

Record 1 of 1

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Active, not recruiting

A Study to Evaluate Similarity of ABP 206 Compared With OPDIVO® (Nivolumab) in Subjects With Resected Melanoma

ClinicalTrials.gov ID NCT05907122

Sponsor Amgen

Information provided by Amgen (Responsible Party)

Last Update Posted 2024-11-27

Study Details Tab

Study Overview

Brief Summary

The purpose of this study is to investigate the pharmacokinetic (PK) similarity and efficacy, safety, and immunogenicity of ABP 206 compared with OPDIVO® (nivolumab) in subjects with resected advanced melanoma.

Detailed Description

Eligible subjects will be randomized in a 1:1:1 ratio to receive either ABP 206, Food and Drug Administration (FDA)-licensed nivolumab, or European Union (EU)-authorized nivolumab.

The treatment period is in alignment with the maximum treatment duration for OPDIVO® (nivolumab, reference product) in the adjuvant setting for melanoma.

Feedback

All subjects will be treated until recurrence of disease, unacceptable toxicity, or subject withdrawal of consent with a maximum of 1 year of treatment.

The total duration of study participation for each subject will be approximately 13 months.

Official Title

A Randomized, Double-blind Study Evaluating Pharmacokinetic Similarity of ABP 206 Compared With OPDIVO® (Nivolumab) in Resected Stage III or Stage IV Melanoma Subjects in the Adjuvant Setting

Conditions ⓘ

Melanoma

Intervention / Treatment ⓘ

- Drug: ABP 206
- Drug: FDA-licensed Nivolumab
- Drug: EU-authorized Nivolumab

Other Study ID Numbers ⓘ

Study Start (Actual) ⓘ

2023-07-26

Primary Completion (Estimated) ⓘ

2025-10-04

Study Completion (Estimated) ⓘ

2025-11-30

Enrollment (Actual) ⓘ

256

Study Type ⓘ

Interventional

Phase ⓘ

Phase 3

Resource links provided by the National Library of Medicine

[MedlinePlus Genetics](https://medlineplus.gov/genetics/) (<https://medlineplus.gov/genetics/>) related topics:

[Melanoma](https://medlineplus.gov/genetics/condition/melanoma) (<https://medlineplus.gov/genetics/condition/melanoma>).

[MedlinePlus](https://medlineplus.gov/) (<https://medlineplus.gov/>) related topics:

[Melanoma](https://medlineplus.gov/melanoma.html) (<https://medlineplus.gov/melanoma.html>).

[Genetic and Rare Diseases Information Center](https://rarediseases.info.nih.gov/gard) (<https://rarediseases.info.nih.gov/gard>) resources:

[Neuroendocrine Tumor](https://rarediseases.info.nih.gov/diseases/13445/neuroendocrine-tumor) (<https://rarediseases.info.nih.gov/diseases/13445/neuroendocrine-tumor>).

[Neuroepithelioma](https://rarediseases.info.nih.gov/diseases/3963/neuroepithelioma) (<https://rarediseases.info.nih.gov/diseases/3963/neuroepithelioma>).

[Drug Information](https://dailymed.nlm.nih.gov/dailymed/) (<https://dailymed.nlm.nih.gov/dailymed/>) available for:

[Nivolumab](https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Nivolumab) ([https://dailymed.nlm.nih.gov/dailymed/search.cfm?](https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Nivolumab)

[labeltype=human&query=Nivolumab](https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Nivolumab)).

[FDA Drug and Device Resources](https://clinicaltrials.gov/fda-links) (<https://clinicaltrials.gov/fda-links>).

Contacts and Locations

This section provides contact details for people who can answer questions about joining this study, and information on where this study is taking place.

To learn more, please see the [Contacts and Locations section in How to Read a Study Record](https://clinicaltrials.gov/study-basics/how-to-read-study-record#contacts-and-locations) (<https://clinicaltrials.gov/study-basics/how-to-read-study-record#contacts-and-locations>).

