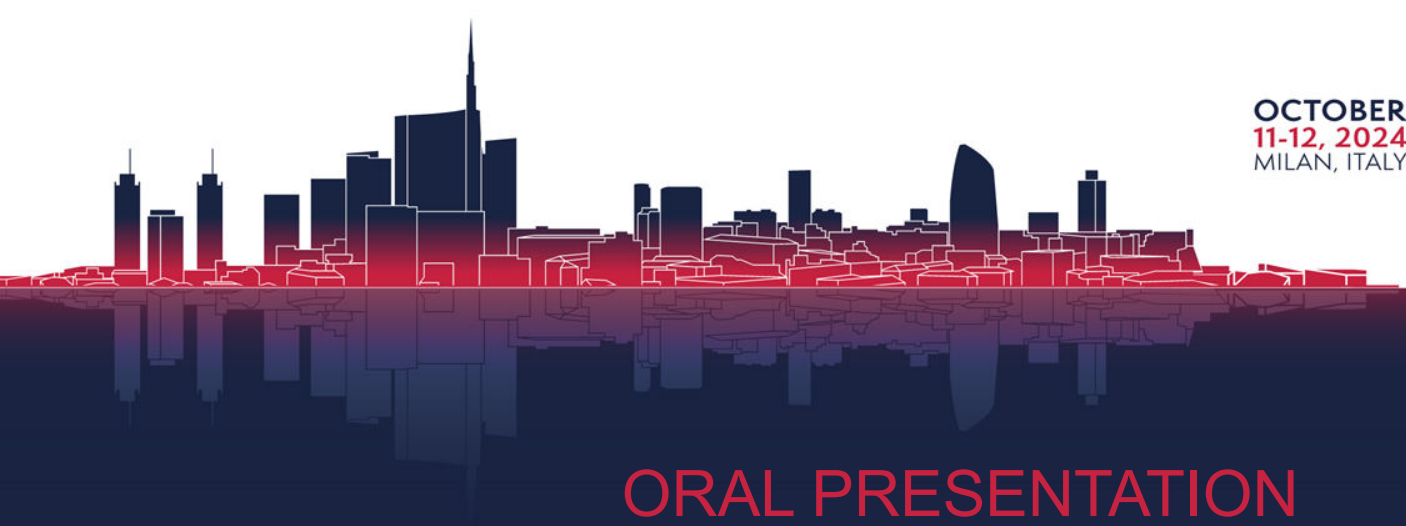

OCTOBER 11-12, 2024 MILAN, ITALY

DeltaCure 3rd International Meeting

ORAL PRESENTATION

Efficacy and Safety of BLV Monotherapy for Chronic Hepatitis Delta: Posttreatment Results Through 24 Weeks After the End of Treatment From an Interim Analysis of a Randomised Phase 3 Study MYR301

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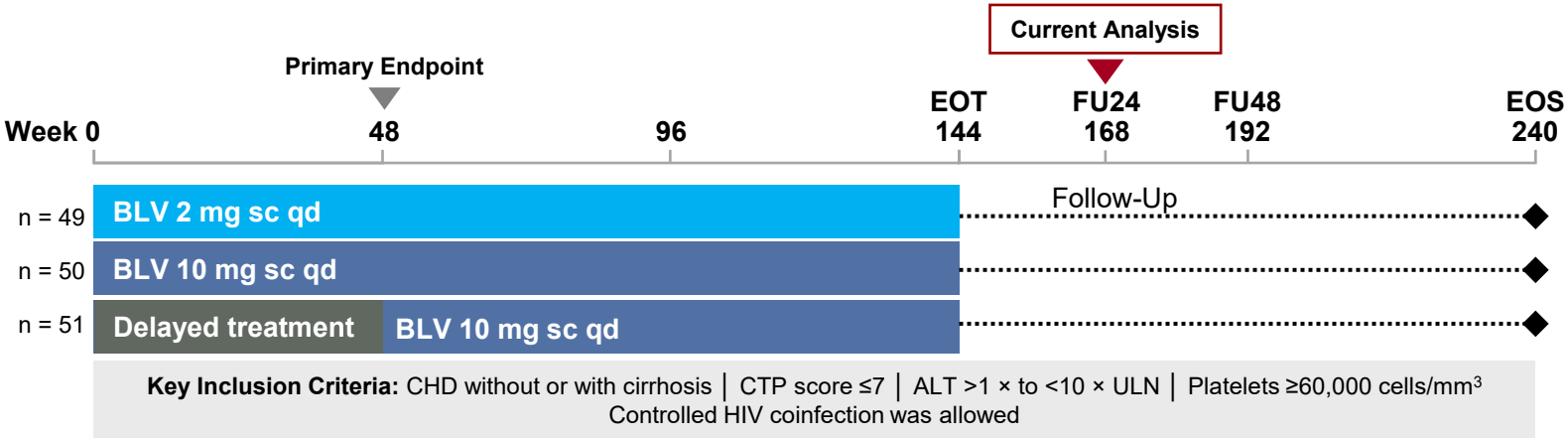
Introduction and Objective

