A Study to Assess Adjuvant Immunotherapy With Nivolumab Plus Relatlimab Versus Nivolumab Alone After Complete Resection of Stage III-IV Melanoma

CLINICALTRIALS.GOV IDENTIFIER	RECRUITMENT STATUS	FIRST POSTED	LAST UPDATE POSTED
NCT05002569	RECRUITING	AUGUST 12, 2021	SEPTEMBER 22, 2022

STUDY DESCRIPTION

Brief Summary

The purpose of this study is to assess nivolumab plus relatlimab fixed-dose combination (FDC) versus nivolumab alone in participants with completely resected stage III-IV melanoma.

Condition or Disease: Melanoma

Intervention/treatment: Biological: Nivolumab
Biological: Nivolumab + Relatlimab Fixed Dose Combination

Phase: Phase 3

DETAILED DESCRIPTION

N/A

STUDY DESIGN

Study Type: Interventional

Estimated Enrollment : 1050 participants

Allocation : Randomized

Intervention Model : Parallel Assignment

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Primary Purpose: Treatment

Official Title: A Study to Assess Adjuvant Immunotherapy With Nivolumab Plus Relatlimab Versus Nivolumab Alone After Complete Resection of Stage III-IV Melanoma

Actual Study Start Date: October 2021

Estimated Primary Completion Date: December 2025

Estimated Study Completion Date: December 2025

ARMS AND INTERVENTIONS

Arm	Intervention/treatment
Experimental: Arm B: Nivolumab Monotherapy	Biological: Nivolumab Specified dose on specified days
Experimental: Arm A: Nivolumab Plus Relatlimab Combination	Biological: Nivolumab + Relatlimab Fixed Dose Combination Specified dose on specified days

OUTCOME MEASURES

Primary Outcome Measures: 1. Recurrence-Free Survival (RFS) time per Investigator assessment [Time Frame: Until recurrence, up to 59 months]

Secondary Outcome Measures:
1. Progression-Free Survival 2 (PFS2) [Time Frame: Until second recurrence, up to 5 years]
2. Overall Survival (OS) [Time Frame: Until death, up to 96 months]
3. Distant Metastasis-Free Survival (DMFS) time per Investigator assessment [Time Frame: Until distant progression, up to 96 months]
4. Incidence of Adverse Events (AEs) [Time Frame: 30 days from participant's last dose]
5. Severity of AEs [Time Frame: 30 days from participant's last dose]
6. Incidence of Serious Adverse Events (SAEs) [Time Frame: 30 days from participant's last dose]
7. Severity of SAEs [Time Frame: 30 days from participant's last dose]
8. Incidence of AEs leading to discontinuation (DC) [Time Frame: 30 days from participant's last dose]
9. Severity of AEs leading to DC [Time Frame: 30 days from participant's last dose]
10. Incidence of immune-mediated AEs (IMAEs) [Time Frame: 135 days from participant's last dose]
11. Severity of IMAEs [Time Frame: 135 days from participant's last dose]
12. Incidence of drug related AEs [Time Frame: 30 days from participant's last dose]
13. Severity of drug related AEs [Time Frame: 30 days from participant's last dose]
14. Incidence of deaths [Time Frame: 30 days from participant's last dose]
15. Incidence of clinically significant changes in clinical laboratory values: Hematology tests [Time Frame: 30 days from participant's last dose]
16. Incidence of clinically significant changes in clinical laboratory values: Chemistry tests [Time Frame: 30 days from participant's last dose]
17. Duration of Treatment on next line therapies [Time Frame: Until end of next-line therapy, up to 5 years]

