



Long-Term Safety and Efficacy Study of Deucravacitinib in Participants With Systemic Lupus Erythematosus

CLINICALTRIALS.GOV IDENTIFIER
NCT03920267

RECRUITMENT STATUS
RECRUITING

FIRST POSTED
APRIL 18, 2019

LAST UPDATE POSTED
OCTOBER 26, 2021

STUDY DESCRIPTION

Brief Summary

The main objective of the trial is to characterize the long-term safety and tolerability of BMS-986165 in subjects with Systemic Lupus Erythematosus (SLE).

Condition or Disease: Systemic Lupus Erythematosus

Intervention/treatment: Drug: BMS-986165

Phase: Phase 2

DETAILED DESCRIPTION

N/A

STUDY DESIGN

Study Type:	Interventional	Actual Study Start Date:	March 2019
Estimated Enrollment :	360 participants	Estimated Primary Completion Date:	November 2023
Intervention Model :	Parallel Assignment	Estimated Study Completion Date:	November 2023
Masking:	Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)		
Primary Purpose:	Treatment		
Official Title:	A Multi-Center Study to Characterize the Long-Term Safety and Efficacy of BMS-986165 in Subjects With Systemic Lupus Erythematosus		

ARMS AND INTERVENTIONS

Arm	Intervention/treatment
Experimental: BMS-986165 Dose 1	Drug: BMS-986165 Specified dose on specified days
Experimental: BMS-986165 Dose 2	Drug: BMS-986165 Specified dose on specified days
Experimental: BMS-986165 Dose 3	Drug: BMS-986165 Specified dose on specified days

OUTCOME MEASURES

Primary Outcome Measures: 1. Number of participants with Adverse Events (AEs) [Time Frame: Up to 30 days after last treatment dose (approximately 178 weeks)]
2. Number of participants with Serious Adverse Events (SAEs) [Time Frame: Up to 30 days after last treatment dose (approximately 178 weeks)]
3. Number of participants with AEs leading to discontinuation [Time Frame: Up to 30 days after last treatment dose (approximately 178 weeks)]
4. Number of participants with abnormal change from baseline in laboratory measurements over time [Time Frame: Up to 30 days after last treatment dose (approximately 178 weeks)]
5. Number of participants with abnormal change from baseline in vital signs over time [Time Frame: Up to 30 days after last treatment dose (approximately 178 weeks)]

ELIGIBILITY CRITERIA

Ages Eligible for Study: 18 to 75 Years (Adult, Older Adult)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: No

Criteria

For more information regarding Bristol-Myers Squibb Clinical Trial participation, please visit www.BMSStudyConnect.com

Inclusion Criteria:

Completion of SLE Study (NCT03252587) through the protocol-required treatment period, and currently receiving blinded study drug. Note: If a subject is not receiving blinded study drug due to exceptional circumstances (eg, missed investigational product [IP] due to COVID-19 pandemic, delays in study approval, etc), the subject may be allowed to enroll with approval from the BMS Clinical Trial Physician or designee.

Exclusion Criteria:

Any disease or medical condition that, in the opinion of the investigator, would make the subject unsuitable for this study, would interfere with the interpretation of subject safety or study results, or considered unsuitable by the investigator for any other reason Evidence of active tuberculosis (TB)

Other protocol defined inclusion/exclusion criteria apply

CONTACTS AND LOCATIONS

Contacts

Contact: Recruiting sites have contact information. Please contact the sites directly. If there is no contact information, please email Clinical.Trials@bms.com

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

Locations

Poland	Local Institution	Stalowa Wola
Poland	Local Institution	Warszawa
Poland	Szpital Uniwersytecki Number 2 im. dr. Jana Bizuela w Bydgoszczy	Bydgoszcz
Poland	Local Institution	Bytom
Poland	Local Institution	Elblag
Poland	Local Institution	Gdynia
Poland	Local Institution	Konskie
Poland	Intermedius	Koscian
Poland	Centrum Medyczne Plejady	Krakow
Poland	Centrum Nowoczesnych Terapii Dobry Lekarz Spolka z ograniczona odpowiedzialnoscia	Krakow
Poland	Centrum Medyczne ProMiMed	Krak
Poland	Zespol Poradni Specjalistycznych REUMED Filia Nr 1 Wallenroda	Lublin
Poland	Medyczne Centrum Hetmanska - Poznan	Poznan
Poland	Local Institution	Poznan
Poland	Centrum Medyczne Medens - Grupowa Praktyka Lekarska	Sosnowiec
Poland	Centrum Medyczne Pratia Warszawa	Warszawa
Poland	Ars Rheumatica - Reumatika Centrum Reumatologii	Warszawa
Poland	Synexus Polska - Wroclaw	Wroclaw
Poland	Centrum Medyczne Oporow	Wroclaw
Poland	Local Institution	Wroclaw
United States, Alabama	University of Alabama at Birmingham - School of Medicine	Birmingham
United States, California	TriWest Research Associates	El Cajon
United States, California	Local Institution	Palm Desert
United States, California	The Lundquist Institute at Harbor-UCLA Medical Center	Torrance
United States, Connecticut	Yale University	New Haven
United States, Florida	Arthritis & Rheumatic Disease Specialties	Aventura
United States, Florida	Bay Area Arthritis and Osteoporosis	Brandon
United States, Florida	University of Florida Health Shands Hospital	Gainesville
United States, Florida	Omega Research Group - MetroWest	Orlando
United States, Florida	Millennium Research	Ormond Beach
United States, Florida	Advent Health Medical Group	Tampa
United States, Georgia	The Emory Clinic	Atlanta
United States, Georgia	North Georgia Rheumatology Group-Duluth	Lawrenceville
United States, New York	New York University School of Medicine	Brooklyn