- Hepatitis delta virus (HDV) infection causes the most severe form of chronic hepatitis,[1,2] with prevalence estimates of between 10 and 20 million people worldwide[3]
- Bulevirtide (BLV) 2 mg is a first-in-class entry inhibitor approved in Europe, the Russian Federation, and Australia for chronic hepatitis delta (CHD)[4,5] and is recommended by the European Association for the Study of the Liver guidelines for the treatment of CHD in adult patients with compensated liver disease[5]
- BLV 2 and 10 mg monotherapy for CHD have been demonstrated to be effective and safe over 144 weeks of treatment[6-8]
- On-treatment improvements in virologic and biochemical responses and liver stiffness, as well as low occurrence of liver-related outcomes, are supportive of the clinical benefits of long-term BLV monotherapy[8]

Objective: To evaluate the long-term efficacy and safety of BLV 2 or 10 mg monotherapy at study week 168, representing up to 144 weeks of treatment and 24 weeks after the end of treatment (EOT)

BLV, bulevirtide; **CHD**, chronic hepatitis delta; **EOT**, end of treatment; **HDV**, hepatitis delta virus. **1**. Alfaiate D, et al. *J Hepatol*. 2020;73(3):533-9. **2.** Rizzetto M, et al. *J Hepatol*. 2021;74(5):1200-11. **3.** Stockdale AJ, et al. *J Hepatol*. 2020;73:523-32. **4.** Hepcludex. European Medicines Agency SmPC. Gilead Sciences, Inc.; 2023. **5.** European Association for the Study of the Liver. *J Hepatol*. 2023;79:433-60. **6.** Wedemeyer H, et al. *N Engl J Med*. 2023;389:22-32. **7**. Wedemeyer H, et al. *J Hepatol*. 2024;81(4):621-9. **8**. Lampertico P, et al. *J Hepatol*. 2024;80(suppl 1):S92.

