Final Results of MYR301: A Randomised Phase 3 Study Evaluating the Efficacy and Safety of BLV Monotherapy for Chronic Hepatitis Delta

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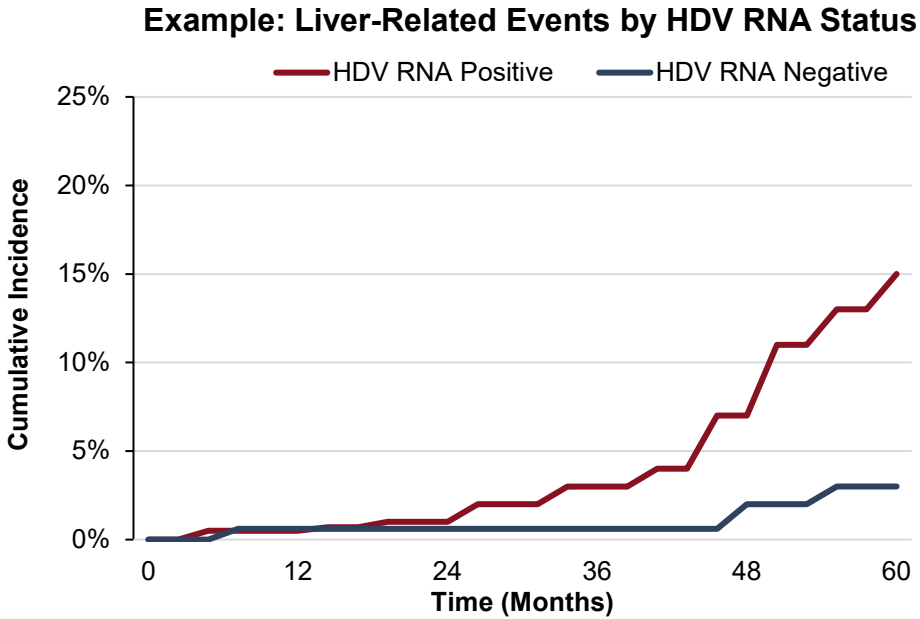
Disclosures

HW reports honoraria for speaking or consulting from Bristol Myers Squibb; Falk; Gilead Sciences, Inc.; GSK; Intercept Pharmaceuticals; Merck Sharp & Dohme; Mirum Pharma; Roche; Takeda; and Vir Biotechnology. **SAleman** received honoraria for lectures and educational events from AbbVie; Biogen; Gilead Sciences, Inc.; GSK; Janssen; Merck Sharp & Dohme; MYR GmbH; Roche; and Spring Bank Pharmaceuticals. **ABlank** received research funding from MYR GmbH. **PA** has received honoraria for lectures from Gilead Sciences, Inc., and Intercept Pharmaceuticals. **PB** has received grants and speaking fees from AbbVie; Bayer; Gilead Sciences, Inc.; Hepatera; Merck Sharp & Dohme; Novo Nordisk; and R-Pharm. **VC** reports being a consultant and giving sponsored lectures for AbbVie; AstraZeneca; Bristol Myers Squibb; Gilead Sciences, Inc.; GSK; Hepatera; Merck Sharp & Dohme; Roche; and R-Pharm. **NM**, **NG**, **VM**, **OS**, **TS**, **ABerger**, **SC**, and **SZ** report nothing to disclose. **AL**, **DM**, **RCM**, **SArterburn**, **FCC**, **ST**, and **AO** are employees of Gilead Sciences, Inc., and may own stock in Gilead Sciences, Inc. **JSW** serves as a consultant for Gilead Sciences, Inc. **MC** reports honoraria from AbbVie; Falk; Gilead Sciences, Inc.; GSK; Janssen-Cilag; Merck Sharp & Dohme; Novartis; Roche; Spring Bank Pharmaceuticals; and Swedish Orphan Biovitrum. **MRB** reports receiving teaching/speaking fees and consulting fees from AbbVie; AstraZeneca; Gilead Sciences, Inc.; Merck Sharp & Dohme–Eisai; and Roche. **PL** reports speaking and teaching fees from and participation in advisory committees or review panels for AbbVie; Aligos Therapeutics; Alnylam Pharmaceuticals; Antios Therapeutics; Arrowhead Pharmaceuticals; Bristol Myers Squibb; Eiger Biopharmaceuticals; Gilead Sciences, Inc.; GSK; Janssen; Merck Sharp & Dohme; MYR GmbH; Roche; and Spring Bank Pharmaceuticals.

Background

- Hepatitis delta virus (HDV) infection causes the most severe form of chronic hepatitis,[1] with prevalence estimates of between 9 and 19 million people worldwide[2,3]
  - The incidence of liver-related events is significantly higher with HDV than without HDV[4]



