# LICAVIR Study Synopsis and Table Shells

**First published:** 20/01/2022

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Study Finalised

## Administrative details

**EU PAS number**

EUPAS44830

**Study ID**

44831

**DARWIN EU® study**

No

**Study countries**

☐ France

**Study description**

A retrospective data collection from a cohort of patients with chronic HCV infection, who developed HCC up to the end of 2019.

**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: 19/07/2021

Actual: 19/07/2021

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**Study start date**

Planned: 19/07/2021

Actual: 19/07/2021

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**Date of final study report**

Planned: 24/09/2021

Actual: 24/09/2021

# Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

AbbVie

## Study protocol

20201014_Abbvie Licavir Synopsis_Final.pdf (245.05 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

P21-900

# 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:**

Secondary use of data

**Main study objective:**

To characterize the de novo HCC cases that occurred with and without DAA treatment.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name**

MAVIRET

**Medical condition to be studied**

Chronic hepatitis C

## Population studied

**Short description of the study population**

Patients with chronic HCV infection, who developed HCC up to the end of 2019.

**Age groups**

- Adults (46 to < 65 years)

**Special population of interest**

Hepatic impaired

**Estimated number of subjects**

397

## Study design details

**Data analysis plan**

A descriptive analysis of patients treated with any DAA who develop HCC after DAA initiation and patients who develop HCC without DAA treatment. No direct comparisons of treatment groups will be performed. Summary statistics were provided as mean (SD) for continuous variables, for all individuals with non-missing values, and N (%) for categorical variables. Patient characteristics were assessed over the period from data start through 1 day prior to HCC diagnosis. For characteristics with multiple measurements or assessments (i.e. labs, fibrosis stage, etc.), the value closest but prior to HCC diagnosis was selected.

## Documents

**Study results**

LICAVIR results abstract.pdf (128.38 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**

Retrospective 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