MYR301 Study Design

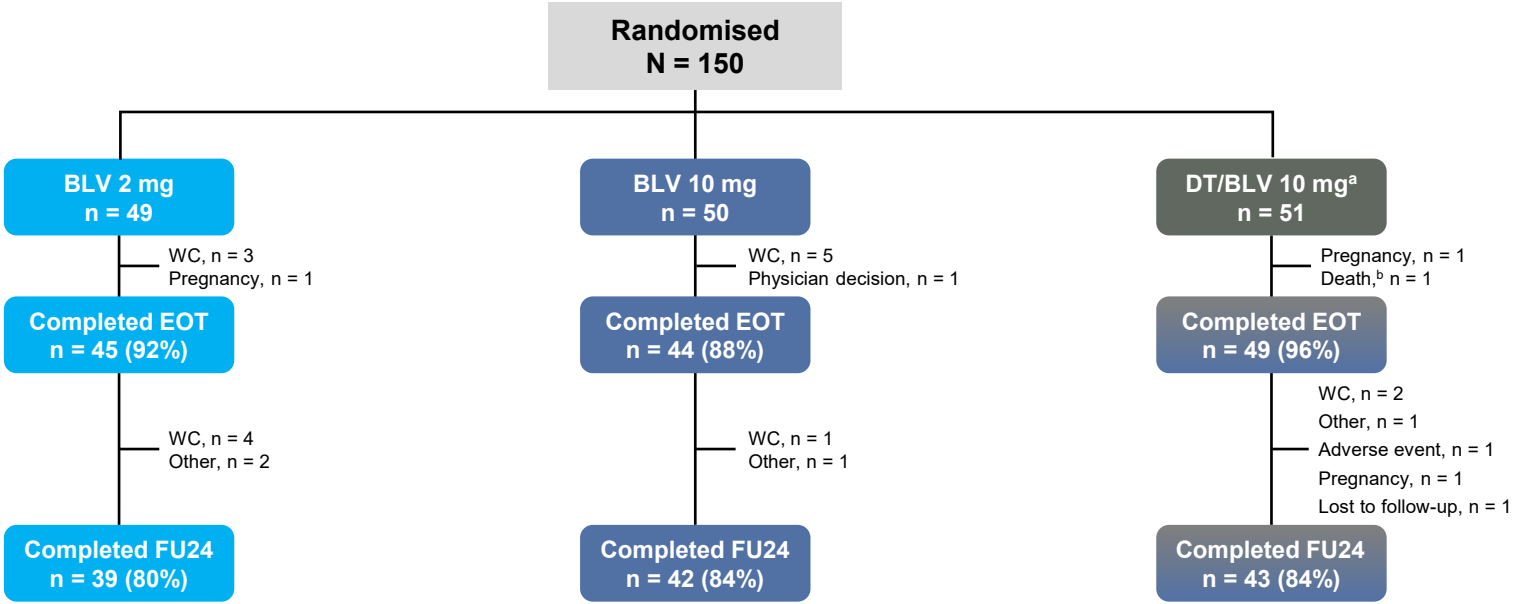


- MYR301 is a multicentre, open-label, randomised, Phase 3 study (NCT03852719) conducted in 4 countries (Germany, Italy, the Russian Federation, and Sweden)
- **Primary endpoint**
  - Combined response at week 48: HDV RNA undetectable or decreased by ≥2 $\log_{10}$ IU/mL from baseline (BL) and alanine aminotransferase (ALT) normalisation[1]
- Safety and efficacy endpoints at week 144 (EOT) and follow-up at 24 weeks after EOT (FU24) are presented

ALT, alanine aminotransferase; **BL**, baseline; **BLV**, bulevirtide; **CHD**, chronic hepatitis delta; **CTP**, Child-Turcotte-Pugh; **EOS**, end of study; **EOT**, end of treatment; **FU24**, follow-up at 24 weeks after EOT (week 168); **FU48**, follow-up at 48 weeks after EOT (week 192); **HDV**, hepatitis delta virus; **qd**, once daily; **sc**, subcutaneous; **ULN**, upper limit of normal.

1. Food and Drug Administration. Chronic hepatitis D virus infection: developing drugs for treatment guidance for industry. Draft guidance. November 2019.

Patient Disposition



- By group, 92% of the BLV 2 mg, 88% of the 10 mg, and 96% of the delayed treatment (DT)/BLV 10 mg groups completed study treatment (EOT)
- After EOT, 80%, 84%, and 84% of these groups, respectively, completed FU24

