Trial Description

Title
A National, Prospective, Non-Interventional Study (NIS) of Nivolumab (BMS-936558) in Patients With Advanced Renal Cell Carcinoma After Prior Therapy

Trial Acronym
[---]*

URL of the trial
[---]*

Brief Summary in Lay Language
A Real-Life Study to Evaluate Efficacy and Safety of Nivolumab in Patients with Advanced Renal Cell Carcinoma after prior therapy.

Brief Summary in Scientific Language
[---]*

Organizational Data

- DRKS-ID: DRKS00011442
- Date of Registration in DRKS: 2017/03/07
- Date of Registration in Partner Registry or other Primary Registry: 2016/10/12
- Investigator Sponsored/Initiated Trial (IST/IIT): no
- Ethics Approval/Approval of the Ethics Committee: [---]*
- (leading) Ethics Committee Nr.: [---]*

Secondary IDs

- Primary Registry-ID: NCT02940639 (ClinicalTrials.gov)
- Sponsor-ID: CA209-653 (Bristol-Myers Squibb)
Health condition or Problem studied

- Free text: Renal Cell Carcinoma
- ICD10: C64 - Malignant neoplasm of kidney, except renal pelvis

Interventions/Observational Groups

- Arm 1: Other: Non Interventional

Characteristics

- Study Type: Non-interventional
- Study Type Non-Interventional: Observational study
- Allocation: [---]*
- Blinding: [---]*
- Who is blinded: [---]*
- Control: [---]*
- Purpose: [---]*
- Assignment: [---]*
- Phase: N/A
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): [---]*

Primary Outcome

- Overall Survival (OS); time frame: Approximately 5 years

Secondary Outcome

- Progression-Free Survival (PFS); time frame: Approximately 5 years
- Overall response rate (ORR); time frame: Approximately 5 years
- Best Overall Response (BOR); time frame: Approximately 5 years
- Best Overall Response Rate (BORR); time frame: Approximately 5 years
- Distribution of socio-demographic characteristics in adult patients with advanced Renal Cell Carcinoma (RCC) initiating Nivolumab treatment; time frame: Approximately 5 years; Socio-demographic characteristics (Gender, Height, Weight, Age) will be summarized using descriptive statistics
- Distribution of clinical characteristics in adult patients with advanced Renal Cell Carcinoma (RCC) initiating Nivolumab treatment; time frame: Approximately 5 years; Clinical characteristics (Initial Diagnosis of RCC, Histological subtypes, Performance status, Comorbidities, history of cancer) will be summarized using descriptive statistics
- Distribution of incidence of Adverse Events (AEs); time frame: Approximately 5 years
- Distribution of severity of Adverse Events (AEs); time frame: Approximately 5 years
- Distribution of management of Adverse Events (AEs); time frame: Approximately 5 years
- Functional Assessment of Cancer Therapy - Kidney Symptom Index (FKSI-19) Questionnaire; time frame: Approximately 5 years
- European Quality of Life-5 Dimensions (EQ-5D) Questionnaire; time frame: Approximately 5 years
- Distribution of Renal Cell Carcinoma (RCC) Treatment History; time frame: At Baseline
- Distribution of Treatment Patterns; time frame: Approximately 5 years; Details on Prior and Evolution of Current Treatment Patterns

Countries of recruitment

- DE Germany

Locations of Recruitment

- Local Institution, Jena

Recruitment

- Planned/Actual: [---]*
- (Anticipated or Actual) Date of First Enrollment: 2016/09/30
- Target Sample Size: 323
- Monocenter/Multicenter trial: Monocenter trial
- National/International: National

Inclusion Criteria

- Gender: Both, male and female
- Minimum Age: 18 Years
- Maximum Age: no maximum age

Additional Inclusion Criteria

- ≥ 18 years
  - diagnosis of advanced RCC (confirmed by histology or cytology)
  - treatment decision to initiate a treatment with nivolumab for the first time for the treatment of RCC (according to the label approved in Germany) has
already been taken

- signed informed consent

### Exclusion criteria

- diagnosis of a cancer other than advanced RCC within the past 5 years, ie, a cancer other than RCC that requires systemic or other treatment. Patients that have been treated curatively more than 5 years ago with no evidence of recurrence and prostate cancer patients in active surveillance can be included

- previous treatment with nivolumab and/or ipilimumab

- current active participation in an interventional clinical trial for treatment of their advanced RCC.

### Addresses

- **Primary Sponsor**
  
  Bristol-Myers Squibb
  
  Telephone: [---]*
  Fax: [---]*
  E-mail: [---]*
  URL: [---]*

- **Contact for Scientific Queries**
  
  Bristol-Myers Squibb
  Bristol-Myers Squibb
  
  Telephone: [---]*
  Fax: [---]*
  E-mail: [---]*
  URL: [---]*

- **Contact for Public Queries**
  
  Recruiting sites have contact information. Please contact the sites directly. If there is no contact information, please email:
  
  Telephone: [---]*
Contact for Public Queries

Recruiting sites have contact information. Please contact the sites directly. If there is no contact information, please email:

Telephone: [---]*
Fax: [---]*
E-mail: Clinical.Trials at bms.com
URL: [---]*

Sources of Monetary or Material Support

Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor

Telephone: [---]*
Fax: [---]*
E-mail: [---]*
URL: [---]*

Status

- Recruitment Status: Recruiting ongoing
- Study Closing (LPLV): [---]*

Trial Publications, Results and other documents

- Further trial documents BMS Clinical Trial Information
- Further trial documents BMS clinical trial educational resource
- Further trial documents Investigator Inquiry form
- Further trial documents FDA Safety Alerts and Recalls

The parameters in ClinicalTrials.gov and DRKS are not identical. Therefore the data import from ClinicalTrials.gov required adjustments. For full details please see the DRKS FAQs.

- Translation on version: 2
- Last processed date by ClinicalTrials.gov: 2016/12/08
- Please note:
  There are additional attributes available concerning this trial. To open an extended view please click here.