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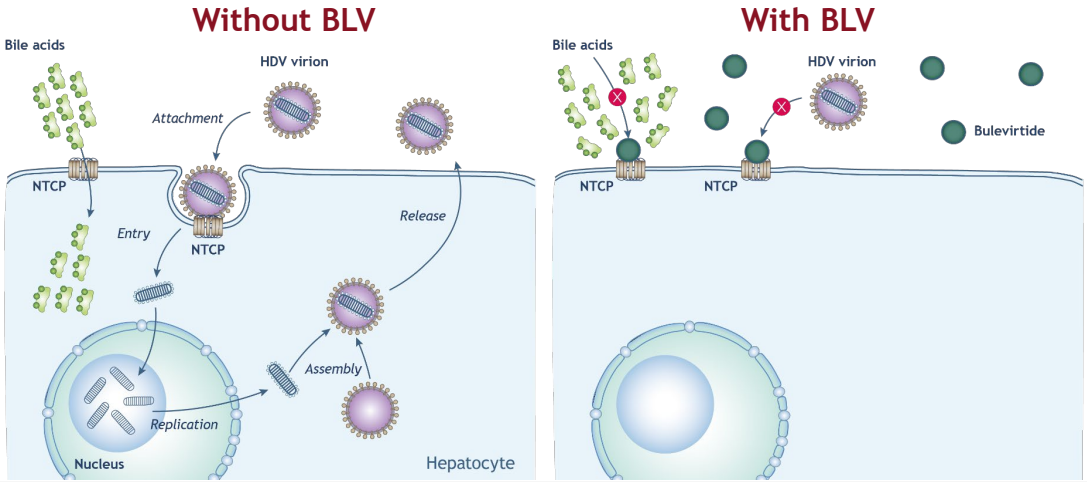
- HDV requires hepatitis B surface antigen (HBsAg) from hepatitis B virus (HBV) to infect hepatocytes[5]
- Bulevirtide (BLV) is a first-in-class HBsAg entry inhibitor
  - BLV selectively binds and inactivates NTCP, blocking HDV entry into hepatocytes[6,7]



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- Bulevirtide (BLV) is a first-in-class HBsAg entry inhibitor
  - BLV selectively binds and inactivates NTCP, blocking HDV entry into hepatocytes[6,7]
- BLV 2 mg is approved in the European Economic Area, Great Britain, Switzerland, the Russian Federation, and Australia for chronic hepatitis delta (CHD) and is recommended by the EASL clinical practice guidelines for the treatment of CHD in adult patients with compensated liver disease[8-10]
- Monotherapy with BLV 2 or 10 mg/day has been demonstrated to be safe and effective over 144 weeks of treatment in both clinical trial and real-world settings[11-14]
- **The availability of off-treatment data is limited**

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Objective of This Analysis

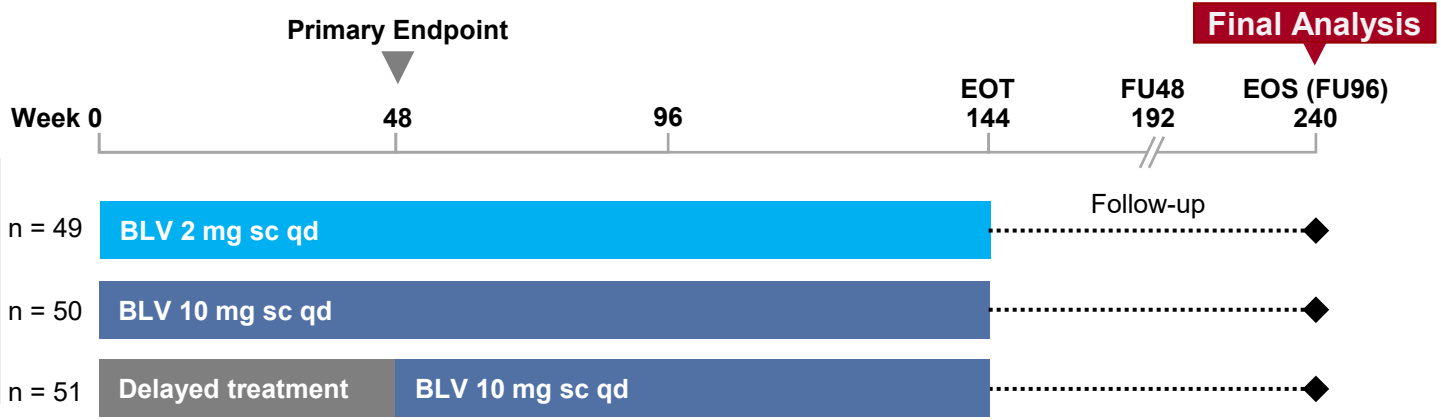
- To evaluate up to 96 weeks of posttreatment safety and efficacy after 96 to 144 weeks of BLV treatment

BLV, bulevirtide.

MYR301 Study Design

Key Inclusion Criteria

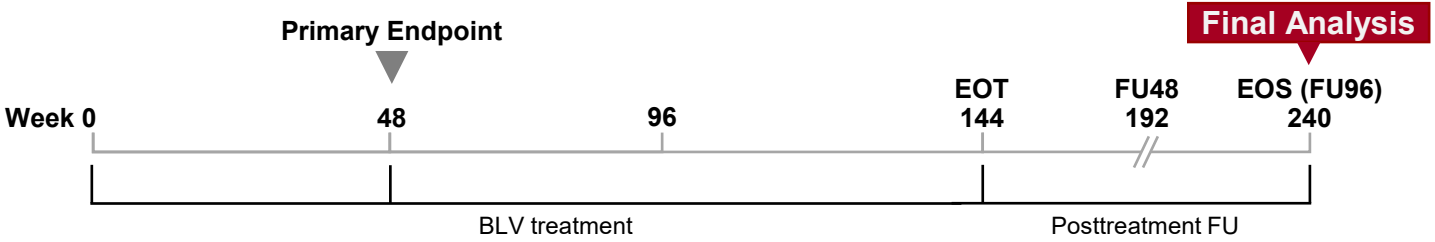
- CHD without or with cirrhosis
- CTP score ≤7
- ALT >1 × to <10 × ULN
- Platelets ≥60,000 cells/mm^3
- Controlled HIV coinfection allowed



- MYR301 was a multicentre, open-label, randomised, Phase 3 study (NCT03852719) conducted in 4 countries (Germany, Italy, Russian Federation, and Sweden)

ALT, alanine aminotransferase; **BLV**, bulevirtide; **CHD**, chronic hepatitis delta; **CTP**, Child-Turcotte-Pugh; **EOS**, end of study; **EOT**, end of treatment (week 144); **FU48**, follow-up at 48 weeks after EOT (week 192); **FU96**, follow-up at 96 weeks after EOT (week 240); **qd**, once daily; **sc**, subcutaneous; **ULN**, upper limit of normal.