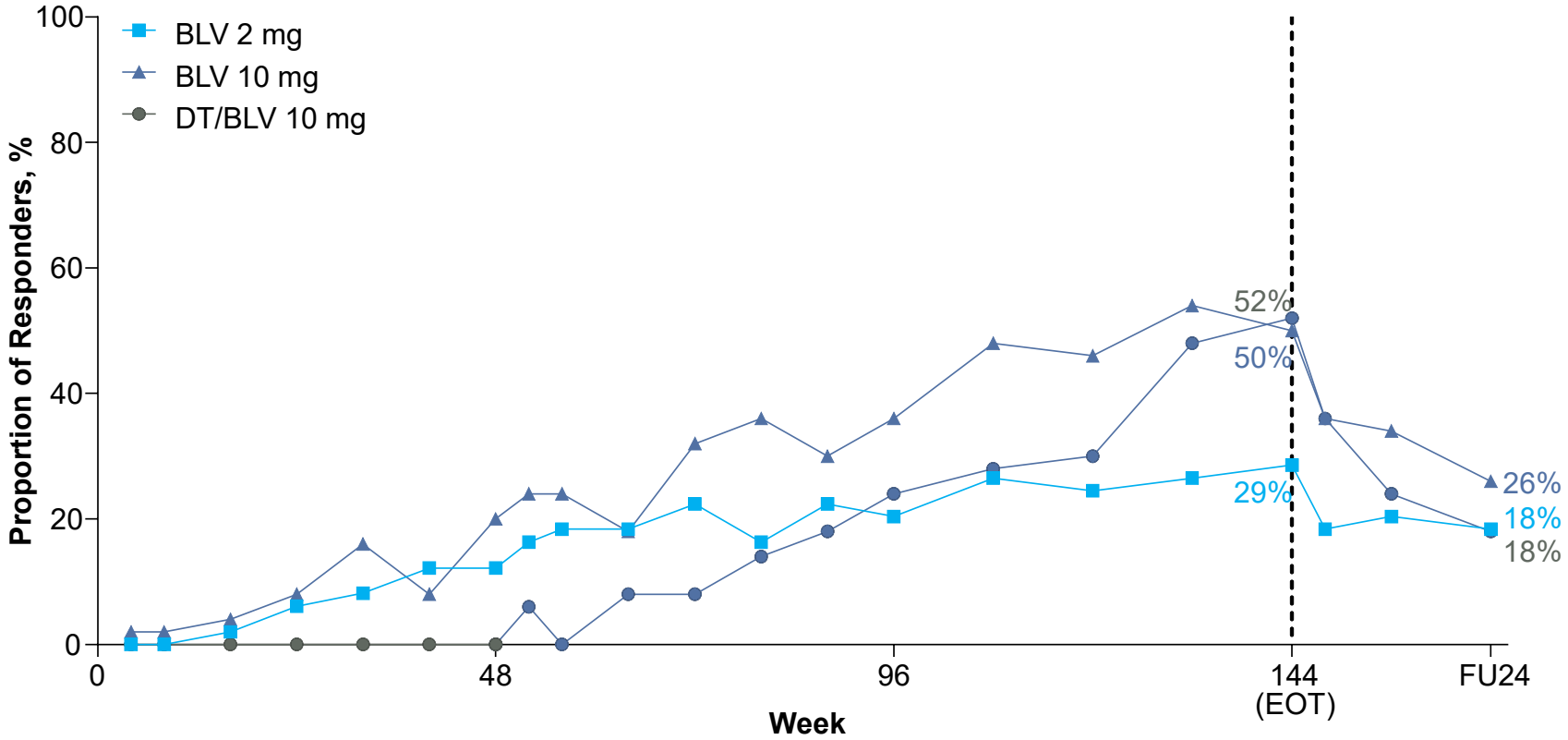
[a]Patients in this group received no treatment for 48 weeks. Beginning at W48, they received BLV 10 mg through study W144. [b]One death due to plasma cell myeloma.
BLV, bulevirtide; **DT**, delayed treatment; **EOT**, end of treatment; **FU24**, follow-up at 24 weeks after EOT (week 168); **W**, week; **WC**, withdrawal of consent (reasons for withdrawal of consent unknown).