This study has 111 locations

United States

California Locations

 **Long Beach, California, United States, 90806**
Cancer and Blood Specialty Clinic

 **Torrance, California, United States, 90502-2004**
The Lundquist Institute - Main

Florida Locations

 **Orlando, Florida, United States, 32804**
AdventHealth

Maryland Locations

-  **Baltimore, Maryland, United States, 21201**
University of Maryland Medical Center-
Greenebaum Cancer Ctr

Montana Locations

-  **Billings, Montana, United States, 59102-6746**
St. Vincent Frontier Cancer Ctr

Argentina

-  **Caba, Argentina, 1125**
Fundación CENIT
-  **Mar del Plata, Argentina, 7600**
CIMMDP
-  **Rosario, Argentina, 2000**
Instituto de Oncología de Rosario
-  **Santa Fe, Argentina, S3000FFU**
ISIS Clinica Especializada

Río Negro Locations

-  **Viedma, Río Negro, Argentina, R8500ACE**
Clínica Viedma

Bosnia and Herzegovina

-  **Mostar, Bosnia and Herzegovina, 88000**
University Clinical Hospital Mostar
-  **Sarajevo, Bosnia and Herzegovina, 71000**
Clinical Center University of Sarajevo
-  **Tuzla, Bosnia and Herzegovina, 75000**
University Clinical Center Tuzla
-  **Zenica, Bosnia and Herzegovina, 72000**
Cantonal hospital Zenica

Republika Srpska Locations

-  **Banjaluka, Republika Srpska, Bosnia and Herzegovina, 78000**
University Clinical Centre of the Republic of
Srpska - Gastroenterology

Brazil

-  **Curitiba, Brazil**
Instituto de Oncologia do Parana

 **Rio de Janeiro, Brazil, 20231-050**
Instituto Nacional de Câncer - INCA

Bahia Locations

 **Salvador, Bahia, Brazil**
Hospital Sao Rafael

Ceará Locations

 **Fortaleza, Ceará, Brazil, 60140-025**
Centro de Oncologia Leonardo da Vinci -ATO
Oncologia

Distrito Federal Locations

 **Brasilia, Distrito Federal, Brazil, 70200 730**
Hospital Sirio Libanes - Brasilia

Pará Locations

 **Belém, Pará, Brazil, 66063-495**
Centro de Tratamento Oncologico

Rio Grande Do Sul Locations

 **Porto Alegre, Rio Grande Do Sul, Brazil, 90610-000**
Hospital Sao Lucas da PUCRS

Santa Catarina Locations

 **Florianopolis, Santa Catarina, Brazil, 888034-000**
CEPON - Centro de Pesquisas Oncológicas

São Paulo Locations

-  **Barretos, São Paulo, Brazil, 14784 400**
Hospital de Cancer de Barretos
-  **Sao Paulo, São Paulo, Brazil, CEP 04501-000**
Hospital e Maternidade Brasil
-  **São José do Rio Preto, São Paulo, Brazil, 15090-000**
Fac Med de Sao Jose do Rio Preto

Chile

-  **Santiago, Chile, 7500653**
Centro de Estudios Clínicos SAGA SpA
-  **Viña Del Mar, Chile, 2520612**
Oncocentro APYS

Croatia

Grad Zagreb Locations

-  **Zagreb, Grad Zagreb, Croatia, 10 000**
University Hospital Centre Zagreb
-  **Zagreb, Grad Zagreb, Croatia, 10000**
KBC "Sestre milosrdnice"

France

Haute-Vienne Locations

-  **Poitiers, Haute-Vienne, France, 21079**
CHU de Poitiers

Hauts-de-Seine Locations

-  **Boulogne Billancourt cedex, Hauts-de-Seine, France, 92104**
Hopital Ambroise Paré - Dermatologie

Georgia

-  **Tbilisi, Georgia, 0112**
ISR-GEO Med Res Clin Healthycore
-  **Tbilisi, Georgia, 0112**
LLC "Todua Clinic"
-  **Tbilisi, Georgia, 0159**
JSC KE Nat Ctr of Exp and Clin Surg