ELIGIBILITY CRITERIA

Ages Eligible for Study: 12 Years and older (Child, Adult, Older Adult)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:
Must have been diagnosed with either Stage IIIA (> 1 mm tumor in lymph node)/B/C/D or Stage IV melanoma by American Joint Committee on Cancer (AJCC) v8 and have histologically confirmed melanoma that is completely surgically resected (free of disease) with negative margins in order to be eligible Participants ≥ 18 years of age must have an Eastern Cooperative Oncology Group (ECOG) performance status of ≤ 1. Adolescent participants between 12 and 17 years of age must have a Lansky/Karnofsky performance score ≥ 80% Complete resection must be performed within 90 days prior to randomization All participants must have disease-free status documented by a complete physical examination within 14 days prior to randomization and imaging studies within 35 days prior to randomization Tumor tissue must be provided for biomarker analyses
Exclusion Criteria:
History of ocular melanoma Untreated/unresected CNS metastases or leptomeningeal metastases Active, known, or suspected autoimmune disease Participants with serious or uncontrolled medical disorder Prior immunotherapy treatment for any prior malignancy: No prior immunotherapies are permitted Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection within 4 weeks prior to screening History of myocarditis, regardless of etiology. Other protocol-defined inclusion/exclusion criteria apply

CONTACTS AND LOCATIONS

Contacts

Contact: BMS Study Connect Contact Center http://www.bmsstudyconnect.com/ 855-907-3286 Clinical.Trials@bms.com
Contact: First line of email MUST contain NCT # and Site #.

Locations

Italy	Local Institution - 0119	Napoli
Italy	Local Institution - 0123	Milano
Italy	Local Institution - 0115	Milan
Italy	Local Institution - 0268	Milan
Italy	Local Institution - 0120	Padova
Italy	Local Institution - 0122	Perugia
Italy	Local Institution - 0121	Siena
United States, Alabama	Local Institution	Birmingham
United States, Arkansas	Highlands Oncology Group-Research Department	Springdale
United States, California	The Angeles Clinic And Research Institute.	Los Angeles
United States, California	Local Institution	Palo Alto
United States, California	San Francisco Oncology Associates	San Francisco
United States, Colorado	Local Institution	Aurora
United States, District of Columbia	Georgetown University Medical Center Lombardi Cancer Center	Washington
United States, Florida	Local Institution	Miami
United States, Florida	University of Miami Hospital and Clinics, Sylvester Cancer Center	Miami
United States, Florida	Sacred Heart Medical Group	Pensacola
United States, Georgia	Winship Cancer Institute of Emory University	Atlanta
United States, Georgia	Northside Hospital	Atlanta
United States, Illinois	Northwestern Memorial Hospital	Chicago
United States, Illinois	Illinois Cancercare, PC	Peoria
United States, Indiana	Fort Wayne Medical Oncology and Hematology, Inc.	Fort Wayne
United States, Iowa	Local Institution	Iowa City
United States, Kansas	Local Institution	Kansas City
United States, Michigan	University Of Michigan	Ann Arbor
United States, Michigan	Local Institution	Grand Rapids

