :	NCT04991935
Other Study ID Numbers :	CC-93538-EE-002, 2020-004335-24
First Posted :	August 5, 2021
Last Update Posted :	May 12, 2022
Last Verified :	May 2022
Individual Participant Data (IPD) Sharing Statement:	
Plan to Share IPD:	Yes
Plan Description:	Information relating to our policy on data sharing and the process for requesting data can be found at the following link: https://www.celgene.com/research-development/clinical-trials/clinical-trials-data-sharing/
Supporting Materials:	Study Protocol, Statistical Analysis Plan (SAP), Informed Consent Form (ICF), Clinical Study Report (CSR), Analytic Code
Time Frame:	See Plan Description
Access Criteria:	See Plan Description
URL:	https://www.celgene.com/research-development/clinical-trials/clinical-trials-data-sharing/
Studies a U.S. FDA-regulated Drug Product:	Yes
Studies a U.S. FDA-regulated Device Product:	No
Keywords provided by Celgene:	*Eosinophilic Esophagitis* *CC-93538* *RPC4046* *Adult* *Adolescent* *Gastrointestinal Diseases* *Esophagitis* *Gastroenteritis Eosinophils* *Eosinophilia* *Esophageal Diseases* *Allergic Diseases* *Antibody, Monoclonal* *Hypersensitivity* *Immunologic factors* *Physiological Effects of Drugs*

Additional relevant MeSH terms :		
	Eosinophilia	*Esophagitis*
	Leukocyte Disorders	*Eosinophilic Esophagitis*
	Hematologic Diseases	*Esophageal Diseases*
	Hypersensitivity, Immediate	*Gastrointestinal Diseases*
	Hypersensitivity	*Digestive System Diseases*
	Immune System Diseases	*Gastroenteritis*