EXPERT, EXPosurE Registry RiociguaT in patients with pulmonary hypertension

First published: 20/03/2014

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS6115

Study ID

43970

DARWIN EU® study

No

Study countries

- [ ] Argentina
- [ ] Australia
- [ ] Austria
- [ ] Belgium
- [ ] Canada
- [ ] Colombia

- [ ] Czechia
- [ ] Denmark
- [ ] Estonia
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Ireland
- [ ] Italy
- [ ] Luxembourg
- [ ] Netherlands
- [ ] Norway
- [ ] Portugal
- [ ] Russian Federation
- [ ] Saudi Arabia
- [ ] Slovakia
- [ ] Spain
- [ ] Sweden
- [ ] Switzerland
- [ ] Taiwan
- [ ] Türkiye
- [ ] United Kingdom

Study description

In accordance with the regulatory guidance this registry has been designed to collect information about the long-term safety of Adempas in real clinical practice outside the regulated environment of a controlled clinical study.

Study status

Finalised

Research institutions and networks

Institutions

Multiple centres: 28 centres are involved in the study

Contact details

Study institution contact

Bayer Clinical Trials Contact Bayer AG Clinical-Trials-contact@bayer.com

Study contact

Clinical-Trials-contact@bayer.com

Primary lead investigator

Bayer Clinical Trials Contact Bayer AG

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 20/11/2014

Actual: 28/01/2014

Study start date

Planned: 30/05/2014

Actual: 31/05/2014

Date of final study report
Planned: 30/04/2019

Actual: 28/05/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer AG

Study protocol

EXPERT_16657_CSP_sign.pdf(1.23 MB)

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

The primary objective is the assessment of long-term safety of adempas in real life clinical practice

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

ADEMPAS

Medical condition to be studied

Pulmonary hypertension

Population studied

Short description of the study population

Patients who have been prescribed Adempas® for a medically appropriate use will be eligible to be included into this registry. Indications and contraindications according to the local market authorization should carefully be considered.

Inclusion criterion/criteria

• Female and male patients who start or are on treatment with Adempas®

• Written informed consent

Exclusion criterion/criteria

• Patients currently participating in an interventional clinical trial

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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)

Special population of interest

Other

Special population of interest, other

Patients with pulmonary hypertension

Estimated number of subjects

900

Study design details

Outcomes

1.Number of adverse events/ serious adverse events 2.all-cause mortality, 1.Number of adverse event (AE) and serious adverse event(SAE) in the different pulmonary hypertension(PH) indications (pulmonary arterial hypertension (PAH) chronic thromboembolic pulmonary hypertension(CTEPH))2. 6 minute walking distance3.Number of hospitalization/outpatient visitsMore details are posted on www.clinicaltrials.gov under NCT02092818.

Data analysis plan

All background variables and outcome parameters will be analyzed descriptively.All analyses will be performed for the total study population and separately for PH subtype

Documents

Study results

16657_EU-PAS_Abstract_2019-06-03.pdf(283.92 KB)

16657_EU-PAS_Abstract_2019-09-06.pdf(282.41 KB)

Study report

16657_EXPERT CSR Addendum_Bayer_16MAR2020_Redacted.pdf(616.81 KB)

16657_EXPERT CSR_Final Report_Bayer_26 JUL 2019_Redacted.pdf(4.2 MB)

16657_EXPERT CSR_Final Report_Bayer_28MAY2019_Redacted.pdf(6.12 MB)

Study, other information

16657_EXPERT CSR_Final Report_Bayer_26 JUL 2019_Redacted.pdf(4.2 MB)

16657_EXPERT CSR_Final Report_Bayer_28MAY2019_Redacted.pdf(6.12 MB)

Data management

Data sources

Data sources (types)

Electronic healthcare records (EHR)

Other

Data sources (types), other

Prospective patient-based data collection

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