United States, New York	Local Institution	Manhasset
United States, New York	New York University School of Medicine	New York
United States, New York	Local Institution	New York
United States, North Carolina	Thurston Arthritis Research Center	Chapel Hill
United States, North Carolina	Joint Muscle Medical Care and Research Institute - Lilington Office	Charlotte
United States, Oklahoma	Local Institution	Oklahoma City
United States, Oklahoma	Oklahoma Medical Research Foundation	Oklahoma City
United States, Pennsylvania	Clinical Research Center of Reading	Wyomissing
United States, South Carolina	Medical University of South Carolina	Charleston
United States, Tennessee	West Tennessee Research Institute	Jackson
United States, Texas	Austin Regional Clinic	Austin
United States, Texas	Tekton Research	Austin
United States, Texas	Local Institution	Dallas
United States, Texas	University of Texas Southwestern Medical Center	Dallas
United States, Texas	Accurate Clinical Management - Greenhouse Road	Houston
United States, Texas	Southwest Rheumatology Research	Mesquite
Argentina, Buenos Aires	Local Institution	Ciudad Aut? De Buenos Aires
Argentina, Buenos Aires	Clinica Adventista Belgrano	Ciudad Autonoma de Buenos Aires
Argentina, Buenos Aires	Aprillus Asistencia e Investigacion	Ciudad Autonoma de Buenos Aires
Argentina, Buenos Aires	Local Institution	Ciudad Autonoma de Buenos Aires
Argentina, Santa FE	Instituto CAICI	Rosario
Argentina, Tucuman	Centro Medico Privado de Reumatologia	San Miguel De Tucum
Argentina	Consultorios Medicos Dr. Catalan Pellet	Caba
Argentina	Consultora Integral de Salud - Centro Medico Privado	Cordoba
Argentina	Local Institution	Cordoba
Argentina	Instituto de Reumatologia	Mendoza
Australia, Queensland	Local Institution	Maroochydore
Brazil, Bahia	SER - Servicios Especializados em Reumatologia da Bahia	Salvador
Brazil, Goias	CIP - Centro Internacional de Pesquisa	GoiA
Brazil, Minas Gerais	Local Institution	Belo Horizonte
Brazil, Minas Gerais	Centro Mineiro de Pesquisa - CMiP	Juiz de Fora
Brazil, Parana	CETI-UFPR Centro de Estudos em Terapias Inovadoras	Curitiba
Brazil, RIO Grande DO SUL	LMK Servicios Medicos S/S Ltda	Porto Alegre
Brazil, SAO Paulo	Local Institution	Porto Alegre
Brazil, SAO Paulo	Centro Multidisciplinar de Estudios Clinicos Unidade Sao Bernardo	Sao Bernardo do Campo
Brazil	Local Institution	Rio de Janeiro
Brazil	CPCLIN - Centro de Pesquisas Clinicas	Sao Paulo
Canada, Alberta	University of Calgary	Calgary
Canada, Ontario	Toronto Western Hospital	Toronto
Colombia	Centro de Investigacion Medico Asistencial CIMEDICAL	Barranquilla
Colombia	Local Institution	Barranquilla
Colombia	Centro de Investigacion en Reumatologia y Especialidades Medicas	Bogot
Colombia	Local Institution	Bucaramanga
Colombia	Preventive Care	Chia
Colombia	Healthy Medical Center	Zipaquirá

