



Long-Term Study That Measures the Safety and Efficacy of Deucravacitinib (BMS-986165) in Participants With Psoriasis

CLINICALTRIALS.GOV IDENTIFIER
NCT04036435

RECRUITMENT STATUS
ACTIVE, NOT RECRUITING

FIRST POSTED
JULY 29, 2019

LAST UPDATE POSTED
JULY 5, 2022

STUDY DESCRIPTION

Brief Summary

The main purpose of this study is to characterize the long-term safety and efficacy of the drug Deucravacitinib (BMS-986165) in patients who have been previously enrolled in an applicable Phase 3 psoriasis study.

Condition or Disease: Psoriasis

Intervention/treatment: Drug: BMS-986165

Phase: Phase 3

DETAILED DESCRIPTION

N/A

STUDY DESIGN

Study Type:	Interventional	Actual Study Start Date:	August 2019
Estimated Enrollment :	1452 participants	Estimated Primary Completion Date:	July 2026
Intervention Model :	Single Group Assignment	Estimated Study Completion Date:	July 2026
Masking:	None (Open Label) ()		
Primary Purpose:	Treatment		
Official Title:	Long-Term Study That Measures the Safety and Efficacy of Deucravacitinib (BMS-986165) in Participants With Psoriasis		

ARMS AND INTERVENTIONS

Arm	Intervention/treatment
Experimental: BMS-986165	Drug: BMS-986165 Specified dose on specified days

OUTCOME MEASURES

Primary Outcome Measures: 1. Incidence of Adverse Events (AEs) [Time Frame: Up to 244 weeks]
2. Incidence of Serious Adverse Events (SAEs) [Time Frame: Up to 244 weeks]
Secondary Outcome Measures: 1. static Physician Global Assessment (sPGA) 0/1 response [Time Frame: Up to 240 weeks]
2. Psoriasis Area and Severity Index (PASI) 75 response [Time Frame: Up to 240 weeks]

ELIGIBILITY CRITERIA

Ages Eligible for Study: 18 Years and older (Adult, Older Adult)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

Completion of the protocol-required treatment period in an applicable study of BMS-986165 in moderate-to-severe psoriasis Women must not be pregnant, lactating, or breastfeeding

Exclusion Criteria:

Any disease or medical condition that the investigator feels that would make the patient unsuitable for this study. To be eligible for the study, a participant must not have active signs or symptoms of tuberculosis (TB) as judged by the investigator.