MYR301 Efficacy Endpoints



Virologic response

- HDV RNA undetectable or decreased by ≥2 $\log_{10}$ IU/mL from baseline

ALT normalisation

- ≤31 U/L for females and ≤41 U/L for males (Russian sites)
- ≤34 U/L for females and ≤49 U/L for males (all other sites)

Undetectable HDV RNA

- HDV RNA levels by RT-PCR using RoboGene 2.0 (limit of detection 6 IU/mL)

Combined response

- Virologic response + ALT normalisation

- The primary endpoint, combined response at week 48, and further on-treatment follow-up were reported previously[1,2]
- **Safety and efficacy endpoints through follow-up 96 weeks after EOT (FU96 [week 240]) are described here**

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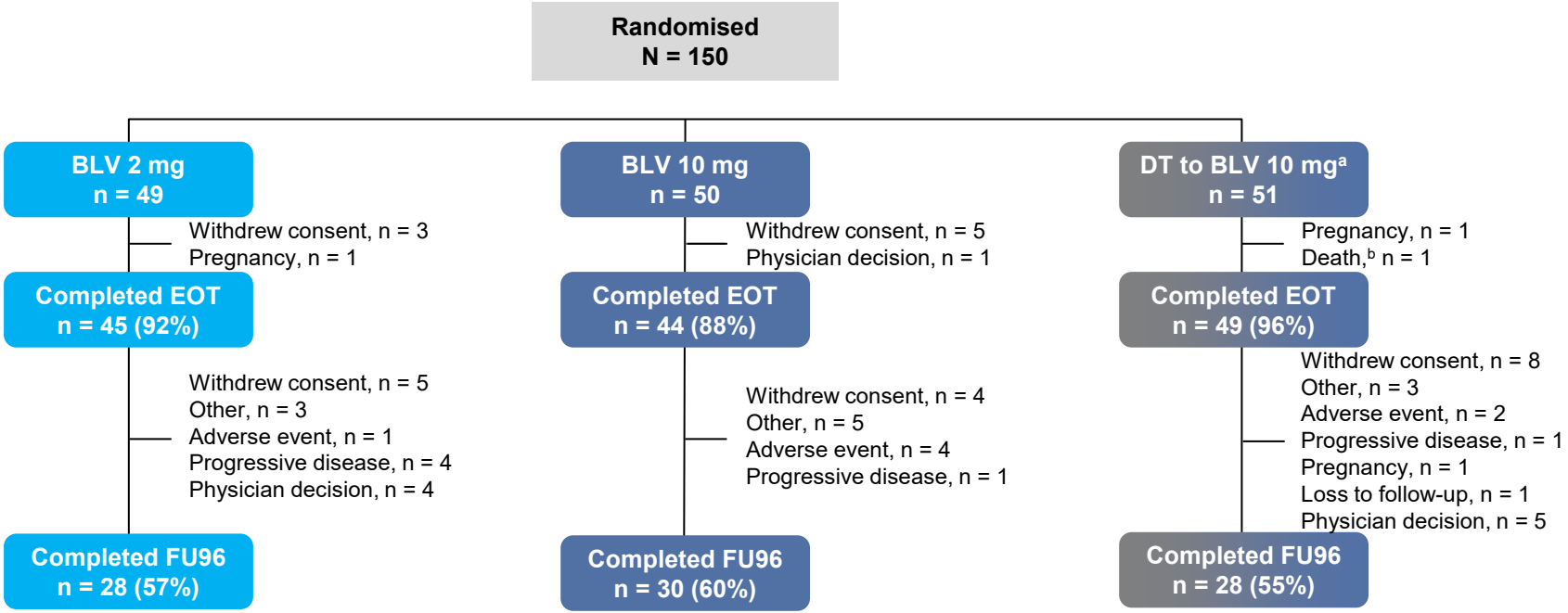
Patient Disposition



- Most patients in all groups continued in the study through EOT
- Early discontinuation during posttreatment follow-up was most commonly due to withdrawal of consent

[a]Patients in this group received no treatment for 48 weeks. Beginning at week 48, they received BLV 10 mg through study week 144. [b]One death due to plasma cell myeloma.
BLV, bulevirtide; **DT**, delayed treatment; **EOT**, end of treatment (week 144); **FU96**, follow-up at 96 weeks after EOT (week 240).

