

# 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

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### Study ID

9783

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### DARWIN EU® study

No

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### Study countries

 Austria

 Germany

 Netherlands

 United Kingdom

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## 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STUDY WITHDRAWN (Notification 13 May 2015).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.

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## 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](mailto:astubbs@Dendreon.com)

**Study contact**

[astubbs@Dendreon.com](mailto:astubbs@Dendreon.com)

## Primary lead investigator

Axel Heidenreich

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 01/03/2014

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### Study start date

Planned: 06/03/2014

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### Data analysis start date

Planned: 30/06/2018

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### Date of interim report, if expected

Planned: 08/07/2015

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### 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

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#### **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

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### **Non-interventional study design, other**

non-interventional PASS

## Study drug and medical condition

## Medicinal product name

PROVENGE

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## 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)
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## 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 from 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

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### 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

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### Check completeness

Unknown

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### Check stability

Unknown

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### Check logical consistency

Unknown

## Data characterisation

## **Data characterisation conducted**

No