Other protocol-defined inclusion/exclusion criteria apply

CONTACTS AND LOCATIONS

Contacts

Locations

United States, Alabama	Total Skin and Beauty Dermatology Center	Birmingham
United States, Alabama	The Kirklín Clinic of UAB Hospital	Birmingham
United States, Arizona	Alliance Dermatology and Mohs Center - Phoenix	Phoenix
United States, Arizona	Arizona Research Center	Phoenix
United States, Arizona	Synexus - Orange Grove Family Practice	Tucson
United States, Arkansas	Johnson Dermatology	Fort Smith
United States, Arkansas	Burke Pharmaceutical Research	Hot Springs
United States, Arkansas	Northwest Arkansas Clinical Trials Center, PLLC	Rogers
United States, California	First OC Dermatology & Belle-Aimee Skincare Clinic Fountain Valley	Fountain Valley
United States, California	Biomedic Skincare-Reena Simone	Fresno
United States, California	Local Institution - 0017	Irvine
United States, California	Interspond - Long Beach Clinical Trials	Long Beach
United States, California	Dermatology Research Associates - Los Angeles	Los Angeles
United States, California	LA Universal Research Center	Los Angeles
United States, California	University of California San Diego Health Systems	San Diego
United States, California	Therapeutics Clinical Research	San Diego
United States, California	University Dermatology Group	San Diego
United States, California	San Luis Dermatology and Laser Clinic	San Luis Obispo
United States, California	Clinical Science Institute	Santa Monica
United States, California	NorthBay Clinical Research	Santa Rosa
United States, California	Synexus - Santa Rosa	Santa Rosa
United States, California	Unison Clinical Trials	Sherman Oaks
United States, California	Care Access Research - Walnut Creek	Walnut Creek
United States, Connecticut	New England Research Associates	Bridgeport
United States, Connecticut	Stamford Therapeutics Consortium	Stamford
United States, Florida	Skin Care Research	Boca Raton
United States, Florida	ERN - Accel Research Sites	DeLand
United States, Florida	Indago Research and Health Center	Hialeah
United States, Florida	Interspond - Savin Medical Group	Miami Lakes
United States, Florida	San Marcus Research Clinic	Miami Lakes
United States, Florida	LCC Medical Research	Miami
United States, Florida	International Dermatology Research	Miami
United States, Florida	Well Pharma Medical Research	Miami
United States, Florida	Local Institution - 0216	Miami
United States, Florida	Progressive Medical Research	Port Orange
United States, Florida	Local Institution - 0233	Tampa
United States, Florida	Olympian Clinical Research - Tampa Office	Tampa
United States, Georgia	Marietta Dermatology & The Skin Cancer Center	Marietta
United States, Georgia	Advanced Medical Research	Sandy Springs
United States, Idaho	Treasure Valley Dermatology & Skin Cancer Center	Meridian
United States, Illinois	Springfield Clinic	Springfield
United States, Illinois	Dundee Dermatology	West Dundee
United States, Indiana	Deaconess Clinic Downtown	Evansville

United States, Indiana	Clinical Research Advantage - Evansville - South Kenmore Drive	Evansville
United States, Indiana	Dawes Fretzin Dermatology Group	Indianapolis
United States, Indiana	The Indiana Clinical Trials Center	Plainfield
United States, Indiana	The South Bend Clinic	South Bend
United States, Kentucky	Skin Sciences	Louisville
United States, Louisiana	Shondra L. Smith, M.D.	Lake Charles
United States, Louisiana	Clinical Trials of America - Monroe	Monroe
United States, Massachusetts	Tufts Medical Center	Boston
United States, Massachusetts	Local Institution - 0291	Boston
United States, Massachusetts	Ora	Chestnut Hill
United States, Massachusetts	ALLCUTIS Research	Methuen
United States, Massachusetts	DermCare Experts	Quincy
United States, Michigan	David Fivenson MD Dermatology	Ann Arbor
United States, Michigan	Hamzavi Dermatology	Fort Gratiot
United States, Michigan	Local Institution - 0025	Troy
United States, Minnesota	Associated Skin Care Specialists - Minnesota Clinical Study Center	New Brighton
United States, Missouri	Washington University School of Medicine - West County Dermatology	Saint Louis
United States, Nevada	Clinical Research Consortium - Las Vegas	Las Vegas
United States, New Jersey	Hassman Research Institute	Berlin
United States, New Jersey	Psoriasis Treatment Center of Central New Jersey	East Windsor
United States, New York	Montefiore Medical Center - Bronx	Bronx
United States, New York	Forest Hills Dermatology Group	Kew Gardens
United States, New York	Mount Sinai West	New York
United States, New York	Local Institution - 0218	Stony Brook
United States, North Carolina	PMG Research of Cary	Cary
United States, North Carolina	Wilmington Dermatology Center	Wilmington
United States, Ohio	Radiant Research - Columbus	Columbus
United States, Ohio	ClinOhio Research Services	Columbus
United States, Ohio	Wright State Research Institute	Fairborn
United States, Oklahoma	Central Sooner Research	Norman
United States, Oklahoma	Unity Clinical Research	Oklahoma City
United States, Oregon	Oregon Dermatology and Research Center	Portland
United States, Oregon	Local Institution - 0167	Portland
United States, Pennsylvania	Dermatology and Skin Surgery Center - Exton	Exton
United States, Pennsylvania	University of Pittsburgh Medical Center	Pittsburgh
United States, South Carolina	Radiant Research - Anderson	Anderson
United States, South Carolina	Clinical Research Center of the Carolinas	Charleston
United States, South Carolina	Local Institution - 0037	Greer
United States, South Carolina	Coastal Carolina Research Center - Mount Pleasant	North Charleston
United States, South Dakota	Health Concepts	Rapid City
United States, Tennessee	Rivergate Dermatology - Main Office	Goodlettsville
United States, Tennessee	Clinical Research Solutions - Jackson	Jackson
United States, Tennessee	Dermatology Associates of Knoxville	Knoxville
United States, Tennessee	The Skin Wellness Center	Knoxville
United States, Texas	Local Institution - 0006	Arlington