Germany

-  **Berlin, Germany, 10117**
Charité - Universitätsmedizin Berlin Kör

Nordrhein-Westfalen Locations

-  **Köln, Nordrhein-Westfalen, Germany, 50937**
University Hospital Cologne AöR

Thüringen Locations

-  **Gera, Thüringen, Germany, 07548**
SRH Wald-Klinikum Gera gGmbH

Italy

-  **Bari, Italy, 70124**
Istituto dei Tumori "Giovanni Paolo II"

-  **Bergamo, Italy, 24127**
ASST Papa Giovanni XXIII
-  **Milano, Italy, 20132**
Ospedale San Raffaele, IRCCS
-  **Milano, Italy, 20141**
Istituto Europeo di Oncologia IRCCS
-  **Napoli, Italy, 80131**
Azienda Ospedaliera Universitaria Federico II
-  **Pavia, Italy, 27100**
Fondazione IRCCS Policlinico San Matteo
-  **Roma, Italy, 00167**
Istituto Dermopatico dell'Immacolata (IDI) -
IRCCS
-  **Siena, Italy, 53100**
Azienda ospedaliero Universitaria Senese -
Policlinico Le Scotte
-  **Varese, Italy, 21100**
ASST Sette Laghi - Ospedale di Circolo
Fondazione Macchi

Forli Locations

-  **Meldola, Forli, Italy, 47014**
Istituto Romagnolo Per Lo Studio Dei Tumori
Dino Amadori IRST S.R.L

Japan

-  **Kumamoto, Japan, 860-8556**
Kumamoto University Hospital - Dermatology
-  **Niigata, Japan, 951-8566**
Niigata Cancer Center Hospital

Aiti [Aichi] Locations

-  **Nagoya, Aiti [Aichi], Japan, 467-8601**
Nagoya City University Hospital - Dermatology

Hokkaidô [Hokkaido] Locations

-  **Sapporo-Shi, Hokkaidô [Hokkaido], Japan,
060-8543**
Sapporo Medical University Hospital

Kagoshima [Kagoshima] Locations

-  **Kagoshima-Shi, Kagoshima [Kagoshima],
Japan, 892-0853**
NHO Kagoshima Medical Center

Tôkyô [Tokyo] Locations

-  **Koto-Ku, Tôkyô [Tokyo], Japan, 135-8550**
Shizuoka Cancer Center - Dermatology
-  **Shinjuku-ku, Tôkyô [Tokyo], Japan, 160-8582**
Keio University Hospital - Dermatology

Ôsaka [Osaka] Locations

-  **Ôsaka-shi, Ôsaka [Osaka], Japan, 541-8567**
Osaka International Cancer Institute -
Dermatological Oncology

Korea, Republic of

Busan Gwang'yeoksi [Pusan-Kwan
Locations

-  **Busan, Busan Gwang'yeoksi [Pusan-Kwan,
Korea, Republic of, 48108**
Inje University Haeundae Paik Hospital

Seoul Teugbyeolsi [Seoul-T'ukp Locations

-  **Seoul, Seoul Teugbyeolsi [Seoul-T'ukp, Korea,
Republic of, 03722**
Severance Hospital, Yonsei University Health
System
-  **Seoul, Seoul Teugbyeolsi [Seoul-T'ukp, Korea,
Republic of, 05505**
Asan Medical Center
-  **Seoul, Seoul Teugbyeolsi [Seoul-T'ukp, Korea,
Republic of, 06351**
Samsung Medical Center

Malaysia

Kelantan Locations

-  **Kubang Kerian, Kelantan, Malaysia, 16150**
Hospital Universiti Sains Malaysia

