Barodelta study: Real world data (RWD) of 498 unique patients with chronic hepatitis Delta treated with bulevirtide (BLV) 2 mg. Analysis from the French National Health Data System (SNDS).

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Barodelta

KEY FINDINGS

- In France, Bulevirtide (BLV) became available in September 2019 through an early access program, was approved in July 2023 and is now reimbursed for all patients with Chronic Hepatits Delta (CHD).
- The Health-care system is universal, with a centralized claim database (French National Health Data System, SNDS).
- Between Sept 2019 and Dec 2022, an exhaustive large cohort of 498 patients receiving BLV was extracted from the database.
- 77% had universal medical coverage or state medical aid, suggesting they had limited income and resources.
- More than half (62%) were impowered to manage BLV at day 15, without difference regarding the status (drug users, state medical aid)
- Adherence was high: 91% at 6 months, 89% at 12 months and 87% at 24 months
- Persistence was 54% at 24 months and did not differ according to patients characteristics and comorbidities.

⇨ French experience demonstrates the BLV can be initiated to large patient profiles, including vulnerable and marginalized populations, with good observance and empowerment rates.

Introduction

- Bulevirtide (BLV), a novel hepatitis delta virus (HDV) entry inhibitor, is fully approved in Europe since July 2023 for the treatment of chronic hepatitis delta (CHD). In France BLV was available through an early access program from September 2019. BLV should be administered at 2 mg once daily by subcutaneous injection as long as a clinical benefit is observed.
- French health-care system is a universal system mainly financed by mandatory health contributions from employers, employees and the self employed without risk of financial issues and is accessible for all person living in France. BLV is reimbursed whatever the patient profile.
- The Barodelta project has two parts. The first on is the evaluation of the HDV landscape in France with an update of the HDV epidemiology data. Here we focus on the results of the second part dedicated to the all patients treated with BLV from 2019 to 2022. Data on patients profile, adherence, empowerment and persistence are presented.

Methods

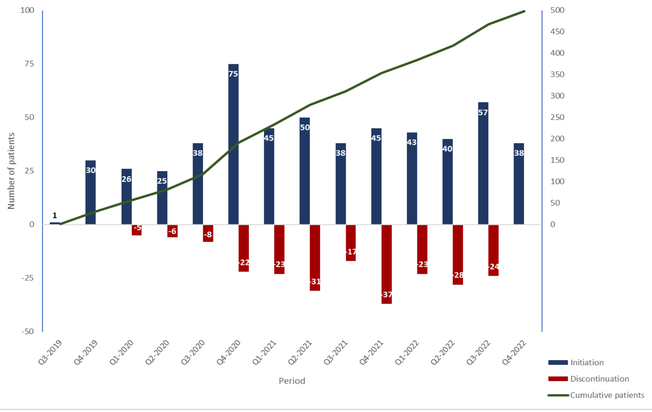
- Retrospective cohort using the French National Health Data System (SNDS) : unique claim database covering continuously ~99% of the population living in France (more than 67 million people).
- Socio-demographic and medical information on all in- and outpatient services reimbursed by the National Health Insurance: dates of medical or paramedical visits, medications, realization (without results) of laboratory tests, imaging procedures and other complementary exams, Long-Term Diseases (LTDs) status.
- All adults patients with BLV initiation from September 2019 to December 2022 included
- **Adherence** estimated by the Medication Possession Ratio (MPR)
- **Treatment discontinuation** : 3 months without treatment. 2 categories of discontinuation : permanent (definitive stop) or temporary (stop followed by reinitiation).
- **Persistence** : probability of no discontinuation of treatment over time, estimated using the Kaplan Meier method

Results

Description of BLV initiation and discontinuation (Figure 1)

- 551 initiations of BLV for 498 patients (51 patients with a temporary discontinuation and 2 patients with 2 temporary discontinuations).

Figure 1 : Initiation and discontinuation of BLV treatment



Characteristics of BLV patients (Table 1)

- Mainly male young patients (mean age = 42,5 Yr).
- 76.7% had limited income and resource suggested by universal medical coverage or state medical aid.
- 11.6% HIV coinfected, 21.3% metabolic syndrome, 7.8% current or former drug users.

Table 1 : Characteristic of BLV patients (N=498)

	BLV patients
Age (Yr)	42.5
Male sex (%)	69.5
Patients with limited income and ressources (%)	76.7
Associated pathologies (%)	
Metabolic syndrome	21.3
HIV coinfection	11.6
Current or former drug user	7.8
Comedications (%)	
NUC	60
Without NUC and IFN	22
IFN before BLV	26
Bitherapy (BLV+IFN)	46

Empowerment (Table 2)

- Autonomy was defined as less than 5 days coverage with a nurse during the first 15 days of treatment.
- At day 15, 62% of patients were empowered to manage BLV.

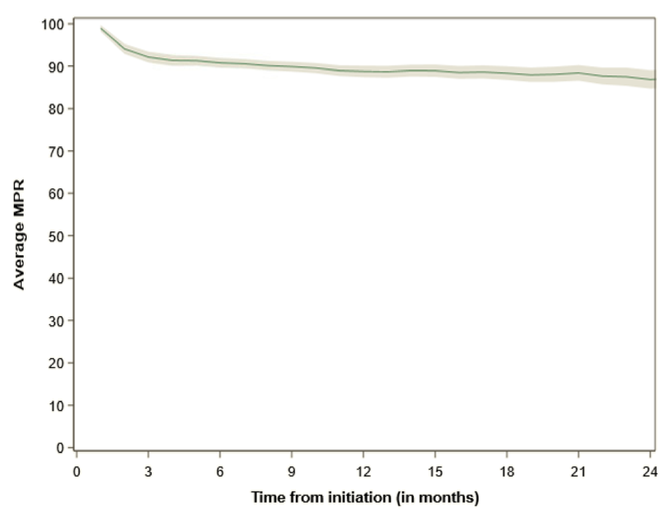
Table 2 : Empowerment of BLV patients – N=498

	BLV patients
Patients' level of autonomy at day 15 (%)	
Autonomous patients (<5d coverage)	62.1
Partially autonomous patients (>5 - <10d coverage)	9.7
Non autonomous patients (>10d coverage)	28.1

Adherence (Figure 2)

- Patient adherence to BLV was 91% at 6 months, 89% at 12 months and 87% at 24 months.

Figure 2 : Adherence to BLV treatment



Persistence

- Among the 191 patients with at least 24 months of follow-up, median duration of treatment was 554 days [min 30 – Max 1170].
- Persistence rate was 54% at 24 months.
- 224 treatment discontinuations were observed.
- No significant correlation between persistence and sociodemographic criteria, comorbidities or comedications could be identified.

Discussion

- First data on real-world use of BLV in all patients treated in France where treatment has been made available since 2019 for all the patients with a CDH.
- High rates of BLV adherence (87%), and patient empowerment (62%) support the possibility to initiate a BLV treatment to a large profile of patients.
- Reasons for discontinuation are not documented in the SNDS. They can be multiple: patient lost to follow up, lack of efficacy, patient lassitude, therapeutic break, long term RNA undetectability, others. Clinical Real World Data will be needed to explore this parameter particulary in a French context where physicians are tempted to propose a finite therapy strategy according to the patient profile.

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