United States, Texas	Bellaire Dermatology	Bellaire
United States, Texas	Dermatology Treatment and Research Center	Dallas
United States, Texas	Local Institution - 0195	Dallas
United States, Texas	Radiant Research - Dallas	Dallas
United States, Texas	Menter Dermatology Research Institute	Dallas
United States, Texas	Center for Clinical Studies - Texas Medical Center	Houston
United States, Texas	Austin Institute for Clinical Research - Pflugerville	Pflugerville
United States, Texas	University of Texas Health Science Center at San Antonio	San Antonio
United States, Texas	Dermatology Clinical Research Center of San Antonio	San Antonio
United States, Texas	Interspond - Acclaim Dermatology	Sugar Land
United States, Texas	Interspond - Houston Center for Clinical Research	Sugar Land
United States, Texas	Center for Clinical Studies - Webster	Webster
United States, Washington	Dermatology Associates of Seattle	Seattle
Australia, Australian Capital Territory	Woden Dermatology	Phillip
Australia, New South Wales	Holdsworth House Medical Practice	Darlinghurst
Australia, New South Wales	St. George Dermatology & Skin Care Centre	Kogarah
Australia, New South Wales	Westmead Hospital	Westmead
Australia, Queensland	The Skin Centre	Benowa
Australia, Queensland	Veracity Clinical Research	Woolloongabba
Australia, South Australia	North Eastern Health Specialists	Hectorville
Australia, Victoria	Box Hill Hospital	Box Hill
Australia, Victoria	Skin and Cancer Foundation	Carlton
Australia, Victoria	Sinclair Dermatology	East Melbourne
Australia, Victoria	The Royal Melbourne Hospital	Parkville
Australia, Western Australia	Fremantle Dermatology	Fremantle
Canada, Alberta	Beacon Dermatology	Calgary
Canada, Alberta	Stratica Medical	Edmonton
Canada, British Columbia	SkinFit MD Laser and Cosmetic Clinic	Surrey
Canada, British Columbia	University of British Columbia	Vancouver
Canada, Manitoba	Wiseman Dermatology Research	Winnipeg
Canada, Ontario	CCA Medical Research	Ajax
Canada, Ontario	Mediprobe Research	London
Canada, Ontario	DermEffects	London
Canada, Ontario	Lynderm Research	Markham
Canada, Ontario	DermEdge	Mississauga
Canada, Ontario	North Bay Dermatology Centre	North Bay
Canada, Ontario	Office of Dr. Niakosari Firouzeh	North York
Canada, Ontario	Institute of Cosmetic and Laser Surgery	Oakville
Canada, Ontario	Skin Centre for Dermatology	Peterborough
Canada, Ontario	The Centre for Dermatology - Richmond Hill	Richmond Hill
Canada, Ontario	Toronto Dermatology Centre	Toronto
Canada, Ontario	Dermatology on Bloor	Toronto
Canada, Ontario	Kim Papp Clinical Research	Waterloo
Canada, Ontario	XLR8 Medical Research	Windsor
Canada, Quebec	Docteur David Gratton Dermatologue	Montreal