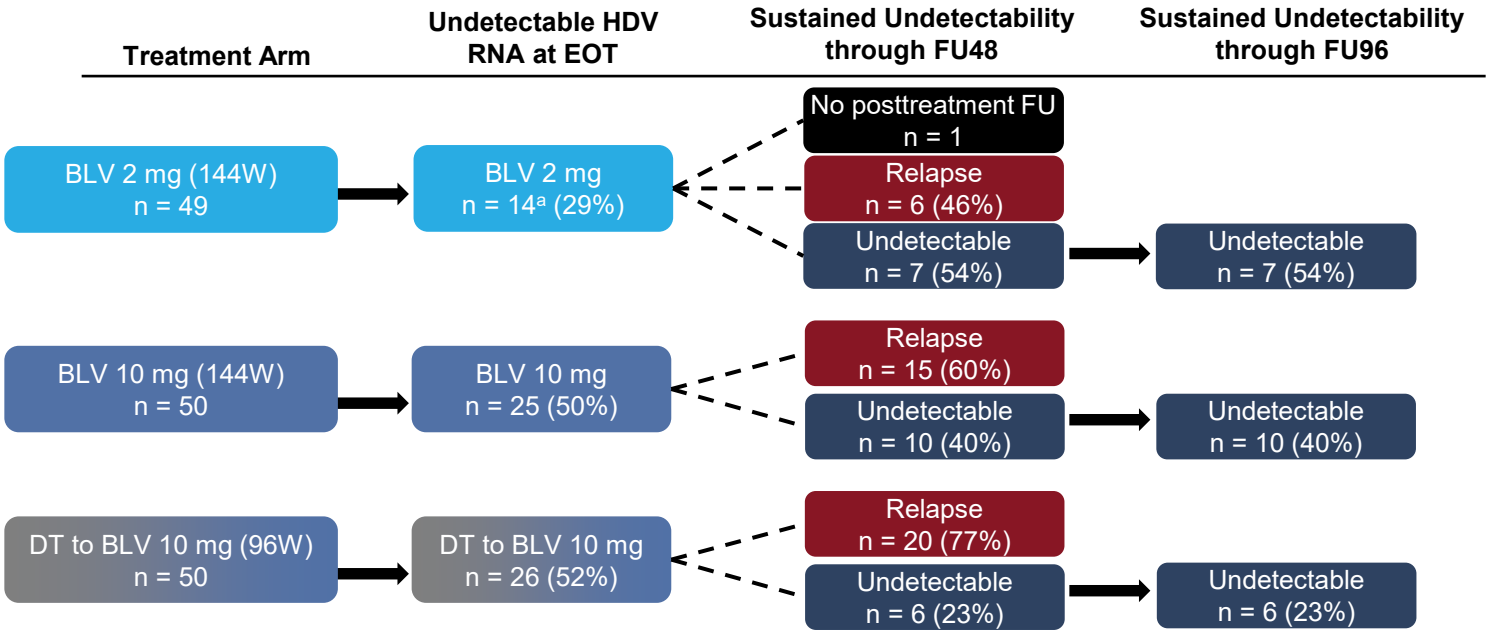
Demographic and Baseline Disease Characteristics

	BLV 2 mg n = 49	BLV 10 mg n = 50	DT to BLV 10 mg n = 51[a]
Age, years, mean (SD)	44 (9)	41 (9)	41 (8)
Male sex, n (%)	30 (61)	30 (60)	26 (51)
Race,[b] n (%)			
White	41 (84)	43 (86)	40 (78)
Asian	8 (16)	6 (12)	11 (22)
Cirrhosis present, n (%)	23 (47)	24 (48)	24 (47)
Liver stiffness, kPa, mean (SD)	14.0 (8.2)	14.8 (9.3)	15.3 (9.0)
ALT, U/L, mean (SD)	108 (63)	123 (81)	102 (62)
HDV RNA, $\log_{10}$ IU/mL, mean (SD)	5.10 (1.19)	4.96 (1.46)	5.08 (1.36)
Genotype HDV-1,[c] n (%)	49 (100)	48 (96)	51 (100)
HBsAg, $\log_{10}$ IU/mL, mean (SD)	3.67 (0.52)	3.61 (0.59)	3.68 (0.47)
HBV DNA, $\log_{10}$ IU/mL, mean (SD)	1.31 (1.28)	1.08 (1.26)	0.89 (0.99)
HBV genotype,[d] n (%)			
A	2 (4)	2 (4)	2 (4)
D	47 (96)	44 (88)	44 (86)
Previous IFN therapy, n (%)	26 (53)	29 (58)	29 (57)
Concomitant HBV NA treatment, n (%)	32 (65)	27 (54)	33 (65)
Started prior to BL	27 (55)	25 (50)	30 (59)

- Nearly half the patients had cirrhosis at baseline (BL); demographic and BL disease characteristics were well balanced between treatment groups

[a]At BL, 51 patients were assigned to DT to BLV 10 mg, and their data are reported here. One patient subsequently withdrew from the DT to BLV 10 mg group before receiving BLV and is not included in subsequent reporting of efficacy and safety. [b]BLV 10 mg arm: Black, n = 1. [c]BLV 10 mg arm: HDV genotype 5, n = 1; missing HDV genotype, n = 1. [d]Other: BLV 10 mg arm: HBV genotype E, n = 1; no data, n = 3; DT to BLV 10 mg arm: unclassified HBV genotype, n = 2; no data, n = 3.
ALT, alanine aminotransferase; **BL**, baseline; **BLV**, bulevirtide; **DT**, delayed treatment; **HBsAg**, hepatitis B surface antigen; **HBV**, hepatitis B virus; **HDV**, hepatitis delta virus; **IFN**, interferon; **NA**, nucleos(t)ide analogue.