Pahang Locations

-  **Pulau Pinang, Pahang, Malaysia**
Hospital Pulau Pinang

Sarawak Locations

-  **Kuching, Sarawak, Malaysia, 93586**

Hospital Umum Sarawak

-  **Kuching, Sarawak, Malaysia**
Hospital Umum Sarawak

Selangor Locations

-  **Putrajaya, Selangor, Malaysia, 62250**
Institut Kanser Negara

Wilayah Persekutuan Kuala Lumpur Locations

-  **Kuala Lumpur, Wilayah Persekutuan Kuala Lumpur, Malaysia, 56000**
Hospital Canselor Tuanku Muhriz UKM
-  **Kuala Lumpur, Wilayah Persekutuan Kuala Lumpur, Malaysia**
Hospital Kuala Lumpur

Mexico

-  **Aguascalientes, Mexico, 20115**
Centro de Inv Medica Aguascalientes
-  **Mexico City, Mexico, 14080**
Oncare Viaducto Napoles
-  **Puebla, Mexico, 72530**
Clinica Integral Internac Oncologia
-  **San Pedro Garza Garcia, Mexico, 66278**
Althian Research Management Center
-  **San Pedro Garza García, Mexico, 66278**
Centro Medico Zambrano Hellion
-  **Tlalnepantla de Baz, Mexico**
Clinical Research Institute S.C.

Jalisco Locations

-  **Guadalajara, Jalisco, Mexico, 44630**
Centro Inmuno Oncolog de Occidente

Nuevo León Locations

-  **Monterrey, Nuevo León, Mexico, 64710**
I CAN ONCOLOGY CENTER SA de CV

San Luis Potosí Locations

-  **San Luis Potosi, San Luis Potosí, Mexico, 78200**
Ctro At Inv Cardio Potosi

Yucatán Locations

-  **Merida, Yucatán, Mexico, 97134**
Centro De Atenc E Inv Clín En Onco

Moldova, Republic of

-  **Chisinau, Moldova, Republic of, MD-2025**
IMSP Institutul Oncologic, ARENSIA

Netherlands

Noord-Brabant Locations

-  **Breda, Noord-Brabant, Netherlands, 4818 CK**
Amphia Ziekenhuis (Amphia Hospital Breda) -
Locatie Molengracht

Romania

-  **Bucuresti, Romania, 022328**
Arensia - Iob

Cluj Locations

-  **Cluj-Napoca, Cluj, Romania, 400015**
Arensia - Iocn

Serbia

-  **Belgrade, Serbia, 11000**
Military Medical Academy
-  **Belgrade, Serbia, 11070**
Specialized hospital Oncomed System
-  **Beograd, Serbia**
Institute for Oncology and Radiology of Serbia
-  **Kragujevac, Serbia, 34000**
University Clinical Center Kragujevac
-  **Nis, Serbia, 18108**
University Clinical Center Nis

Vojvodina Locations

-  **Sremska Kamenica, Vojvodina, Serbia, 21204**
Vojvodina Institute for Oncology