United States, Minnesota	Virginia Piper Cancer Institute	Minneapolis
United States, New Jersey	John Theurer Cancer Center	Hackensack
United States, New Jersey	Atlantic Health System Morristown Medical Center	Morristown
United States, New York	NYU Langone Health-Perlmutter Cancer Center	New York
United States, New York	Memorial Sloan Kettering Nassau	New York
United States, North Carolina	Levine Cancer Institute-Cutaneous Malignancies/Immunotherapy	Charlotte
United States, North Carolina	Duke Cancer Institute	Durham
United States, Ohio	Cleveland Clinic-Taussig Cancer Center	Cleveland
United States, Pennsylvania	Lehigh Valley Health Network	Allentown
United States, Pennsylvania	UPMC Hillman Cancer Center	Pittsburgh
United States, South Carolina	Medical University Of South Carolina	Charleston
United States, Tennessee	The West Clinic	Germantown
United States, Tennessee	Vanderbilt-Ingram Cancer Center	Nashville
United States, Texas	Texas Oncology-Central Austin Cancer Center	Austin
United States, Texas	Texas Oncology Sammons Cancer Center	Dallas
United States, Texas	University of Texas MD Anderson Cancer Center-Melanoma Medical Oncology	Houston
United States, Virginia	Inova Schar Cancer Institute	Fairfax
Argentina, Cordoba	Local Institution - 0004	Córdoba
Argentina, Distrito Federal	Local Institution - 0001	Caba
Argentina, Distrito Federal	Local Institution - 0005	Ciudad Autónoma de Buenos Aires
Argentina, Distrito Federal	Local Institution - 0002	Ciudad de Buenos Aires
Argentina	Local Institution - 0003	Buenos Aires
Australia, New South Wales	Local Institution - 0030	Waratah
Australia, New South Wales	Local Institution - 0252	Westmead
Australia, New South Wales	Local Institution - 0032	Wollstonecraft
Australia, Northern Territory	Local Institution - 0254	Tiwi
Australia, Queensland	Local Institution - 0028	Brisbane
Australia, Queensland	Local Institution - 0027	Southport
Australia, South Australia	Local Institution - 0250	Woodville
Australia, Victoria	Local Institution	Ballarat Central
Australia, Victoria	Local Institution - 0035	Ballarat
Australia, Victoria	Local Institution - 0253	Heidelberg
Australia, Victoria	Local Institution - 0031	Melbourne
Australia, Western Australia	Local Institution - 0251	Murdoch
Australia, Western Australia	Local Institution - 0029	Perth
Austria, Steiermark	Local Institution - 0082	Graz
Austria	Local Institution - 0086	Salzburg
Austria	Local Institution - 0084	Vienna
Belgium	Local Institution - 0110	Brussels
Belgium	Local Institution - 0105	Brussels
Belgium	Local Institution - 0109	Liège
Belgium	Local Institution - 0106	Wilrijk
Brazil, Bahia	Local Institution - 0071	Salvador
Brazil, Ceara	Local Institution - 0072	Fortaleza
Brazil, Espirito Santo	Local Institution - 0068	Vitória

Brazil, Minas Gerais	Local Institution - 0047	Belo Horizonte
Brazil, Rio Grande Do Sul	Local Institution - 0056	Ijui
Brazil, RIO Grande DO SUL	Local Institution - 0257	Porto Alegre
Brazil, RIO Grande DO SUL	Local Institution - 0049	Porto Alegre
Brazil, RIO Grande DO SUL	Local Institution - 0048	Santa Cruz do Sul
Brazil, SAO Paulo	Local Institution - 0070	Barretos
Brazil	Local Institution - 0058	Rio de Janeiro
Canada, British Columbia	Local Institution	Vancouver
Canada, Nova Scotia	Local Institution - 0197	Halifax
Canada, Ontario	Local Institution	Toronto
Canada, Quebec	Local Institution - 0158	Montreal
Canada, Quebec	Local Institution - 0159	Montréal
Canada, Quebec	Local Institution - 0160	Quebec City
Canada, Quebec	Local Institution	Sherbrooke
Canada	Local Institution - 0155	Edmonton
Chile, Metropolitana	Local Institution - 0013	Santiago
Chile, Metropolitana	Local Institution - 0006	Santiago
Chile, Metropolitana	Local Institution - 0014	Santiago
China, Beijing	Local Institution - 0259	Beijing
China, Beijing	Local Institution - 0261	Beijing
China, Beijing	Local Institution - 0214	Beijing
China, Chongqing	Local Institution - 0241	Chongqing
China, Fujian	Local Institution - 0245	Fuzhou City
China, Guangdong	Local Institution - 0217	Guangzhou
China, Henan	Local Institution - 0226	Zhengzhou Shi
China, Hubei	Local Institution - 0237	Wuhan
China, Hunan	Local Institution - 0234	Changsha Shi
China, Jiangsu	Local Institution - 0215	Nanjing
China, Jilin	Local Institution - 0219	Changchun
China, Liaoning	Local Institution - 0242	Shenyang
China, Sichuan	Local Institution	Chengdu
China, Tianjin	Local Institution	Tianjin
China, Xinjiang	Local Institution	Urumqi
China, Yunnan	Local Institution - 0222	Kunming
China, Zhejiang	Local Institution	Hangzhou
China	Local Institution - 0244	Taiyuan
Czechia	Local Institution - 0156	Brno
Czechia	Local Institution - 0091	Hradec Kralove
Czechia	Local Institution - 0026	Ostrava
Czechia	Local Institution - 0062	Prague
Denmark	Local Institution - 0022	Aalborg
Denmark	Local Institution - 0018	Copenhagen
Denmark	Local Institution - 0020	Odense
Finland	Local Institution - 0007	Helsinki
Finland	Local Institution - 0019	Tampere

