A Study of NKTR-214 Combined With Nivolumab vs Nivolumab Alone in Participants With Previously Untreated Inoperable or Metastatic Melanoma

CLINICALTRIALS.GOV IDENTIFIER	RECRUITMENT STATUS	FIRST POSTED	LAST UPDATE POSTED
NCT03635983	RECRUITING	AUGUST 17, 2018	NOVEMBER 17, 2020

STUDY DESCRIPTION

Brief Summary

The purpose of the study is to test the effectiveness (how well the drug works), safety, and tolerability of the investigational drug called NKTR-214, when combined with nivolumab versus nivolumab given alone in participants with previously untreated melanoma skin cancer that is either unable to be surgically removed or has spread

Condition or Disease: Melanoma

Intervention/treatment: Biological: NKTR-214
Biological: Nivolumab

Phase: Phase 3

DETAILED DESCRIPTION

N/A

STUDY DESIGN

Study Type: Interventional

Estimated Enrollment : 764 participants

Intervention Model : Parallel Assignment

Masking: None (Open Label) ()

Primary Purpose: Treatment

Official Title: A Phase 3, Randomized, Open-label Study of NKTR-214 Combined With Nivolumab Versus Nivolumab in Participants With Previously Untreated Unresectable or Metastatic Melanoma

Actual Study Start Date: September 2018

Estimated Primary Completion Date: April 2022

Estimated Study Completion Date: June 2025

ARMS AND INTERVENTIONS

Arm	Intervention/treatment
Experimental: Combination NKTR-214 + Nivolumab	Biological: NKTR-214 Specified dose on specified days Biological: Nivolumab Specified dose on specified days
Experimental: Monotherapy Nivolumab	Biological: Nivolumab Specified dose on specified days

OUTCOME MEASURES

Primary Outcome Measures:
1. Overall response rate (ORR) by Blinded Independent Central Review (BICR) [Time Frame: Approximately 16 months]
2. Progression-free survival (PFS) by BICR [Time Frame: Approximately 22 months]
3. Overall survival (OS) [Time Frame: Up to 59 months]

Secondary Outcome Measures:
1. Clinical benefit rate (CBR) [Time Frame: Approximately 16 months]
2. Duration of response (DoR) [Time Frame: Approximately 16 months]
3. Time to response (TTR) [Time Frame: Approximately 16 months]
4. ORR by investigator and in biomarker population [Time Frame: Approximately 16 months]
5. PFS by investigator and in biomarker population [Time Frame: Approximately 22 months]
6. OS in biomarker population [Time Frame: Up to 59 months]
7. Incidence of participants with non-serious Adverse Events (AEs) [Time Frame: Up to 5 years]
8. Incidence of participants with Serious Adverse Events (SAEs) [Time Frame: Up to 5 years]
9. Incidence of treatment-related AEs [Time Frame: Up to 5 years]
10. Incidence of treatment-related SAEs [Time Frame: Up to 5 years]
11. Incidence of laboratory abnormalities in blood [Time Frame: Up to 5 years]
12. Incidence of laboratory abnormalities in blood serum [Time Frame: Up to 5 years]
13. Incidence of laboratory abnormalities in urine [Time Frame: 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

For more information regarding Bristol-Myers Squibb Clinical Trial participation, please visit www.BMSStudyConnect.com
Inclusion Criteria:
Eastern Cooperative Oncology Group (ECOG) performance status of ≤1 (adults 18 years or older)/Lansky Performance Score ≥ 80% (minors ages 12-17 only)
Histologically confirmed stage III (unresectable) or stage IV melanoma Treatment-naive participants (ie, no prior systemic anticancer therapy for unresectable or metastatic melanoma) with the exception of prior adjuvant and/or neoadjuvant treatment for melanoma with approved agents
Exclusion Criteria:
Active brain metastases or leptomeningeal metastases Uveal melanoma Participants with an active, known or suspected autoimmune disease
Other protocol defined inclusion/exclusion criteria could apply

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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

United States, Arizona	Local Institution	Tucson
United States, California	UC San Diego Moores Cancer Ctr	La Jolla
United States, California	Local Institution	Los Angeles
United States, California	Stanford Cancer Center	Stanford
United States, Colorado	University Of Colorado	Aurora
United States, Connecticut	Smilow Cancer Center at Yale New Haven Hospital	New Haven
United States, Florida	Mount Sinai Comprehensive Cancer Center	Miami Beach
United States, Florida	Sylvester Comprehensive Cancer Center	Miami
United States, Florida	Moffitt Cancer Center	Tampa
United States, Georgia	Winship Cancer Institute, Emory University	Atlanta
United States, Kentucky	University of Louisville Hospital	Louisville
United States, Massachusetts	Dana-Farber Cancer Institute	Boston
United States, Michigan	Local Institution	Ann Arbor
United States, Minnesota	Local Institution	Fridley
United States, Minnesota	Local Institution	Minneapolis
United States, Missouri	Washington University School Of Medicine	Saint Louis
United States, New Jersey	The Cancer Center At Hackensack University Medical Center	Hackensack
United States, New Jersey	Local Institution	New Brunswick
United States, New York	Local Institution	Buffalo
United States, New York	Memorial Sloan Kettering Nassau	New York
United States, Ohio	Local Institution	Cleveland
United States, Ohio	Cleveland Clinic	Cleveland
United States, Oregon	Portland Providence Medical Center	Portland
United States, Oregon	Oregon Health & Science University	Portland
United States, Pennsylvania	St. Luke's Hospital & Health Network	Easton
United States, Pennsylvania	Fox Chase Cancer Center	Philadelphia
United States, Texas	MD Anderson Cancer Center	Houston
United States, Virginia	Inova Schar Cancer Institute	Fairfax
Argentina, Buenos Aires	Hospital Aleman	Autonoma
Argentina, Buenos Aires	Clinica Adventista Belgrano	Ciudad Autonoma de Buenos Aires

