A Study to Compare Nivolumab Administered Subcutaneously vs Intravenous in Melanoma Participants Following Complete Resection

CLINICALTRIALS.GOV IDENTIFIER	RECRUITMENT STATUS	FIRST POSTED	LAST UPDATE POSTED
NCT05297565	RECRUITING	MARCH 28, 2022	MAY 16, 2022

STUDY DESCRIPTION

Brief Summary

The purpose of this study is to compare the drug levels of nivolumab administered subcutaneously versus intravenous administration in participants with melanoma following complete resection.

Condition or Disease: Melanoma

Intervention/treatment: Biological: Nivolumab/rHuPH20
Biological: Nivolumab

Phase: Phase 3

DETAILED DESCRIPTION

N/A

STUDY DESIGN

Study Type: Interventional

Estimated Enrollment : 286 participants

Allocation : Randomized

Intervention Model : Parallel Assignment

Masking: None (Open Label) ()

Primary Purpose: Treatment

Official Title: A Study to Compare Nivolumab Administered Subcutaneously vs Intravenous in Melanoma Participants Following Complete Resection

Estimated Study Start Date: May 2022

Estimated Primary Completion Date: December 2023

Estimated Study Completion Date: August 2026

ARMS AND INTERVENTIONS

Arm	Intervention/treatment
Experimental: Part 1 Arm A: Subcutaneous Nivolumab	Biological: Nivolumab/rHuPH20 Specified dose on specified days
Experimental: Part 2: Subcutaneous Nivolumab	Biological: Nivolumab/rHuPH20 Specified dose on specified days
Active Comparator: Part 1 Arm B: Intravenous Nivolumab	Biological: Nivolumab Specified dose on specified days

OUTCOME MEASURES

Primary Outcome Measures:
1. Time-averaged nivolumab serum concentration over the first 28 days (Cavgd28) [Time Frame: Up to 28 days]
2. Minimum nivolumab serum concentration at steady-state (Cminss) [Time Frame: Up to 28 days]

Secondary Outcome Measures:
1. Number of participants with adverse events (AEs) [Time Frame: Up to 15 months]
2. Number of participants with serious adverse events (SAEs) [Time Frame: Up to 15 months]
3. Number of participants with treatment-related AEs [Time Frame: Up to 15 months]
4. Number of participants with immune-mediated adverse events (IMAEs) [Time Frame: Up to 15 months]
5. Number of participants with AEs leading to discontinuation [Time Frame: Up to 15 months]
6. Number of participants with death [Time Frame: Up to 15 months]
7. Number of participants with laboratory abnormalities [Time Frame: Up to 15 months]
8. Recurrence-free survival (RFS) rates (per investigator) [Time Frame: Up to 36 months]
9. Overall survival (OS) rates [Time Frame: Up to 36 months]
10. Minimum nivolumab serum concentration on Day 28 (Cmind28) [Time Frame: Up to 28 days]
11. Maximum nivolumab serum concentration after the first dose (Cmax1) [Time Frame: Up to 28 days]
12. Time to maximum nivolumab serum concentration after the first dose (Tmax) [Time Frame: Up to 28 days]
13. Maximum nivolumab serum concentration at steady-state (Cmaxss) [Time Frame: Up to 17 weeks]
14. Time-averaged nivolumab serum concentration at steady-state (Cavgss) [Time Frame: Up to 17 weeks]
15. Minimum nivolumab serum concentration at steady-state (Cminss) [Time Frame: Up to 17 weeks]
16. Percentage of participants who develop anti-nivolumab antibodies [Time Frame: Up to 15 months]
17. Percentage of participants who develop neutralizing antibodies [Time Frame: Up to 15 months]
18. Percentage of participants with the impact of anti-nivolumab antibodies on AEs [Time Frame: Up to 15 months]
19. Percentage of participants with administration-related reactions [Time Frame: Up to 15 months]

20. Percentage of participants with events within MedDRA standardized MedDRA query (SMQ) anaphylactic reactions [Time Frame: Up to 15 months]
21. Mean Cancer Treatment Satisfaction Questionnaire (CTSQ) domain scores [Time Frame: Up to 1 year]
22. Mean CTSQ Satisfaction domain score change from baseline at each assessment time point [Time Frame: Up to 1 year]

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:
Stage IIIA/B/C/D or Stage IV melanoma and have histologically confirmed melanoma that is completely surgically resected (free of disease) with negative margins Complete resection performed within 12 weeks prior to randomization or treatment assignment Eastern Cooperative Oncology Group (ECOG) performance status of ≤ 1
Exclusion Criteria:
History of uveal or mucosal melanoma Untreated/unresected CNS metastases or leptomeningeal metastases Active, known or suspected autoimmune disease Serious or uncontrolled medical disorder 4 weeks prior to screening Concurrent malignancy (present during screening) requiring treatment or history of prior malignancy active within 2 years prior to randomization or treatment assignment. Participants with history of prior early stage basal/squamous cell skin cancer or non-invasive or in situ cancers that have undergone definitive treatment at any time are eligible Prior immunotherapy treatments for any prior malignancies are not permitted
Other protocol-defined inclusion/exclusion criteria apply

CONTACTS AND LOCATIONS

Contacts

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

Locations

United States, Indiana	Ft. Wayne Medical Oncology and Hematology	Fort Wayne
Spain	Local Institution - 0001	Barcelona

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 : NCT05297565

Other Study ID Numbers : CA209-6GE, 2021-003208-42, U1111-1266-6116

First Posted : March 28, 2022

Last Update Posted : May 16, 2022

Last Verified : May 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:
Skin Cancer
rHuPH20 OPDIVO®

Additional relevant MeSH terms :

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