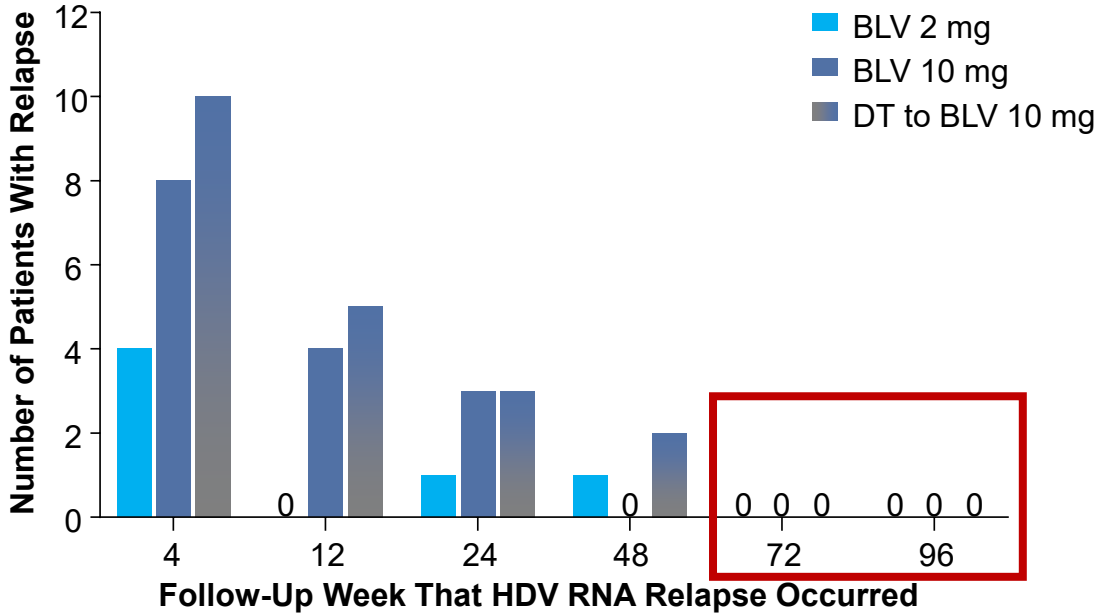
A Subset of Patients Sustained Undetectability Through FU96



- HDV RNA relapse was defined as HDV RNA undetectable at EOT and ≥1 HDV RNA sample during the follow-up period with observed detectable HDV RNA
- Across all arms, 65 of 149 (44%) patients had undetectable HDV RNA at EOT, of whom 64 had available follow-up data
  - Of these, 23 (36%) had sustained undetectability through FU96, and all relapses occurred by FU48

For missing values, the missing-equals-failure approach was used.
[a]One patient in the BLV 2 mg group had no FU data and was excluded from posttreatment calculations.
BLV, bulevirtide; **DT**, delayed treatment; **EOT**, end of treatment (week 144); **FU**, follow-up; **FU48**, follow-up at 48 weeks after EOT (week 192); **FU96**, follow-up at 96 weeks after EOT (week 240); **HDV**, hepatitis delta virus; **W**, week.

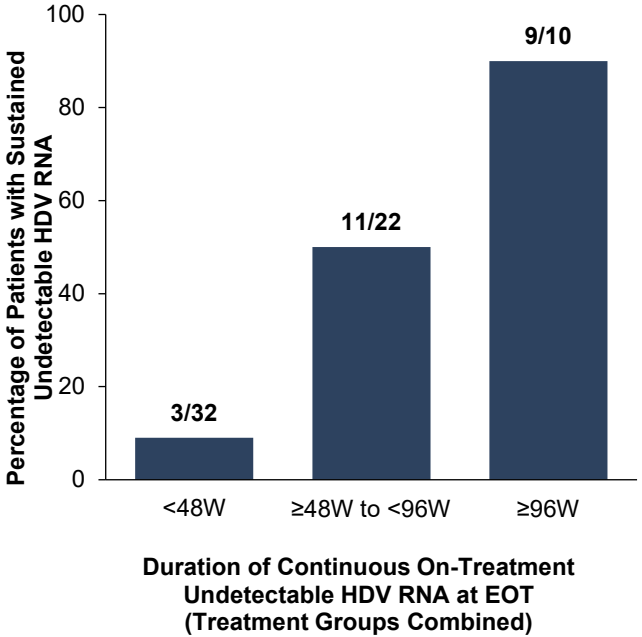
No New Relapses Occurred After 48 Weeks of Follow-up



- 93% (38/41) of relapses occurred within 24 weeks after EOT

Missing values were excluded from analysis.
BLV, bulevirtide; **DT**, delayed treatment; **EOT**, end of treatment (week 144); **FU96**, follow-up at 48 weeks after EOT (week 192); **HDV**, hepatitis delta virus.

Longer Duration of On-Treatment Undetectability Predicts Sustained Posttreatment Undetectability



For more information, please see:
Aleman et al, OS-066; Viral Hepatitis B/D Current Clinical Practice; 09/05/2025 (08:30–09:45)

- 90% of patients who had ≥96 weeks of continuously undetectable HDV RNA at EOT had sustained undetectability off treatment

Missing values were excluded from analysis.
EOT, end of treatment (week 144); **HDV**, hepatitis delta virus; **W**, week.