Finland	Local Institution - 0015	Turku
France, Val-de-Marne	Local Institution - 0040	Villejuif
France	Local Institution - 0043	Dijon
France	Local Institution - 0044	Marseille
France	Local Institution - 0039	Nantes
France	Local Institution - 0042	Paris
France	Local Institution - 0041	Pierre-Bénite
France	Local Institution - 0046	Toulouse
Germany	Local Institution - 0073	Buxtehude
Germany	Local Institution - 0077	Dresden
Germany	Local Institution - 0074	Erlangen
Germany	Local Institution - 0131	Essen
Germany	Local Institution - 0081	Gera
Germany	Local Institution - 0079	Hannover
Germany	Local Institution - 0075	Heidelberg
Germany	Local Institution - 0078	Lübeck
Germany	Local Institution - 0083	Minden
Germany	Local Institution - 0076	Munich
Germany	Local Institution - 0092	Tübingen
Germany	Local Institution - 0080	Wuerzburg
Greece	Local Institution - 0114	Athens
Greece	Local Institution - 0113	Neo Faliro
Greece	Local Institution - 0112	Thessaloniki
Israel	Local Institution - 0116	Afula
Israel	Local Institution - 0118	Jerusalem
Israel	Local Institution - 0199	Ramag Gan
Israel	Local Institution - 0117	Ramat Gan
Mexico, Distrito Federal	Local Institution - 0100	Benito Juarez
Mexico, Jalisco	Local Institution - 0021	Zapopan
Mexico, Nuevo LEON	Local Institution - 0093	Mexico
Mexico	Local Institution - 0098	Oaxaca
Norway, Akershus	Local Institution - 0009	Lørenskog
Norway	Local Institution - 0017	Oslo
Norway	Local Institution - 0023	Stavanger
Portugal	Local Institution - 0249	Coimbra
Portugal	Local Institution	Lisboa
Portugal	Local Institution	Lisbon
Portugal	Local Institution	Porto
Romania	Local Institution	Brasov
Romania	Local Institution - 0065	Cluj
Romania	Local Institution - 0066	Craiova
Romania	Local Institution - 0064	Floresti/ Cluj
Romania	Local Institution	Iasi
Spain	Local Institution - 0188	Badajoz
Spain	Local Institution - 0201	Barcelona

Spain	Local Institution - 0153	Granada
Spain	Local Institution - 0150	Madrid
Spain	Local Institution - 0151	San Sebastian
Spain	Local Institution - 0152	València
Sweden	Local Institution - 0010	Gothenburg
Sweden	Local Institution - 0011	Lund
Sweden	Local Institution - 0012	Solna
Switzerland	Local Institution - 0085	Basel
Switzerland	Kantonsspital Graubünden-Medizin	Chur
Switzerland	Local Institution - 0090	Zürich
United Kingdom, Lanarkshire	Local Institution - 0187	Glasgow
United Kingdom, Nottinghamshire	Local Institution - 0101	Nottingham
United Kingdom	Local Institution	Bristol
United Kingdom	Local Institution - 0232	Oxford
United Kingdom	Local Institution	Southampton
United Kingdom	Local Institution	Swansea

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 :	NCT05002569
Other Study ID Numbers :	CA224-098, 2021-001641-13
First Posted :	August 12, 2021
Last Update Posted :	September 22, 2022
Last Verified :	September 2022
Studies a U.S. FDA-regulated Drug Product:	Yes
Studies a U.S. FDA-regulated Device Product:	No
Keywords provided by Bristol-Myers Squibb:	*Melanoma* *Relatlimab Nivolumab* *Opdivo*

Additional relevant MeSH terms :

Melanoma	*Neoplasms by Histologic Type*
Neuroendocrine Tumors	*Neoplasms*
Neuroectodermal Tumors	*Neoplasms, Nerve Tissue*
Neoplasms, Germ Cell and Embryonal	*Nevi and Melanomas*