BL Demographics and Disease Characteristics

	BLV 2 mg (n = 49)	BLV 10 mg (n = 50)	DT/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 (1.20)	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)	1.30 (1.29)	1.08 (1.26)	0.89 (0.99)
HBV genotype, n (%)			
A	2 (4)	2 (4)	2 (4)
D	47 (96)	44 (88)	44 (86)
Other[d]/missing	0	4 (8)	5 (10)
Previous IFN therapy, n (%)	26 (53)	29 (58)	29 (57)
Concomitant HBV NA treatment,[e] n (%)	32 (65)	27 (54)	32 (63)

[a]At BL, 51 patients were assigned to DT/BLV 10 mg, and their data are reported here. One patient subsequently withdrew from the DT/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 GT 5, n = 1; missing HDV GT, n = 1. [d]BLV 10 mg arm: HBV GT E, n = 1; DT/BLV 10 mg arm: unclassified HBV GT, n = 2. [e]All patients who started NA therapy at or after BL, except 1, started at BL or within 2 days of BL. **ALT**, alanine aminotransferase; **BL**, baseline; **BLV**, bulevirtide; **DT**, delayed treatment; **GT**, genotype; **HBsAg**, hepatitis B surface antigen; **HBV**, hepatitis B virus; **HDV**, hepatitis delta virus; **IFN**, interferon; **NA**, nucleos(t)ide analogue.

Undetectable (TND) HDV RNA Through EOT and FU24

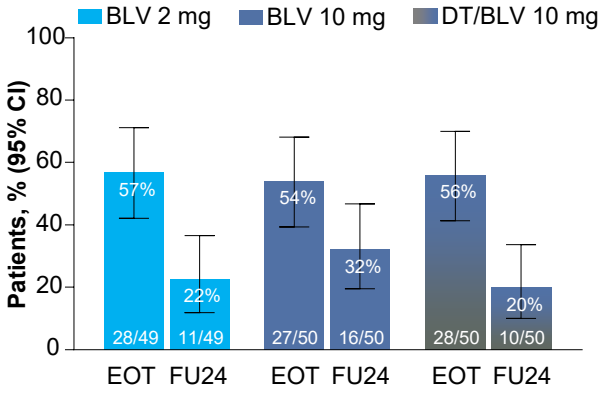


Missing values equal failure. DT/BLV 10 mg group initiated BLV at W48.

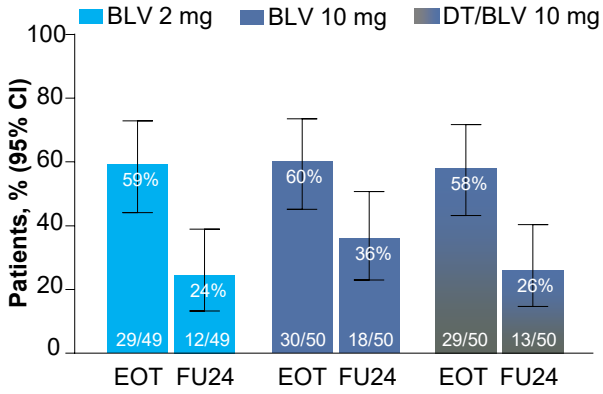
BLV, bulevirtide; **DT**, delayed treatment; **EOT**, end of treatment; **FU24**, follow-up at 24 weeks after EOT (week 168); **HDV**, hepatitis delta virus; **TND**, target not detected; **W**, week.

Efficacy at EOT and FU24

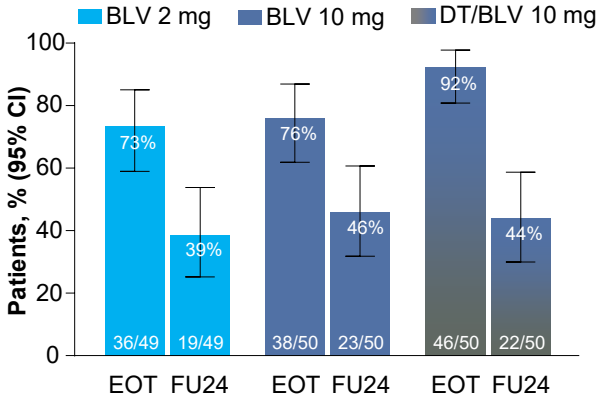
Combined Response[a]