More Than 1/5 of Patients Had Undetectable HDV RNA at FU96

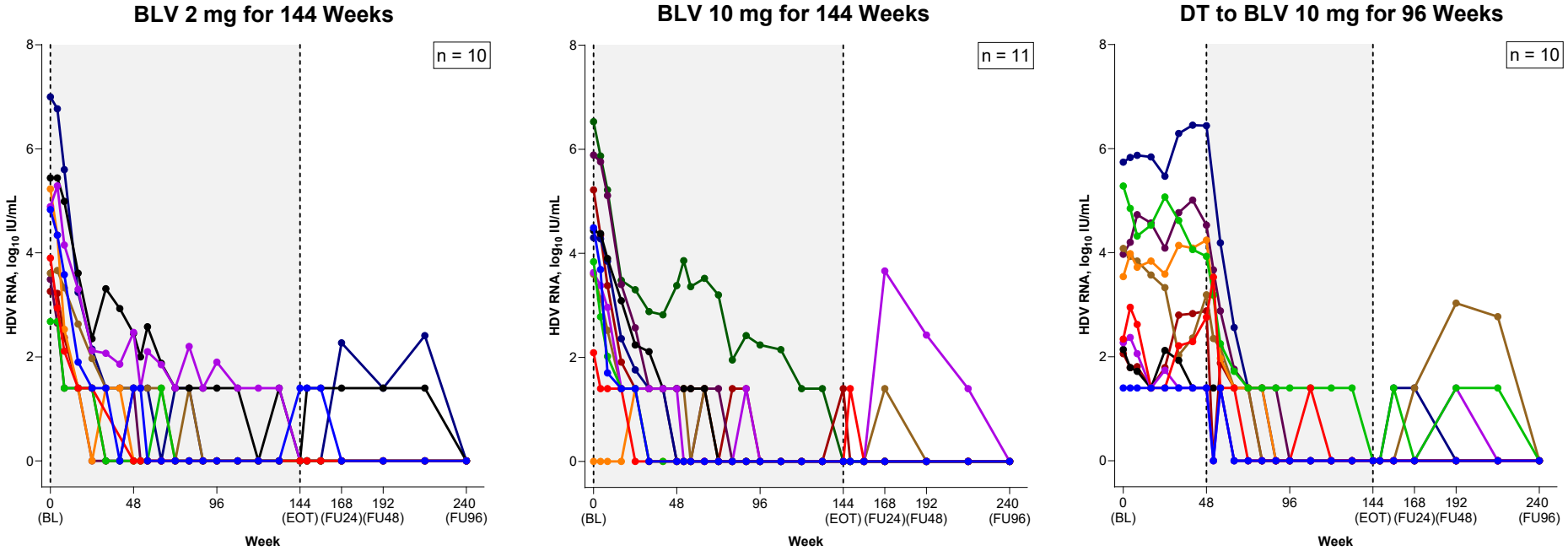
Number of Patients, n (%)	BLV 2 mg n = 49			BLV 10 mg n = 50			DT to BLV 10 mg n = 50		
Time point	EOT (W144 of BLV)	FU48	FU96	EOT (W144 of BLV)	FU48	FU96	EOT (W96 of BLV)	FU48	FU96
CR	28 (57)	11 (22)	12 (24)[a]	27 (54)	10 (20)	12 (24)[a]	28 (56)	9 (18)	12 (24)[a]
VR	36 (73)	14 (29)	16 (33)[a]	38 (76)	20 (40)[a]	15 (30)[a]	46 (92)	14 (28)	16 (32)[b]
ALT normalisation	29 (59)	13 (27)	12 (24)[a]	30 (60)	14 (28)	16 (32)[b]	29 (58)	12 (24)	14 (28)[a]
Undetectable HDV RNA	14 (29)	8 (16)	10 (20)	25 (50)	12 (24)	11 (22)	26 (52)	8 (16)	10 (20)
Change from BL in liver stiffness, kPa, LS mean (95%CI)[c]	−5.2 (−6.9, −3.6)	−3.7 (−5.3, −2.2)	−1.2 (−3.7, 1.3)	−4.0 (−5.7, −2.4)	−3.7 (−5.3, −2.1)	−3.3 (−5.8, −0.8)	−4.2 (−5.4, −3.0)	−1.9 (−3.5, −0.3)	−3.6 (−6.1, −1.0)

- Overall, 21% of patients had undetectable HDV RNA at FU96

For missing values, the missing-equals-failure approach was used. [a]Includes 1 responder who restarted BLV prior to the visit. [b]Includes 2 responders who restarted BLV prior to the visit. [c]LS means and 95% CIs were based on the mixed-effects model for repeated measurements for change from BL with treatment (BLV 2 mg, BLV 10 mg, and DT to BLV 10 mg groups), region, presence of cirrhosis, visit and treatment by visit interaction as fixed effects, and BL value as a covariate. **ALT**, alanine aminotransferase; **BL**, baseline; **BLV**, bulevirtide; **CR**, combined response; **DT**, delayed treatment; **EOT**, end of treatment (week 144); **FU48**, follow-up at 48 weeks after EOT (week 192); **FU96**, follow-up at 96 weeks after EOT (week 240); **HDV**, hepatitis delta virus; **LS**, least squares; **VR**, virologic response; **W**, week.

