A Registry in the European Union of Provenge Therapy in Men with Metastatic Castrate-Resistant Prostate Cancer (START)

First published: 18/12/2014

Last updated: 21/05/2015

Study Planned

Administrative details

EU PAS number

EUPAS8254

Study ID

9783

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Germany
- [ ] Netherlands
- [ ] United Kingdom

Study description

STUDY WITHDRAWN (Notification 13 May 2015). This is a multicenter, non-interventional registry designed to evaluate the risk of ischemic stroke or MI in subjects with mCRPC who receive commercial Provenge in the EU.

Study status

Planned

Research institutions and networks

Institutions

Department for Urology, University Hospital RWTH Aachen

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Charité-Universitätsmedizin

First published: 01/02/2024

Last updated: 01/02/2024

Institution

University Medical Centre Hamburg-Eppendorf

Germany

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility

Medical Department, Division of Hematology, Oncology and Tumor Immunology, Charité University Medicine Berlin Augustenburger Platz,1 13353 Berlin, Germany, Martini-Clinic on the grounds of the University Clinic Hamburg-Eppendorf Martinistrasse 52, 20246 Hamburg, Germany, University Clinic Frankfurt, Department for Urology and Pediatric Urology Theodor-Stern-Kai 7, 60590 Frankfurt/M. Germany

Contact details

Study institution contact

Andy Stubbs astubbs@Dendreon.com

Study contact

astubbs@Dendreon.com

Primary lead investigator

Axel Heidenreich

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 01/03/2014

Study start date
Planned: 06/03/2014

Data analysis start date
Planned: 30/06/2018

Date of interim report, if expected
Planned: 08/07/2015

Date of final study report
Planned: 31/12/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Dendreon Corporation

Regulatory

Was the study required by a regulatory body?

Yes

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

To evaluate the risk of ischemic stroke or MI following treatment with Provenge relative to the risk reported in external databases of patients with mCRPC not treated with Provenge.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

non-interventional PASS

Study drug and medical condition

Name of medicine

PROVENGE

Medical condition to be studied

Prostate cancer metastatic

Hormone-refractory prostate cancer

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

850

Study design details

Outcomes

The primary endpoint is incidence of ischemic stroke or MI occurring from the first infusion through 60 days after the final infusion of Provenge. To assess the primary endpoint, data from this registry will be combined with data from PROCEED, the US registry enrolling >1500 men with advanced prostate cancer. •Collect data on the occurrence of DVT or PE following treatment with Provenge•Collect data on the occurrence of SAEs following treatment with

Provenge•Collect data on OS in subjects who receive Provenge•Describe time to first prostate cancer intervention in subjects who receive Provenge •Describe changes in PSA levels, use of other prostate cancer interventions after treatment with Provenge

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Data analysis plan

The primary endpoint is the incidence of ischemic stroke or MI occurring form the time of first infusion through 60 days after the final infusion and will be assessed combining data from this registry and PROCEED. It will be summarized in aggregate and where possible by subgroup. The incidence, incidence rate per patient-year, and 95% confidence intervals will be calculated. Comparisons to external databases will be performed by calculating incidence risk ratios and their corresponding 95% confidence intervals. Secondary endpoints to be evaluated include the incidence of ischemic stroke, MI, DVT, and PE as well as overall survival, incidence of SAEs, prostate cancer interventions, and serum PSA levels. An exploratory meta-analysis combining data from this registry,PROCEED and completed/ongoing Provenge studies in subjects with advanced prostate cancer to evaluate the risk of MI in patients with mCRPC treated with Provenge relative to not treated with Provenge will be performed.

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection, The data from the 850 subjects from this registry will be combined with data from the PROCEED registry and other completed and on-going Provenge trials in subjects with advanced prostate cancer and compared to external databases.

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No