Canada, Quebec	Siena Medical Research	Montreal
Canada	Centre de Recherche Dermatologique du Quebec Metropolitain	Quebec
China, Beijing	Local Institution	Beijing
China, Beijing	Local Institution	Beijing
China, Chongqing	Local Institution	Chongqing
China, Hubei	Local Institution	Wuhan
China, Hubei	Local Institution	Wuhan
China, Jiangsu	Local Institution - 0312	Nanjing
China, Jilin	Local Institution	Changchun
China, Liaoning	Local Institution	Dalian
China, Shanxi	Local Institution	Taiyuan
China, Shanghai	Local Institution	Shanghai
China, Sichuan	Local Institution	Chengdu
China, Zhejiang	Local Institution	Hangzhou
China, Zhejiang	Local Institution	Hangzhou
China, Zhejiang	Local Institution	Hangzhou
China, Zhejiang	Local Institution	Hangzhou
Czechia	Nemocnice Jihlava	Jihlava 1
Czechia	Nemocnice Novy Jicin a.s.	Novy Jicin
Czechia	MUDr. Helena Korandova	Olomouc
Czechia	Fakultni Nemocnice Ostrava	Ostrava
Czechia	Clintrial	Praha 10
Czechia	Sanatorium profesora Arenbergera	Praha 1
Czechia	Krajska zdravotni - Masarykova nemocnice v Usti nad Labem	Usti nad Labem
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France	Centre Hospitalier Universitaire de Nice Hopital IArchet	Nice cedex 3
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Germany	Hautarztpraxis Dr. Niesmann & Dr. Othlinghaus	Bochum
Germany	Hautarztpraxis Dr. Beatrice Gerlach	Dresden
Germany	Synexus Frankfurt Clinical Research	Frankfurt am Main
Germany	Local Institution - 0263	Hamburg
Germany	Dermakiel - Allergie Und Haut Centrum	Kiel
Germany	Praxis Dr. Beate Schwarz	Langenau
Germany	Praxis Dr. med. Wilfried Steinborn	Straubing
Germany	CentroDerm Privatlinik	Wuppertal
Hungary	Qualiclinic Egyszegugyi Szolgaltato es Kutatasszervezo Kft.	Budapest
Hungary	Synexus Magyarország	Budapest
Hungary	Semmelweis Egyetem	Budapest
Hungary	Synexus Magyarország Egyszegugyi Szolgaltato - Debrecen Affiliated Site	Debrecen
Hungary	Debreceni Egyetem Klinikai Kozpont	Debrecen
Hungary	Synexus Magyarország Egyszegugyi Szolgaltato - Gyula	Gyula
Hungary	Josa Andras Oktatokorhaza - Szabolcs Szatmar-Bereg Megyei Onkormanyzat	Nyiregyhaza
Hungary	Pecsi Tudomanyegyetem Klinikai Kozpont	Pecs
Hungary	Allergo-Derm Bakos	Szolnok
Hungary	Synexus Magyarország Egyszegugyi Szolgaltato - Zalaegerszeg	Zalaegerszeg