South Africa

Gauteng Locations

 **Johannesburg, Gauteng, South Africa, 2196**
Medical Oncology Cent of Rosebank

 **Parktown, Johannesburg, Gauteng, South Africa, 2193**
Wits Clinical Research

 **Pretoria, Gauteng, South Africa, 0181**
Mary Potter Oncology Centre

Western Cape Locations

 **Cape Town, Western Cape, South Africa, 7700**
Rondebosch Oncology Centre

 **Kraaifontein, Western Cape, South Africa, 7570**
Cape Town Oncology Trials

Spain

 **Barcelona, Spain, 08025**
Hospital de La Santa Creu i Sant Pau

 **Barcelona, Spain, 08035**
Hospital Universitari Vall D Hebron

 **Barcelona, Spain, 08036**
Hospital Clinic De Barcelona

 **Valencia, Spain, 46014**
Consortio Hospital General Universitario de Valencia

Andalucía Locations

 **Sevilla, Andalucía, Spain, 41009**
Hospital Universitario Virgen De La Macarena

Barcelona Locations

 **Badalona, Barcelona, Spain, 08916**
Institut Català d'Oncologia-Hospital Universitari Germans Trias i Pujol

Cáceres Locations

 **Caceres, Cáceres, Spain, 10003**
Hospital San Pedro de Alcántara

Madrid Locations

 **Madrid,, Madrid, Spain, 28033**
M.D. Anderson Center Madrid

Murcia, Región De Locations

 **El Palmar, Murcia, Región De, Spain, 30120**
H.U.V.Arrixaca

Taiwan

 **Taipei, Taiwan, 11696**
Taipei Municipal Wanfang Hospital - Managed
by Taipei Medical University

Taichung Municipality Locations

 **Taichung, Taichung Municipality, Taiwan, 40447**
China Medical University Hospital - Internal
Medicine

Taipei Locations

 **New Taipei City, Taipei, Taiwan, 23561**
Taipei Medical University - Shuang Ho Hospital
Ministry of Health and Welfare

Thailand

 **Songkhla, Thailand, 90110**
Prince of Songkla University - Faculty of
Medicine

Khon Kaen Locations

 **Khonkaen, Khon Kaen, Thailand, 40002**
Khon Kaen University, Srinagarind Hospital

Krung Thep Maha Nakhon [Bangko
Locations

 **Bangkok, Krung Thep Maha Nakhon [Bangko, Thailand, 10330**
King Chulalongkorn Memorial Hospital [Medical
Oncology]

 **Bangkok, Krung Thep Maha Nakhon [Bangko, Thailand, 10700**
Siriraj Hospital

Vietnam

Ha Noi, Thu Do Locations

 **Hanoi, Ha Noi, Thu Do, Vietnam, 100000**
Vietnam National Cancer Hopsital

 **Hanoi, Ha Noi, Thu Do, Vietnam, 10000**

Ho Chi Minh, Thanh Pho [Sai Go Locations

 Ho Chi Minh, Ho Chi Minh, Thanh Pho [Sai Go,
Vietnam, 70000
HCM Oncology Hospital

Participation Criteria

Researchers look for people who fit a certain description, called [eligibility criteria](#). Some examples of these criteria are a person's general health condition or prior treatments.

For general information about clinical research, read [Learn About Studies](#) (<https://clinicaltrials.gov/study-basics/learn-about-studies>).

Eligibility Criteria

Description

Inclusion Criteria:

- At least 18 years of age
- Completely removed melanoma by surgery performed within 12 weeks of randomization
- Advanced Melanoma
- Tumor tissue from the resected site of the disease must be available for biomarker analyses in order to be randomized
- Subject has an Eastern Cooperative Oncology Group (ECOG) performance status score of 0 or 1

Exclusion Criteria:

- Previous anti-cancer treatment
- Known hypersensitivity to monoclonal antibodies or to any of the excipients of the study drug
- Ocular or uveal melanoma or history of carcinomatosis meningitis
- History of auto-immune disease
- Subject has medical conditions requiring systemic immunosuppression with either corticosteroids or other immunosuppressive medications within 14 days of the first dose of the investigational product

Other protocol-defined inclusion/exclusion criteria apply

Ages Eligible for Study ⓘ

18 Years to 99 Years (Adult, Older Adult)

Sexes Eligible for Study ⓘ

All

Accepts Healthy Volunteers ⓘ

No

Study Plan

This section provides details of the study plan, including how the study is designed and what the study is measuring.

How is the study designed?

Design Details

Primary Purpose ⓘ : Treatment

Allocation ⓘ : Randomized

Interventional Model ⓘ : Parallel Assignment

Masking ⓘ : Double (Participant, Investigator)

Masking Description: The study is double-blinded; therefore, the investigators, study personnel (with the exception of the data monitoring committee, authorized unblinded sponsor and contract research organization staff, and unblinded site pharmacy staff), and the study subjects will remain blinded to treatment allocation. ABP 206 and nivolumab will be coded and labeled to protect blinding.