Argentina, Distrito Federal	Local Institution	Buenos Aires
Argentina	Local Institution	Caba
Argentina	Instituto Medico Especialazado Alexander Fleming	Caba
Argentina	Local Institution	Cordoba
Australia, New South Wales	Local Institution	Coffs Harbour
Australia, New South Wales	Local Institution	North Sydney
Australia, Queensland	Local Institution	Cairns
Australia, Queensland	Local Institution	Greenslopes
Australia, Queensland	Local Institution	Woolloongabba
Australia, South Australia	Local Institution	Elizabeth Vale
Australia, Victoria	Local Institution	Melbourne
Australia, Victoria	Local Institution	Melbourne
Australia, Western Australia	Local Institution	Nedlands
Australia, Western Australia	Local Institution	Nedlands
Austria	Med University Graz Dermatology	Graz
Austria	PMU Salzburg	Salzburg
Austria	Medizinische Universtaet Wien	Wien
Belgium	Local Institution	Brussels
Belgium	Local Institution	Hasselt
Belgium	Local Institution	Leuven
Brazil, Ceara	Local Institution	Fortaleza
Brazil, Minas Gerais	Local Institution	Belo Horizonte
Brazil, RIO Grande DO SUL	Local Institution	Ijui
Brazil, RIO Grande DO SUL	Local Institution	Porto Alegre
Brazil, Santa Catarina	Local Institution	Itajai
Brazil, SAO Paulo	Local Institution	Barretos
Brazil	Local Institution	Rio De Janeiro
Brazil	Local Institution	Sao Paulo
Canada, Alberta	Local Institution	Edmonton
Canada, British Columbia	Local Institution	Abbotsford
Canada, Newfoundland and Labrador	Local Institution	St. John's
Canada, Ontario	Local Institution	Hamilton
Canada, Ontario	Local Institution	Kitchener
Canada, Ontario	Local Institution	Toronto
Canada, Ontario	Local Institution	Toronto
Canada	Local Institution	Quebec
Chile, Metropolitana	Local Institution	Santiago
Chile, Metropolitana	Local Institution	Santiago
Czechia	Klinika komplexni onkologicke pece	Brno
Czechia	Klinika onkologie a radioterapie	Hradec Kralove
Czechia	Dermatovenerologicka klinika 3. LF UK a FNKV	Praha 10
Czechia	Dermatovenerologicka klinika VFN a 1. LF UK	Praha 2
Finland	Local Institution	KYS
Finland	Local Institution	Tampere
Finland	Local Institution	Turku

France	Local Institution	Bordeaux
France	Hopital Claude Huriez	LILLE Cedex
France	Hopital Saint Eloi	Montpellier Cedex 05
France	Hotel Dieu - Chu De Nantes	Nantes Cedex 01
France	Chu De Nice Hopital De Cimiez	Nice Cedex 1
France	Hopital Saint Louis	Paris
France	Centre Hospitalier Lyon Sud	Pierre Benite
France	Hopital Charles Nicolle C H U Rouen	Rouen
France	Hopital Nord - CHU de Saint-Etienne	Saint Priest en Jarez
France	Institut Claudius Regaud	Toulouse Cedex 9
France	Institut Gustave Roussy	Villejuif
Germany	Elbe Klinikum Buxtehude	Buxtehude
Germany	Universitaetsklinikum Carl Gustav Carus	Dresden
Germany	Universitaetsklinik Essen	Essen
Germany	Georg August Universitaet Goettingen	Goettingen
Germany	Universitaets-Krankenhaus Eppendorf	Hamburg
Germany	Medizinische Hochschule Hannover (Hannover Medical School)	Hannover
Germany	Nationales Centrum Fuer Tumorerkrakungen (Nct) Heidelberg	Heidelberg
Germany	Universitaetsklinikum Schleswig-Holstein	Kiel
Germany	Universitatsklinikum AoR Klinik fur Dermatologie, Venerologie und Allergologie	Leipzig
Germany	Ludwig-Maximilians-Universitaet	Muenchen
Germany	Fachklinik Hornheide	Muenster
Germany	University Hospital of Regensburg	Regensburg
Germany	Universitaetsklinikum Tuebingen	Tuebingen
Germany	Univ. Klinikum Wuerzburg	Wuerzburg
Greece	Laiko General Hospital Of Athens	Athens
Greece	Metropolitan Hospital	Neo Faliro
Greece	Interbalkan European Medical Center	Thessaloniki
Ireland, Cork	Local Institution	Wilton
Ireland, Dublin	Local Institution	Dublin 7
Ireland	Local Institution	Dublin
Ireland	Local Institution	Dublin
Ireland	Local Institution	Galway
Israel	Local Institution	Beer Sheva
Israel	Local Institution	Jerusalem
Israel	Local Institution	Ramat-gan
Italy	IRCCS Giovanni Paolo II Istituto Oncologico	Bari
Italy	Local Institution	Bergamo
Italy	Local Institution	Candiolo, Torino
Italy	Local Institution	Genova
Italy	Local Institution	Meldola (fc)
Italy	Local Institution	Milano
Italy	Local Institution	Milan
Italy	Instituto Nazionale Tumori Fondazione G. Pascale	Napoli
Italy	Istituto Oncologico Veneto IOV	Padova