Israel	Local Institution	Haifa
Israel	Local Institution	Petah Tikva
Israel	Local Institution	Ramat Gan
Japan, Aichi	Nagoya City University Hospital	Nagoya
Japan	Local Institution - 0073	Osaka
Japan, Fukuoka	Fukuoka University Hospital	Fukuoka-shi
Japan, Hokkaido	Sapporo Skin Clinic	Sapporo
Japan, Hyogo	Kobe University Hospital	Kobe
Japan, Kanagawa	Tokai University Hospital	Isehara City
Japan, Kanagawa	Local Institution - 0075	Yokohama-Shi
Japan, Kanagawa	Yokohama City University Hospital	Yokohama
Japan, Kochi	Local Institution - 0076	Nankoku
Japan, Kyoto	University Hospital - Kyoto Prefectural University of Medicine	Kyoto-city
Japan, Kyoto	Kyoto University Hospital	Kyoto-City
Japan, MIE	Mie University Hospital	Tsu
Japan, Nagano	Shinshu University Hospital	Matsumoto
Japan, Okayama	Kurashiki Central Hospital	Kurashiki
Japan, Shizuoka	Hamamatsu University Hospital	Hamamatsu
Japan, Tochigi	Jichi Medical University Hospital	Shimotsuke
Japan, Tokyo	Teikyo University Hospital	Itabashi-Ku
Japan, Tokyo	Nihon University Itabashi Hospital	Itabashi-ku
Japan, Tokyo	The Jikei University Hospital	Minato-ku
Japan, Tokyo	NTT Medical Center Tokyo	Shinagawa
Japan, Tokyo	Tokyo Medical University Hospital	Shinjuku-ku
Japan, Tokyo	Japan Community Health Care Organization Tokyo Yamate Medical Center	Shinjuku-ku
Japan	Kumamoto University Hospital	Kumamoto
Japan	Nippon Life Hospital	Osaka
Korea, Republic of	Local Institution	Bucheon-si
Korea, Republic of	Local Institution	Busan
Korea, Republic of	Local Institution	Goyang-si
Korea, Republic of	Local Institution - 0310	Gwangju
Korea, Republic of	Local Institution	Hwaseong-si
Korea, Republic of	Local Institution	Incheon
Korea, Republic of	Local Institution	Incheon
Korea, Republic of	Local Institution	Seongnam-si
Korea, Republic of	Local Institution	Seongnam-si
Korea, Republic of	Local Institution	Seoul
Korea, Republic of	Local Institution - 0305	Seoul
Korea, Republic of	Local Institution	Seoul
Korea, Republic of	Local Institution	Seoul
Korea, Republic of	Local Institution	Seoul
Korea, Republic of	Local Institution	Seoul
Korea, Republic of	Local Institution	Seoul
Korea, Republic of	Local Institution	Seoul
Korea, Republic of	Local Institution	Suwon
New Zealand	Local Institution	Mount Cook

New Zealand	Local Institution	Tauranga
Poland	Local Institution - 0104	Bialystok
Poland	ZDROWIE OSTEO-MEDIC s.c. Lidia i Artur Racewicz, Agnieszka i Jerzy Supronik	Bialystok
Poland	ClinicMed Daniluk Nowak Spolka Jawna	Bialystok
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Poland	Synexus Polska Oddzial w Gdansk	Gda?sk
Poland	Synexus Polska Oddzial w Gdyni	Gdynia
Poland	Zespol Naukowo-Lecznicy Iwolang	Iwonicz-Zdroj
Poland	Synexus - Katowice	Katowice
Poland	Krakowskie Centrum Medyczne	Krakow
Poland	Pratia MCM Krakow	Krak
Poland	Centrum Terapii Wspolczesnej	Lodz
Poland	Dermed Centrum Medyczne	Lodz
Poland	Dermoklinika Centrum Medyczne S.C. M. Kierstan, J. Narbutt, A. Lesiak	Lodz
Poland	Centrum Medyczne All-Med	Lodz
Poland	Niepubliczny Zaklad Opieki Zdrowotnej MED-LASER	Lublin
Poland	Miejski Szpital Zespolony w Olsztynie	Olsztyn
Poland	DermoDent - Centrum Medyczne Czajkowsy	Osielsko
Poland	Solumed Centrum Medyczne	Poznan
Poland	Local Institution - 0103	Poznan
Poland	ETG - Siedlce	Siedlce
Poland	ETG - Skierniewice	Skierniewice
Poland	Local Institution - 0125	Torun
Poland	Klinika Ambroziak	Warsaw
Poland	Clinical Research Group	Warszawa
Poland	High-Med Przychodnia Specjalistyczna	Warszawa
Poland	ETG - Warszawa	Warszawa
Poland	Royalderm Agnieszka Nawrocka	Warszawa
Poland	Cityclinic Przychodnia Lekarsko-Psychologiczna Matusiak Spolka Partnerska	Wroc?aw
Poland	dermMedica Sp. z o.o.	Wroclaw
Poland	WroMedica	Wroclaw
Poland	Centrum Medyczne Oporow	Wroclaw
Puerto Rico	GCM Medical Group	San Juan
Russian Federation	Ural Scientific Research Institute of Dermatovenereology and Immunopathology	Ekaterinburg
Russian Federation	Azbuka Zdorovyia Medical Center	Kazan
Russian Federation	SBHI Clinical Skin and Venereology Dispensary of the Ministry of Health of Krasnodar Region	Krasnodar
Russian Federation	NIARMEDIK - Clinic on Clinic on Kitai Gorod	Moscow
Russian Federation	Clinical Medical Center of Moscow State Medico-Stomatological University named after AI Evdokimov	Moscow
Russian Federation	Ars Vitae Multidisciplinary Medical Center	Moscow
Russian Federation	State budgetary institution of Ryazan region - Regional Clinical Skin and Venereal Dispensary	Ryazan
Russian Federation	Clinic of Skin Diseases of Pierre Wolkenstein	Saint Petersburg
Russian Federation	Polyclinic of Private Security Personnel	Saint Petersburg
Russian Federation	Saint-Petersburg SBHI Dermatological and Venereological Dispensary No. 10 - Clinic of Dermatology	Saint Petersburg

