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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/) related topics:
Melanoma (https://medlineplus.gov/genetics/condition/melanoma)

MedlinePlus (https://medlineplus.gov/) related topics:
Melanoma (https://medlineplus.gov/melanoma.html)

Genetic and Rare Diseases Information Center (https://rarediseases.info.nih.gov/gard) resources:
Neuroendocrine Tumor (https://rarediseases.info.nih.gov/diseases/13445/neuroendocrine-tumor) Neuroepithelioma (https://rarediseases.info.nih.gov/diseases/3963/neuroepithelioma)

Drug Information (https://dailymed.nlm.nih.gov/dailymed/) available for:
Nivolumab (https://dailymed.nlm.nih.gov/dailymed/search.cfm?labeltype=human&query=Nivolumab)

FDA Drug and Device Resources (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).

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 Crt

Argentina

Caba, Argentina, 1125
Fundación CENIT

Mar del Plata, Argentina, 7600
CIMMDP

Rosario, Argentina, 2000
Instituto de Oncologia 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

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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"

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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

Kagosima [Kagoshima] Locations

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

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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

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

Korea, Republic of

Busan Gwang'yeogsi [Pusan-Kwan Locations

Busan, Busan Gwang'yeogsi [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

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Hospital Umum Sarawak

Kuching, Sarawak, Malaysia
Hospital Umum Sarawak

Selangor Locations

Putrajaya, Selangor, Malaysia, 62250
Institut Kanser Negara

Wilayah Persekutuan Kuala Lump Locations

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

Kuala Lumpur, Wilayah Persekutuan Kuala Lump, 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
Consorcio 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

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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

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Hanoi Oncology Hospital

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.

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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.

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Arms and Interventions

Participant Group/Arm	Intervention/Treatment
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

Outcome Measure	Measure Description	Time Frame

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 (Ctrough)	The PK similarity (Ctrough) 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).	Randomization 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 (Baseline) 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 (Baseline) 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)