Italy	Azienda Ospedaliera Universitaria Senese	Siena
Italy	Local Institution	Torino
Mexico, Distrito Federal	Local Institution	Ciudad de Mexico
Mexico, Jalisco	Local Institution	Zapopan
Mexico, Nuevo LEON	Local Institution	Monterrey
Mexico, Nuevo LEON	Local Institution	Monterrey
Mexico, Quintana ROO	Local Institution	Benito Juarez
Mexico	Local Institution	Puebla
Mexico	Local Institution	San Luis Potosi
Netherlands	Local Institution	Amsterdam
Netherlands	Local Institution	Amsterdam
Netherlands	Local Institution	Leiden
Netherlands	Local Institution	Nijmegen
Netherlands	Local Institution	Untrecht
New Zealand	Local Institution	Auckland
New Zealand	Local Institution	Christchurch
New Zealand	Local Institution	Wellington
Poland	Local Institution	Bialystok
Poland	Local Institution	Bydgoszcz
Poland	Local Institution	Lublin
Poland	Local Institution	Warszawa
Poland	Local Institution	Wroclaw
Portugal	Local Institution	Lisboa
Portugal	Local Institution	Porto
Romania	Local Institution	Bucharest
Romania	Local Institution	Cluj-Napoca
Romania	Local Institution	Craiova
Romania	Local Institution	Floresti
Romania	Local Institution	Oradea
Russian Federation	Local Institution	Krasnoyarsk
Russian Federation	Local Institution	Moscow
Russian Federation	Local Institution	Moscow
Russian Federation	Local Institution	Moscow
Spain	H. Univ. Vall dHebron	Barcelona
Spain	Hospital Clinic I Provincial	Barcelona
Spain	Hospital Universitario Reina Sofia	Cordoba
Spain	Complejo Hospitalario de Jaen	Jaen
Spain	Hospital Gral. Univ. Gregorio Maranon	Madrid
Spain	Hospital Clinico Univ. de Santiago-CHUS	Santiago Compostela
Spain	Hospital General Universitario De Valencia	Valencia
Sweden	Local Institution	Gothenburg
Sweden	Local Institution	Lund
Switzerland	Universitatsspital Bern, Inselspital	Bern
Switzerland	Centre Hospitalier Universitaire Vaudois	Lausanne
Switzerland	Universitaetsspital Zuerich	Zuerich

United Kingdom, Greater London	Local Institution	London
United Kingdom, Hampshire	Local Institution	Southampton
United Kingdom, Midlothian	Local Institution	Edinburgh
United Kingdom	Local Institution	Belfast
United Kingdom	Local Institution	Cambridge
United Kingdom	Local Institution	Cottingham
United Kingdom	Local Institution	Liverpool
United Kingdom	Local Institution	London
United Kingdom	Local Institution	Manchester
United Kingdom	Local Institution	Sutton.
United Kingdom	Local Institution	Tauton

Sponsors and Collaborators

Bristol-Myers Squibb

Nektar Therapeutics

Investigator

Study Director :	Bristol-Myers Squibb	Bristol-Myers Squibb

MORE INFORMATION

Other Publications	Khushalani NI, Diab A, Ascierto PA, Larkin J, Sandhu S, Sznol M, Koon HB, Jarkowski A, Zhou M, Statkevich P, Geese WJ, Long GV. Bempegaldesleukin plus nivolumab in untreated, unresectable or metastatic melanoma: Phase III PIVOT IO 001 study design. Future Oncol. 2020 Oct;16(28):2165-2175. doi: 10.2217/fon-2020-0351. Epub 2020 Jul 29.
Responsible Party :	Bristol-Myers Squibb
ClinicalTrials.gov Identifier :	NCT03635983
Other Study ID Numbers :	CA045-001, 2018-001423-40, 17-214-08
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Studies a U.S. FDA-regulated Drug Product:	Yes
Studies a U.S. FDA-regulated Device Product:	No
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Additional relevant MeSH terms :	*Melanoma* *Neuroendocrine Tumors* *Neuroectodermal Tumors* *Neoplasms, Germ Cell and Embryonal* *Neoplasms by Histologic Type* *Neoplasms* *Neoplasms, Nerve Tissue* *Nevi and Melanomas*