Russian Federation	Klinika Kozhnykh I Venericheskikh Bolezney	Saratov
Russian Federation	Smolensk State Medical University	Smolensk
Russian Federation	MUZ Clinical Hospital of Emergency Medical Care n.a. N.V. Soloviev	Yaroslavl
Spain	Local Institution - 0223	Alcorcon
Spain	Hospital Universitari Germans Trias i Pujol	Badalona
Spain	Hospital Universitario Cruces	Barakaldo
Spain	Local Institution - 0225	Cordoba
Spain	Hospital Universitario de Gran Canaria Doctor Negrin	Las Palmas De Gran Canaria
Spain	Hospital Universitario Ramon Y Cajal	Madrid
Spain	Hospital de Manises	Manises
Spain	Hospital Universitario Virgen de la Victoria	Mãa
Spain	Hospital Universitario Quironsalud Madrid	Pozuelo de Alarcon
Sweden	Ladulaas Kliniska Studier	Boras
Sweden	ProbarE i Lund	Lund
Sweden	Local Institution - 0186	Solna
Taiwan	Local Institution	Kaohsiung
Taiwan	Local Institution - 0297	Kaohsiung
Taiwan	Local Institution	Taipei City
Taiwan	Local Institution	Taipei
Taiwan	Local Institution - 0153	Taipei
Taiwan	Local Institution	Taipei
Taiwan	Local Institution	Taipei
United Kingdom	MAC Clinical Research - Cannock	Cannock
United Kingdom	Synexus - Lancashire Clinical Research Centre	Chorley
United Kingdom	Synexus - Manchester Clinical Research Centre	Chorley
United Kingdom	Synexus - Merseyside Clinical Research Centre	Chorley
United Kingdom	Mounts Bay Medical	Cornwall
United Kingdom	The Dudley Group NHS Foundation Trust	Dudley
United Kingdom	MAC Clinical Research - Stockton	Durham
United Kingdom	MAC Clinical Research - Blackpool	Lancashire
United Kingdom	Burbage Surgery	Leicestershire
United Kingdom	Guys and Saint Thomas NHS Foundation Trust	London
United Kingdom	MAC Clinical Research - Manchester	Manchester
United Kingdom	Salford Royal NHS Foundation Trust	Manchester
United Kingdom	MAC Clinical Research - Liverpool	Prescot

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 : NCT04036435

Other Study ID Numbers : IM011-075, 2019-000612-29

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Studies a U.S. FDA-regulated Drug Product: Yes
Studies a U.S. FDA-regulated Device Product: No
Keywords provided by Bristol-Myers Squibb: *Psoriasis*
Additional relevant MeSH terms : *Psoriasis* *Skin Diseases*
Skin Diseases,
Papulosquamous