A national, multicenter, prospective, single-arm registry PASS of pulmonary hypertension patients treated with Riociguat (Adempas®) in China (MK-4836-001) (EXPERT China)

First published: 12/02/2021

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS39007

Study ID

47274

DARWIN EU® study

No

Study countries

China

Study description

The primary objective of this study is to assess long-term safety of Adempas® in Chinese participants with pulmonary arterial hypertension (PAH) or Chronic Thromboembolic Pulmonary Hypertension (CTEPH). In addition, the study will prospectively collect data on clinical effectiveness, resource use, and how Adempas® is used by pulmonary hypertension (PH) experts in real-world clinical practice.

Study status

Finalised

Research institutions and networks

Institutions

Merck Sharp & Dohme LLC

United States

First published: 01/02/2024

Last updated: 08/07/2025

Institution | Pharmaceutical company

Merck Investigational Site China

Contact details

Study institution contact

Clinical Trials Disclosure Merck Sharp & Dohme LLC

ClinicalTrialsDisclosure@merck.com

Study contact

ClinicalTrialsDisclosure@merck.com

Primary lead investigator

Clinical Trials Disclosure Merck Sharp & Dohme LLC

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 28/03/2017

Study start date

Actual: 26/03/2019

Data analysis start date

Actual: 27/09/2020

Date of final study report

Planned: 18/03/2021

Actual: 10/03/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharpe & Dohme LLC

Study protocol

MK-4836-001-01-Prot_Final Redaction.pdf (377.18 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Other study registration identification numbers and links

The Drug Clinical Trial Registration and Information Posting Platform (Center for Drug Evaluation, NMPA) No. CTR20171218,,URL: http://www.chinadrugtrials.org.cn/index.html

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

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The primary objective is the assessment of long-term safety of Adempas® in real-world clinical practice.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

ADEMPAS

Medical condition to be studied

Pulmonary arterial hypertension

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 Chinese label for Adempas® should be carefully considered.

Inclusion Criterion/Criteria

• Patients who have been diagnosed with PAH or CTEPH

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

• WHO Function Class II-III for patients newly treated with Adempas®

• Written informed consent

Exclusion Criterion/Criteria

• Patients currently participating in an interventional clinical trial (If a patient is currently in the CHEST or PATENT (riociguat) long term extension trials, then the
patient can be considered for transition into EXPERT China study after the last dosing of riociguat.)

• Female patient who is pregnant

• Patients with severe hepatic impairment (Child Pugh grade C)

• Patients with SBP<95 mmHg when newly treated with Adempas®

• Patients who have been diagnosed with idiopathic interstitial pneumonia

• Co-administration with specific PDE 5 inhibitors (such as sildenafil, tadalafil or

vardenafil) or nonspecific PDE 5 inhibitors (such as dipyridamole or theophylline)
• Co-administration with nitrates or nitric oxide donors (such as amyl nitrite) in any form
• Any condition which, in the opinion of the investigator may confound the results or result in unwarranted risk in administering Adempas® to the patient.

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

Pulmonary Arterial Hypertension patients

Estimated number of subjects

80

Study design details

Outcomes

Incidence of adverse events Incidence of serious adverse events Incidence of all-cause mortality, Incidence of adverse events (AE) and Serious Adverse Events (SAE) in the different PH indications (PAH, CTEPH) Incidence of AE of

special interest (Symptomatic hypotension and hemoptysis) Change from baseline in clinical parameters at follow up of PH participants Number of hospitalizations/outpatient visits Dosage and change in treatment for subgroups

Data analysis plan

Analyses will be of an explorative and descriptive nature. There is no formal hypothesis testing. All background variables and outcome parameters will be analyzed descriptively with appropriate statistical methods: Categorical variables by frequency tables, and continuous variables by summary statistics. Continuous variables will also be described by absolute value and as change from baseline per analysis time point, if applicable. All analyses will be performed for the total study population (overall analysis) and separately for PH subtype and relevant subgroups, (e.g. age, gender, incident and prevalent patients, functional class at baseline, titrated dose), if patient numbers are sufficient.

Documents

Study results

MK-4836-001-final-report-MAR-2021-EXPERT-CHINA_Final Redaction.pdf (688.45 KB)

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

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