Transient Virologic Relapse Occurred in Some Patients During Follow-Up

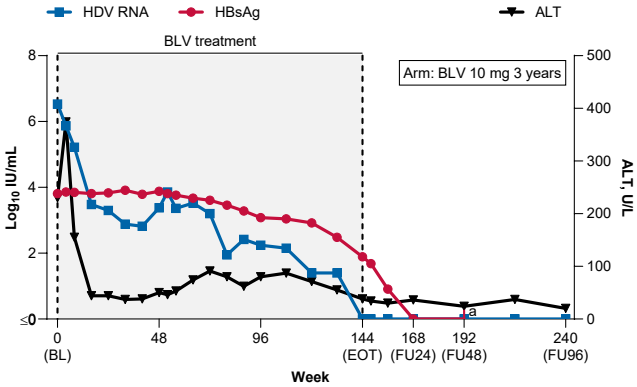
All Patients Achieving Undetectable HDV RNA at FU96



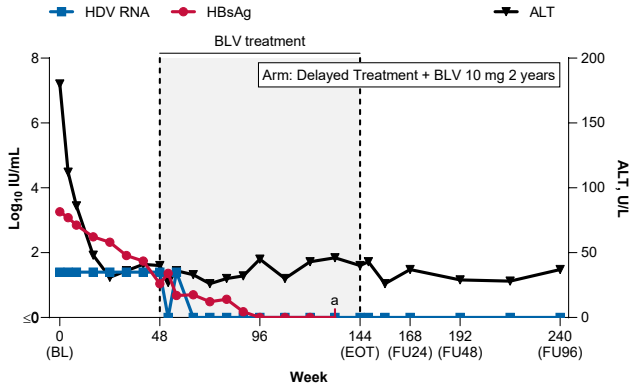
- While most patients who had undetectable HDV RNA at FU96 had sustained undetectability throughout follow-up, some had low-level viraemia at EOT or transient virologic relapses earlier during follow-up

Missing values were excluded from analysis.
BL, baseline; **BLV**, bulevirtide; **DT**, delayed treatment; **EOT**, end of treatment (week 144); **FU24**, follow-up at 24 weeks after EOT (week 168); **FU48**, follow-up at 48 weeks after EOT (week 192); **FU96**, follow-up at 96 weeks after EOT (week 240); **HDV**, hepatitis delta virus.

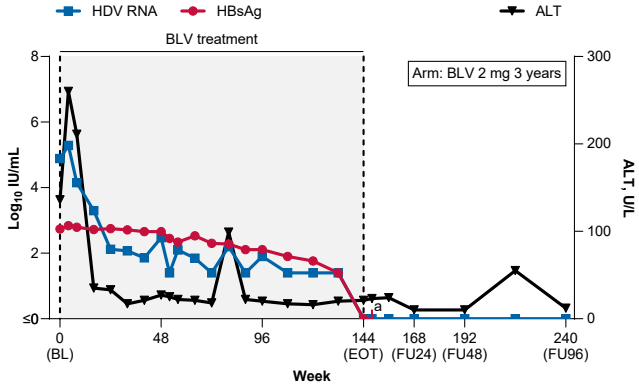
HBsAg Loss Occurred in 4 Patients



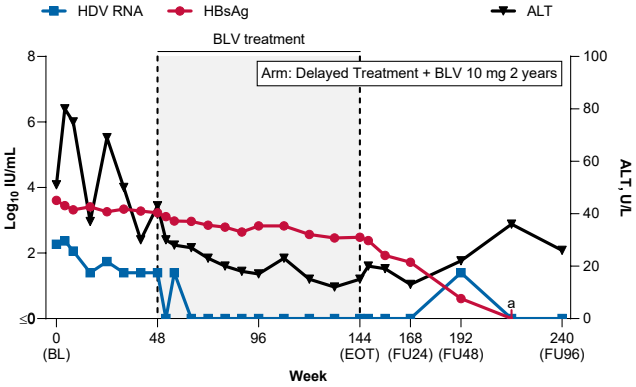
Patient: 04-03-303
Age: 34 years
Cirrhosis: Absent
Prior HBV medication: Yes (Tenofovir, continued on study)
Anti-HBsAg positive at baseline
HBV genotype: D
HDV genotype: HDV-1



Patient: 01-01-305
Age: 41/42 years
Cirrhosis: Present
Prior HBV medication: No
On-study HBV medication: Yes (Tenofovir started at Week 0)
Anti-HBsAg positive: None
HBV genotype: D
HDV genotype: HDV-1



Patient: 01-07-316
Age: 52 years
Cirrhosis: Absent
Prior HBV medication: No
On-study HBV medication: No
Anti-HBsAg positive at follow-up weeks 24, 72, 96
HBV genotype: D
HDV genotype: HDV-1



Patient: 01-06-317
Age: 38/39 years
Cirrhosis: Absent
Prior HBV medication: No
On-study HBV medication: No
Anti-HBsAg positive: None
HBV genotype: D
HDV genotype: HDV-1

[a]Denotes the time point at which HBsAg loss occurred.
ALT, alanine aminotransferase; **BL**, baseline; **BLV**, bulevirtide; **EOT**, end of treatment (week 144); **FU24**, follow-up at 48 weeks after EOT (week 168); **FU48**, follow-up at 48 weeks after EOT (week 192); **FU96**, follow-up at 96 weeks after EOT (week 240); **HBsAg**, hepatitis B surface antigen; **HBV**, hepatitis B virus; **HDV**, hepatitis delta virus.