Arms and Interventions

Participant Group/Arm i	Intervention/Treatment i
Experimental: ABP 206 Subjects will receive Dose A of ABP 206 via intravenous (IV) infusion.	Drug: ABP 206 ABP 206 will be given intravenously over a period of 30 minutes, every 4 weeks (Q4W) for a total of 12 months.
Active Comparator: FDA-licensed Nivolumab Subjects will receive Dose A of FDA-licensed Nivolumab via IV infusion.	Drug: FDA-licensed Nivolumab - FDA-licensed Nivolumab will be given intravenously over a period of 30 minutes, Q4W for a total of 12 months. - Other Names: - OPDIVO®
Active Comparator: EU-authorized Nivolumab Subjects will receive Dose A of EU-authorized Nivolumab via IV infusion.	Drug: EU-authorized Nivolumab - FDA-licensed Nivolumab will be given intravenously over a period of 30 minutes, Q4W for a total of 12 months. - Other Names: - OPDIVO®

What is the study measuring?

Primary Outcome Measures i

Outcome Measure	Measure Description	Time Frame
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Area Under the Serum Concentration-time Curve from Time Zero to 28 Days (AUC0-28d)	The PK similarity (AUC0-28d) of ABP 206 compared with nivolumab will be demonstrated in subjects with advanced melanoma in the adjuvant setting.	Day 1 (Postdose) through Day 28
Area Under the Serum Concentration-time Curve Over the Dosing Interval at Steady State (AUCtau_SS)	The PK similarity (AUCtau_ss) of ABP 206 compared with nivolumab will be demonstrated in subjects with advanced melanoma in the adjuvant setting.	Week 17 through Week 21

Secondary Outcome Measures

Outcome Measure	Measure Description	Time Frame
Maximum Observed Serum Concentration Following the First Dose (Cmax_dose 1)	The comparison of PK (Cmax_dose 1) of ABP 206 with nivolumab will be determined in subjects with advanced melanoma in the adjuvant setting.	Week 1 (Baseline) through Week 9, Week 17 to 29, Week 41, and Week 53 (End of Study)

Maximum Observed Serum Concentration at Steady State (Cmax _{ss})	The comparison of PK (Cmax _{ss}) of ABP 206 with nivolumab will be determined in subjects with advanced melanoma in the adjuvant setting.	Week 1 (Baseline) through Week 9, Week 17 to 29, Week 41, and Week 53 (End of Study)
Serum Concentrations at Predose (C _{trough})	The PK similarity (C _{trough}) of ABP 206 compared with nivolumab determined in subjects with advanced melanoma in the adjuvant setting.	Week 1 (Baseline) through Week 9, Week 17 to 29, Week 41, and Week 53 (End of Study)
Number of Subjects With Treatment-Emergent Serious Adverse Events	The safety (treatment-emergent serious adverse events) of ABP 206 compared with nivolumab will be assessed in subjects with advanced melanoma in the adjuvant setting.	Week 1 (First dose of study drug) through Week

			53 (End of Study)	
	Number of Subjects With Treatment-Emergent Adverse Events	The safety (treatment-emergent adverse events) of ABP 206 compared with nivolumab will be assessed in subjects with advanced melanoma in the adjuvant setting.	Week 1 (First dose of study drug) through Week 53 (End of Study)	
	Number of Subjects With Treatment-emergent Adverse Events-of-interest	The safety (treatment-emergent adverse events-of-interest) of ABP 206 compared with nivolumab will be assessed in subjects with advanced melanoma in adjuvant setting.	Week 1 (First dose of study drug) through Week 53 (End of Study)	
	Number of Subjects With Anti-drug Antibodies (ADAs)	The immunogenicity of ABP 206 compared with nivolumab will be assessed in subjects with advanced melanoma in the adjuvant setting.	Predose on Week 1 (Baseline), Weeks 5, 9, 17, 21, 29, 41, and at Week 53 (End	

