Clinical Benefit of Bulevirtide Therapy in Adult Patients With Chronic Hepatitis Delta Compared to a Historical Control Group Receiving Standard of Care

First published: 05/02/2025

Last updated: 04/12/2025

Study Ongoing

Administrative details

EU PAS number

EUPAS1000000463

Study ID

1000000463

DARWIN EU® study

No

Study countries

Austria

Belgium

France

- Germany
- Greece
- Italy
- Netherlands
- Romania
- Spain
- Sweden
- United Kingdom
- United States

Study description

GS-EU-589-6575: This is an observational, multicenter, multicounty study. In which the primary objective is to compare the risk of liver-related events in patients treated with bulevirtide (BLV(GS-4438), Hepcludex®) to a historical group of adult patients who received standard of care were not treated with BLV during up to 5 years of follow-up time.

Study status

Ongoing

Research institutions and networks

Institutions

Gilead Sciences

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Institution | Pharmaceutical company

Contact details

Study institution contact

Gilead Study Director ClinicalTrialDisclosure@gilead.com

Study contact

ClinicalTrialDisclosure@gilead.com

Primary lead investigator

Gilead Study Director

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 18/11/2024

Study start date

Planned: 04/03/2025

Actual: 25/03/2025

Date of final study report

Planned: 31/03/2034

Study protocol

GS-ES-589-6575-appendix-16.1.1-protocol amendment 1_f-redact.pdf (12.05 MB)

GS-EU-589-6575-appendix-16.1.1- Original Protocol_f-redact.pdf (2.93 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Study design:

This is an observational, multicenter, multi-country study comparing the risk of liver-related events in patients treated with BLV (2 mg or 10 mg) to a historical control group of adult patients who received standard of care and were not treated with BLV during up to 5 years of follow-up time.

Main study objective:

1. The primary objective of the study is to compare the risk of liver-related events (i.e., development of cirrhosis, hepatic decompensation [i.e., ascites, hepatic encephalopathy, portal hypertension-related GIB, jaundice)], HCC, liver

transplantation, and liver-related death) in adult patients with CHD treated with BLV monotherapy (2 mg or 10 mg without concomitant Peg-IFNα) to the risk of liver-related events in a historical control group of adult patients with CHD not treated with BLV and receiving standard of care (i.e., off-label treatment with Peg-IFNα or no CHD treatment) for up to 5 years following cohort entry (defined as BLV treatment initiation in the BLV group or first date in the study period when a historical control patients had a health care encounter and met all inclusion and exclusion criteria).
2. The secondary objectives of the study are:
• To compare the risk of each type of liver-related event (i.e., development of cirrhosis, hepatic decompensation, liver transplantation, HCC, and liver-related death) in patients treated with BLV monotherapy with the historical control group receiving standard of care.
• To compare the risk of liver-related events in patients treated with BLV 2 mg or BLV 10 mg with or without concomitant Peg-IFNα (i.e., patients initiating BLV monotherapy who may add concomitant Peg-IFNα during the course of BLV treatment) with the historical control group receiving standard of care (i.e., off-label treatment with Peg-IFNα or no CHD treatment).

Study drug and medical condition

Medicinal product name

HEPCLUDEX

Medicinal product name, other

Bulevirtide, BLV(GS-4438)

Study drug International non-proprietary name (INN) or common name

BULEVIRTIDE ACETATE

Anatomical Therapeutic Chemical (ATC) code

(J05A) DIRECT ACTING ANTIVIRALS

DIRECT ACTING ANTIVIRALS

Medical condition to be studied

Chronic hepatitis

Population studied

Age groups

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Study design details

Setting

This study will include patients from health centers in Europe and North America. Efforts will be made to enroll the same sites for data collection on patients in both the historical control and BLV-treated groups. If the historical control group includes patients from sites not included in the BLY-treated group,

these sites will be clinical centers in No1th American and European countries with comparable patient management and care.

Outcomes

This study will utilize an independent Hepatic Events Adjudication Committee (HEAC) to review and independently adjudicate liver-related events to ensure that liver-related events are assessed in a consistent and transparent manner. The same operational definitions of liver-related events, including for cirrhosis events, will be applied to all patients in the BLV-treated and historical control groups in order to ensure consistency.

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)

Administrative healthcare records (e.g., claims)

Cancer registry

Electronic healthcare records (EHR)

Other

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Yes

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

No