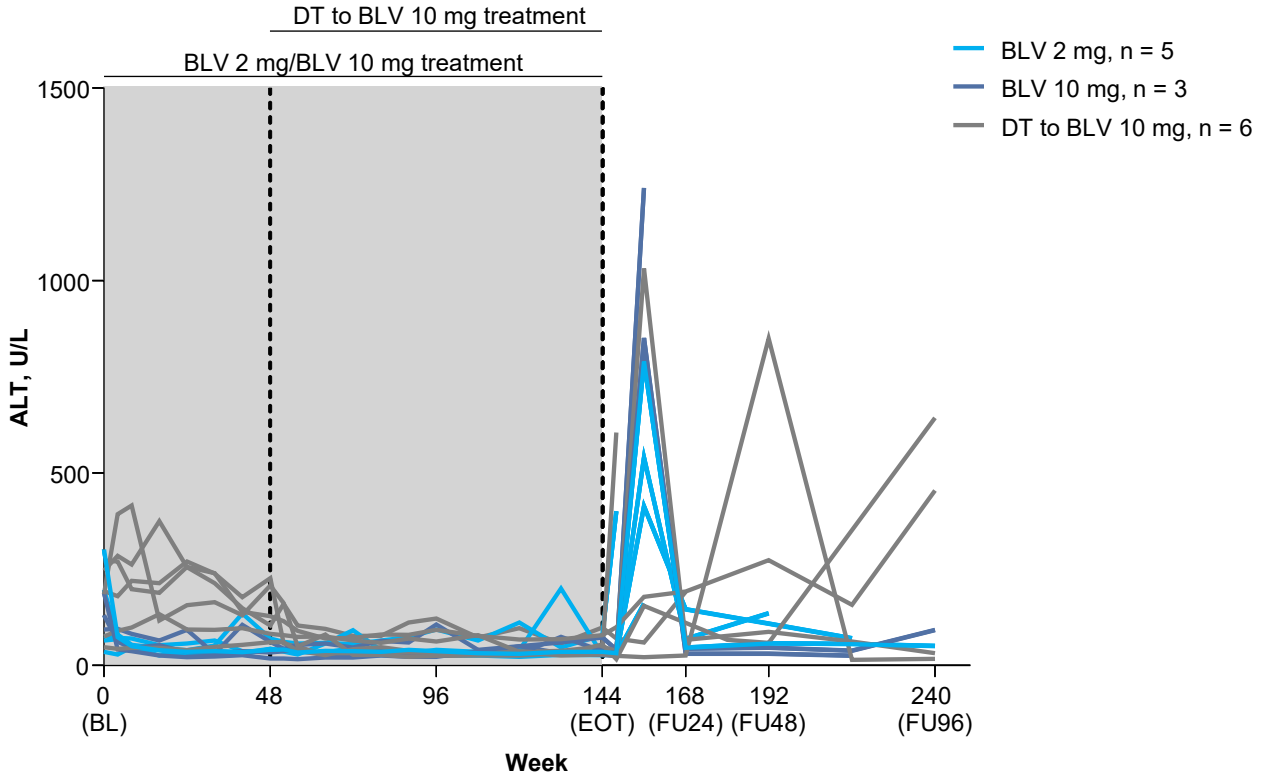
Liver-Related Clinical Outcomes Were Rare

Patients, n/N	BLV 2 mg n = 49		BLV 10 mg n = 50		DT to BLV 10 mg n = 50	
Time point	**BL to EOT**	**EOT to FU96**	**BL to EOT**	**EOT to FU96**	**W48 (DT) to EOT**	**EOT to FU96**
Liver-related clinical outcomes	0/49	2/46[a]	0/50	1/47[a]	1/50	1/49[a]

- During treatment:
  - 1 case of nonserious ascites in the DT to BLV 10 mg group
- During the posttreatment phase:
  - 1 case of bleeding from varices and 1 instance of hepatocellular carcinoma in the BLV 2 mg group
  - 1 case of hepatic encephalopathy in the BLV 10 mg group
  - 1 case of ascites in the DT to BLV 10 mg group

Observed case: missing values remain missing. Potential liver-related clinical outcomes included but were not limited to cirrhosis development; liver decompensation, including development or worsening jaundice, coagulopathy, ascites, hepatic encephalopathy, bleeding from varices, and liver failure; hepatocellular carcinoma development; liver transplant; and liver-related death. Missing values remained missing. Posttreatment events were those that started after the last dose date of BLV. [a]Liver-related clinical outcomes were reported posttreatment through FU96. **BL**, baseline; **BLV**, bulevirtide; **DT**, delayed treatment; **EOT**, end of treatment (week 144); **FU48**, follow-up at 48 weeks after EOT (week 192); **FU96**, follow-up at 96 weeks after EOT (week 240); **W**, week.

Posttreatment ALT Flares Were Mostly Early and Resolved



- Patients with posttreatment ALT >10 × the upper limit of normal (ULN)

ALT, alanine aminotransferase; **BL**, baseline; **BLV**, bulevirtide; **DT**, delayed treatment; **EOT**, end of treatment (week 144); **FU24**, follow-up at 48 weeks after EOT (week 168); **FU48**, follow-up at 48 weeks after EOT (week 192); **FU96**, follow-up at 96 weeks after EOT (week 240).

Summary and Conclusions

- A subgroup of patients treated with BLV achieved sustained undetectable HDV RNA
  - The highest proportion was seen in patients with ≥96 weeks of on-treatment undetectability[1]
  - Sustained undetectability was seen in patients with and without cirrhosis[1]
  - No relapses occurred after the first year of follow-up
- Viral relapse and rebound can be associated with hepatitis flares in some cases
- Long-term BLV therapy is safe, with very few liver-related events observed
  - Markers of disease progression improved throughout 144 weeks of treatment

1. Aleman S, et al. Oral presentation at EASL 2025; May 7–10, 2025. 1756.
BLV, bulevirtide; **EOT**, end of treatment (week 144); **FU**, follow-up; **HDV**, hepatitis delta virus.

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