			of Study)	
Recurrence-free Survival (RFS)	The RFS is assessed to compare the efficacy of ABP 206 with nivolumab in subjects with advanced melanoma in the adjuvant setting. The RFS is defined as the time between the date of randomization and the date of first recurrence (local, regional, distant metastasis) or death (whatever the cause), or date of last visit/contact with disease assessments (for subjects who remain alive and whose disease has not recurred).		Rando mizatio n through 12 months (or until RFS criteria is met)	
Time to reach Cmax following the first dose (Tmax_dose 1)	The comparison of PK (Tmax_dose 1) of ABP 206 with nivolumab will be determined in subjects with advanced melanoma in the adjuvant setting.		Week 1 (Baselin e) through Week 9, Week 17 to 29, Week 41, and Week 53 (End of Study)	
Time to reach Cmax at steady state (Tmax_ss)	The comparison of PK (Tmax_SS) of ABP 206 with nivolumab will be determined in subjects with advanced melanoma in the adjuvant setting.		Week 1 (Baselin e) through Week 9, Week 17 to 29,	

		Week 41, and Week 53 (End of Study)
Serum Concentrations (Ctrough)	The comparison of PK (Ctrough) of ABP 206 with nivolumab will be determined in subjects with advanced melanoma in the adjuvant setting.	At Week 5 (Pre-dose), and at Weeks 17 and 21 (Pre-dose)

Collaborators and Investigators

This is where you will find people and organizations involved with this study.

Sponsor ⓘ

Amgen

Investigators ⓘ

- Study Director: MD, Amgen

Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted ⓘ

2023-06-08

First Submitted that Met QC Criteria ⓘ

2023-06-08

First Posted ⓘ

2023-06-18

Study Record Updates

Last Update Submitted that met QC Criteria ⓘ

2024-11-26

Last Update Posted ⓘ

2024-11-27

Last Verified ⓘ

2024-11

More Information

Terms related to this study

Keywords Provided by Amgen

Pharmacokinetic similarity study
Adjuvant melanoma treatment
Advanced Melanoma

Additional Relevant MeSH Terms

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

Skin Diseases
Melanoma
Antineoplastic Agents, Immunological
Antineoplastic Agents
Immune Checkpoint Inhibitors
Molecular Mechanisms of Pharmacological Action
Nivolumab

Plan for Individual Participant Data (IPD)

Plan to Share Individual Participant Data (IPD)?

Yes

IPD Plan Description

De-identified individual patient data for variables necessary to address the specific research question in an approved data sharing request.

IPD Sharing Access Criteria

Qualified researchers may submit a request containing the research objectives, the Amgen product(s) and Amgen study/studies in scope, endpoints/outcomes of interest, statistical analysis plan, data requirements, publication plan, and qualifications of the researcher(s). In general, Amgen does not grant external requests for individual patient data for the purpose of re-evaluating safety and efficacy issues already addressed in the product labelling. Requests are reviewed by a committee of internal advisors. If not approved, a Data Sharing Independent Review Panel will arbitrate and make the final decision. Upon approval, information necessary to address the research question will be provided under the terms of a data-sharing agreement. This may include anonymized individual patient data and/or available supporting documents, containing fragments of analysis code where provided in analysis specifications. Further details are available at the URL below.

IPD Sharing Time Frame

Data sharing requests relating to this study will be considered beginning 18 months after the study has ended and either 1) the product and indication have been granted marketing authorization in both the US and Europe or 2) clinical development for the product and/or indication discontinues and the data will not be submitted to regulatory authorities. There is no end date for eligibility to submit a data-sharing request for this study.

IPD Sharing Supporting Information Type

Study Protocol
Statistical Analysis Plan (SAP)
Informed Consent Form (ICF)

IPD Sharing Url

<http://www.amgen.com/datasharing> (http://www.amgen.com/datasharing).

Drug and device information, study documents, and helpful links

Studies a U.S. FDA-Regulated Drug Product

Yes

Studies a U.S. FDA-Regulated Device Product

No

Helpful Links Provided by Amgen

[AmgenTrials clinical trials website](http://www.amgentrials.com) (http://www.amgentrials.com).