A Single-Arm Retrospective Study to Evaluate Safety and Efficacy in Patients with Acute Hepatitis C Virus (HCV) Infection Treated with 8 Weeks of Glecaprevir/Pibrentasvir

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Study Finalised

Administrative details

EU PAS number

EUPAS39656

Study ID

48811

DARWIN EU® study

No

Study countries

Australia

Canada

France

Italy

Spain

United Kingdom

United States

Study description

This study aims to demonstrate safety and efficacy for once-daily (QD)glecaprevir (GLE) and pibrentasvir (PIB) at the dose of GLE 300 mg and PIB 120 mg in acute HCV patients.

Study status

Finalised

Contact details

Study institution contact

Clinical Trial Disclosure AbbVie CT.Disclosures@abbvie.com

Study contact

CT.Disclosures@abbvie.com

Primary lead investigator

Clinical Trial Disclosure AbbVie

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/05/2020

Actual: 01/05/2020

Study start date

Planned: 29/04/2021

Actual: 20/05/2021

Date of final study report

Planned: 13/12/2022

Actual: 22/02/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AbbVie

Study protocol

h20315-protocol-synopsis-nis-version date 24feb2021.pdf (163.24 KB)

p20315-protocol-pmos-amendment1_Redacted.pdf (647.96 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

H20-315, P20-315

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The primary objective of this study is to demonstrate the efficacy of GLE/PIB prescribed for 8 weeks in patients with acute HCV genotype (GT)1 – GT6 infection by comparing the SVR12 rate from this study to the historical SVR12 rate in people with chronic HCV infection who were treated with GLE/PIB.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Single-arm, retrospective study (patient chart review)

Study drug and medical condition

Medicinal product name, other

Mavyret

Medical condition to be studied

Acute hepatitis C

Population studied

Short description of the study population

The study population included adolescent and adult patients with acute hepatitis C virus (HCV) infection who had prescribed treatment with glecaprevir plus pibrentasvir (GLE/PIB) identified through the medical charts.

Inclusion criteria:

1. Evidence of acute HCV infection is defined as physician diagnosis of acute HCV infection and 1 of the following:

a. negative anti-HCV antibody, HCV RNA and/or HCV core antigen followed by a positive HCV RNA or HCV core antigen followed by initiating GLE/PIB treatment within a 9-month period

OR

b. negative anti-HCV antibody, HCV RNA and/or HCV core antigen followed by a positive HCV RNA or HCV core antigen followed by initiating GLE/PIB treatment within a 12-month period; AND risk behaviour 6 months prior to positive HCV RNA or HCV core antigen

OR

c. clinical signs and symptoms compatible with acute hepatitis (ALT > 5 × ULN and/or jaundice) in the absence of a history of chronic liver disease or other cause of acute hepatitis and positive HCV RNA or HCV core antigen followed by initiating GLE/PIB treatment within a 9-month period; AND risk behaviour 6 months prior to positive HCV RNA or HCV core antigen

OR

d. negative anti-HCV antibody with a positive HCV RNA or HCV core antigen followed by initiating GLE/PIB treatment within a 6-month period

2. Age 12 years or older.

3. Treatment-naïve, i.e., no prior treatment, including interferon, for this HCV infection.

4. Evidence of 8 weeks total of GLE/PIB prescription provided to patient.

5. Patient received treatment with GLE/PIB, as confirmed by investigator.

Exclusion criteria:

• History of liver decompensation.

• Liver or kidney transplant history.

Age groups

- Adolescents (12 to < 18 years)
- 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 acute HCV infection

Estimated number of subjects

250

Study design details

Outcomes

The primary efficacy endpoint is the achievement of SVR12 (sustained virologic response 12 weeks after the last dose of the drug) for each patient in the modified Full Analysis Set (mFAS) population. The secondary efficacy endpoints are: -Achievement of SVR12 for each patient in the FAS population. -On-treatment virologic failure for each patient in the FAS population. -Post-treatment relapse for each patient in the FAS population who completed treatment as planned. -Post-treatment reinfection with HCV for each patient in the FAS population.

Data analysis plan

The primary and secondary endpoints will be summarized with counts and percentages. Two-sided 95% confidence intervals for the percentages will also be calculated using Wilson's score method.

Documents

Study results

P20315-pmos-results-rpt_abstract_Redacted.pdf (243.07 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

Patient chart review

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