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STUDY WITHDRAWN (Notification 13 May 2015).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

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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

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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

**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