Germany	Local Institution	Hannover
Hungary	Local Institution	Budapest
Hungary	Debreceni Egyetem Klinikai Kozpont	Debrecen
Hungary	Bekes Megyei Pandy Kalman Korhaz	Gyula
Hungary	Szegedi Tudomanyegyetem	Szeged
Israel	Local Institution	Ramat-Gan
Japan, Chiba	National Hospital Organization Chibahigashi National Hospital	Chiba-shi
Japan, Fukuoka	Hospital of the University of Occupational and Environmental Health Japan	Kitakyushu
Japan, Hokkaido	Sapporo City General Hospital	Sapporo-Shi
Japan, Hokkaido	Hokkaido University Hospital	Sapporo
Japan, Ishikawa	Local Institution	Kanazawa
Japan, Miyagi	Tohoku University Hospital	Sendai City
Japan, Tochigi	Jichi Medical University Hospital	Shimotsuke-city
Japan, Tokyo	St. Lukes International Hospital	Chuo-ku
Japan	Juntendo University Hospital	Tokyo
Japan	Center Hospital of the National Center for Global Health and Medicine	Tokyo
Japan	Nihon University Itabashi Hospital	Tokyo
Korea, Republic of	Local Institution	Seoul
Korea, Republic of	Local Institution	Suwon
Mexico, Distrito Federal	CAIMED Investigacion en Salud	Mexico City
Mexico, Distrito Federal	Centro de Investigacion y Tratamiento Reumatologico	Mexico
Mexico, Guanajuato	Consultorio Medico de Reumatologia	Leon
Mexico, Guanajuato	Centro de Investigacion Farmacologica del Bajio	Leon
Mexico, Jalisco	Investigacion Biomedica para el Desarrollo de Farmacos S.A. de C.V.	Guadalajara
Mexico, Jalisco	Centro Integral de Reumatologia	Guadalajara
Mexico, Jalisco	Juan Alberto Rodriguez Ruiz	Zapopan
Mexico, Nuevo LEON	Accelerium Clinical Research	Monterrey
Mexico	Centro de Alta Especialidad en Reumatologia e Investigacion del Potosi	San Luis Potosi
Mexico	FAICIC Clinical Research	Veracruz
Romania	Centrul Medical de Diagnostic si Tratament Ambulatoriu Neomed	Brasov
Romania	Local Institution	Bucuresti
Romania	Local Institution	Bucuresti
Romania	Local Institution	Bucuresti
Romania	Local Institution	Bucuresti
Romania	Local Institution	Cluj-Napoca
Romania	Spitalul Clinic Judeean de UrgenΔ Sfantul Apostol Andrei	Galati
Romania	Spitalul Judetean de Urgenta Valcea	Ramnicu Valcea
Russian Federation	Municipal Institution City Clinical Hospital #40	Ekaterinburg
Russian Federation	Medical Center Maksimum Zdorovia	Kemerovo
Russian Federation	Local Institution	Kemerovo
Russian Federation	Medical Center Health Family	Novosibirsk
Russian Federation	Orenburg State Medical University	Orenburg
Russian Federation	Local Institution	Petrozavodsk
Russian Federation	S.M. Kirov Military Medical Academy	Saint - Petersburg
Russian Federation	Local Institution	Saint Petersburg

Russian Federation	Local Institution	Saint-Petersburg
Russian Federation	Departmental Hospital at Smolensk Station of JSC RZhD	Smolensk
Russian Federation	Federal Almazov North-West Medical Research Centre	St. Petersburg
Russian Federation	Local Institution	Tolyatti
Russian Federation	Biomed	Vladimir
Russian Federation	Clinical Hospital named after NA Semashko	Yaroslavl
Russian Federation	Municipal Institution of Health Protection	Yaroslavl
Spain	Local Institution	A Coru
Spain	Hospital Regional Universitario de Malaga Hospital General	Malaga
Spain	Corporacio Sanitaria Parc Tauli	Sabadell
Spain	Hospital Universitario Nuestra Senora de Valme	Sevilla
Taiwan	Local Institution	Taichung
Taiwan	Local Institution	Taipei City
Taiwan	Local Institution	Taipei
Taiwan	Local Institution	Taipei

Sponsors and Collaborators

Bristol-Myers Squibb

Investigator

Study Director : Bristol-Myers Squibb Bristol-Myers Squibb

MORE INFORMATION

Responsible Party : Bristol-Myers Squibb

ClinicalTrials.gov Identifier : NCT03920267

Other Study ID Numbers : IM011-074, 2018-003471-35

First Posted : April 18, 2019

Last Update Posted : October 26, 2021

Last Verified : October 2021

Studies a U.S. FDA-regulated Drug Product: Yes

Studies a U.S. FDA-regulated Device Product: No

Keywords provided by Bristol-Myers Squibb: *Systemic Lupus Erythematosus*

Additional relevant MeSH terms : *Lupus Erythematosus, Systemic* *Autoimmune Diseases*
Connective Tissue Diseases *Immune System Diseases*