CheckMate 592

An Exploratory Study of the Effects of Nivolumab Combined With Ipilimumab in Patients With Treatment-Naive Stage IV or Recurrent Non-Small Cell Lung Cancer (NSCLC)

NCT-Nummer:
NCT03001882

Studienbeginn:
März 2017

Letztes Update:
14.10.2020

Wirkstoff:
Nivolumab, Ipilimumab
Indikation (Clinical Trials):
Lung Neoplasms, Carcinoma, Non-Small-Cell Lung

Geschlecht:
Alle

Altersgruppe:
Erwachsene (18+)

Phase:
Phase 2

Sponsor:
Bristol-Myers Squibb

Collaborator:
Yale University

Studien-Informationen

Brief Summary:

The purpose of this study is to explore the possible links between participant characteristics and their cancer, with how effective the combination of nivolumab with ipilimumab is, in participants

with Stage IV or recurrent Non-Small Cell Lung Cancer (NSCLC).

Ein-/Ausschlusskriterien

For more information regarding Bristol-Myers Squibb Clinical Trial participation, please visit www.BMSStudyConnect.com

Inclusion Criteria:

- Histologically confirmed, stage IV or recurrent non-small cell lung cancer with no prior systemic anticancer therapy given as primary therapy for advanced or metastatic disease

- Measurable disease by CT or MRI

- Must have full activity or, if limited, must be able to walk and carry out light activities such as light house work or office work

Exclusion Criteria:

- Participants with untreated central nervous system metastases

- Participants with active, known or suspected autoimmune disease

- Prior treatment with any drug that targets T cell co-stimulations pathways (such as checkpoint inhibitors)

Other protocol defined inclusion/exclusion criteria could apply

Studien-Rationale

Primary outcome:

1. Objective Response Rate (ORR) of patient subgroups defined by baseline biomarkers (Time Frame - Approximately 48 months)

Secondary outcome:

1. Objective Response Rate (ORR) (Time Frame - Approximately 48 months)

2. Disease Control Rate (DCR) of patient subgroups defined by baseline biomarkers (Time Frame - Approximately 48 months)

3. Duration of Response (DOR) of patient subgroups defined by baseline biomarkers (Time Frame - Approximately 48 months)

4. Time to Response (TTR) of patient subgroups defined by baseline biomarkers (Time Frame - Approximately 48 months)

5. Progression Free Survival (PFS) of patient subgroups defined by baseline biomarkers (Time Frame - Approximately 48 months)

6. Overall Survival (OS) of patient subgroups defined by baseline biomarkers (Time Frame - Approximately 48 months)

7. Incidence of Adverse Events (AEs) (Time Frame - Approximately 48 months)

8. Incidence of Serious Adverse Events (SAEs) (Time Frame - Approximately 48 months)

Geprüfte Regime

- Nivolumab (Opdivo / BMS-936558 /):
  Specified dose on specified days
- Ipilimumab (Yervoy / BMS-734016 /):
  Specified dose on specified days

Studienleiter

Bristol-Myers Squibb
Study Director
Bristol-Myers Squibb

Kontakt

Recruiting sites have contact information. Please contact the sites directly. If there is no contact information,
Kontakt:
Phone: please email:
E-Mail: Clinical.Trials@bms.com

First line of the email MUST contain NCT# and Site #.

Studienlocations (3 von 35)

Highland Oncology Group
72762 Springdale
United States

Status: Aktiv, nicht rekrutierend

Yale University
06520 New Haven
United States

Status: Aktiv, nicht rekrutierend

Cancer Specialists of North FL
32256 Jacksonville
United States

Status: Aktiv, nicht rekrutierend

Winship Cancer Institute, Emory University
30322 Atlanta
United States

Status: Aktiv, nicht rekrutierend

Washington University School Of Medicine
63110 Saint Louis
United States

Status: Aktiv, nicht rekrutierend

Montefiore - Einstein Center for Cancer Care
10461 Bronx
United States

Status: Aktiv, nicht rekrutierend

Local Institution
10016 New York
United States

Status: Zurückgezogen

Cleveland Clinic
44195 Cleveland
United States

Status: Aktiv, nicht rekrutierend

The Cleveland Clinic Foundation

44195 Cleveland
United States

Status: Aktiv, nicht rekrutierend

Bon Secours-St Francis Hosp
29607 Greenville
United States

Status: Aktiv, nicht rekrutierend

Tennessee Oncology, PLLC
37203 Nashville
United States

Status: Aktiv, nicht rekrutierend

Local Institution
9000 Gent
Belgium

Status: Aktiv, nicht rekrutierend

Local Institution
B-7100 Haine Saint Paul
Belgium

Status: Aktiv, nicht rekrutierend

Local Institution
4000 Liege
Belgium

Status: Aktiv, nicht rekrutierend

Local Institution
9100 Sint-Niklaas
Belgium

Status: Aktiv, nicht rekrutierend

Institut Curie
75248 Paris Cedex 5

France

Status: Aktiv, nicht rekrutierend

Centre Hospitalier Lyon Sud
69495 Pierre Benite
France

Status: Aktiv, nicht rekrutierend

Local Institution
67091 Strasbourg Cedex
France

Status: Aktiv, nicht rekrutierend

Local Institution
83000 Toulon
France

Status: Aktiv, nicht rekrutierend

Klinik Essen-Mitte
45136 Essen
(Nordrhein-Westfalen)
Germany

Status: Aktiv, nicht rekrutierend

Klinikverbund Kempten-Oberallgau
87509 Immenstadt
(Bayern)
Germany

Status: Aktiv, nicht rekrutierend

Klinik Lowenstein gGmbH
74245 Lowenstein
(Baden-Württemberg)
Germany

Status: Aktiv, nicht rekrutierend

Brustzentrum Klinikum Stuttgart/Frauenklinik

Kriegsbergstraße 60
70174 Stuttgart
Deutschland

Status: Aktiv, nicht rekrutierend

ASST Papa Giovanni XXIII
24127 Bergamo
Italy

Status: Aktiv, nicht rekrutierend

Aou Policlinico V. Emanuele Di Catania
95123 Catania
Italy

Status: Aktiv, nicht rekrutierend

Azienda Ospedaliero Universitaria di Parma
43100 Parma
Italy

Status: Abgeschlossen

Azienda Ospedaliera Di Perugia
06132 Perugia
Italy

Status: Aktiv, nicht rekrutierend

Local Institution
1066 CX Amsterdam
Netherlands

Status: Rekrutierend

Local Institution
6525 GA Nijmegen
Netherlands

Status: Aktiv, nicht rekrutierend

Prof Dr I Chiricuta Institute of Oncology

400015 Cluj-Napoca
Romania

Status: Aktiv, nicht rekrutierend

Sf. Nectarie Oncology Center
200347 Craiova
Romania

Status: Aktiv, nicht rekrutierend

Instituto Catalan De Oncologia
08908 Barcelona
Spain

Status: Aktiv, nicht rekrutierend

Hosp Univer 12 De Octubre
28041 Madrid
Spain

Status: Aktiv, nicht rekrutierend

Hospital Universitario La Paz
28046 Madrid
Spain

Status: Aktiv, nicht rekrutierend

Hosp Univ Virgen Macarena
41009 Sevilla
Spain

Status: Aktiv, nicht rekrutierend

Quelle: ClinicalTrials.gov