ALT Normalisation[b]



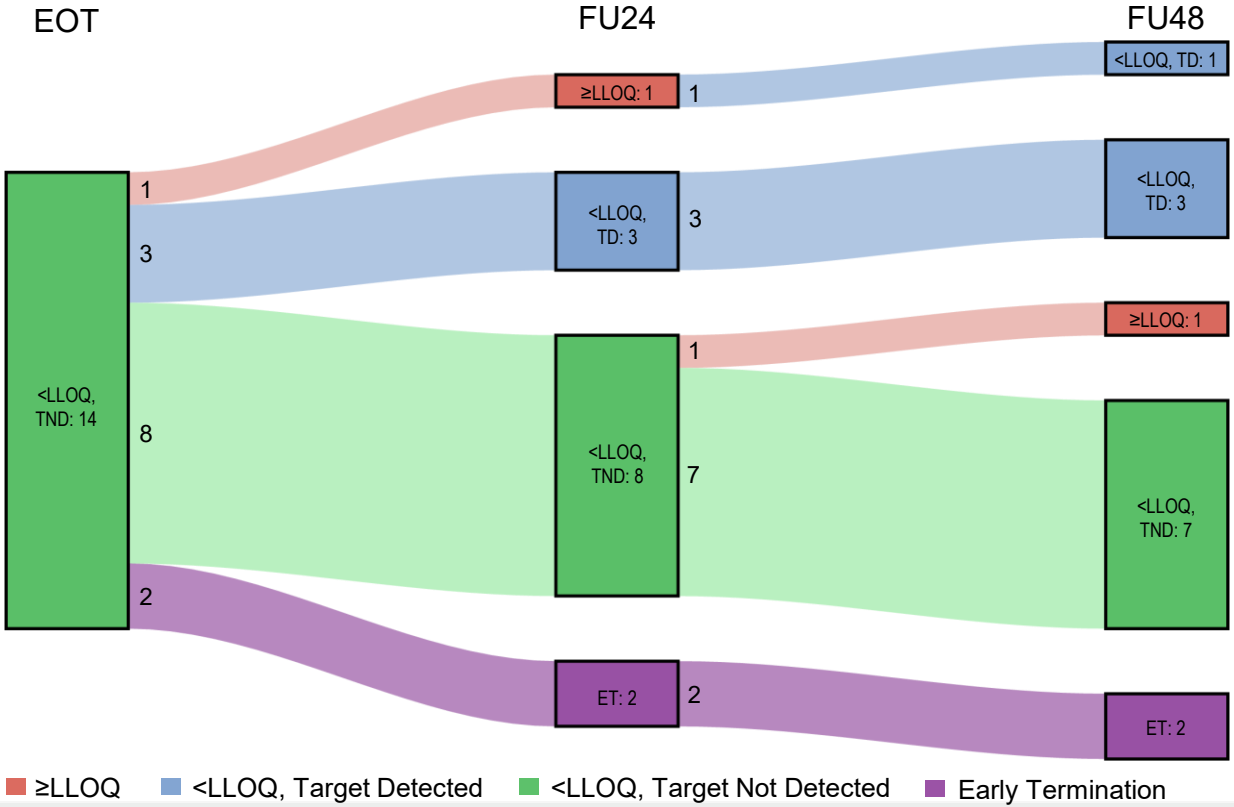
Virologic Response[c]



- Combined response, ALT normalisation, and virologic response rates were similar between groups at EOT, and decreased from EOT to FU24

Patients with missing values were considered nonresponders; 95% CIs were calculated based on the Clopper-Pearson exact method.
[a]Virologic response and ALT normalisation. [b]ALT normalisation was defined at Russian sites as ≤31 U/L for females and ≤41 U/L for males and at all other sites as ≤34 U/L for females and ≤49 U/L for males. [c]Undetectable HDV RNA or ≥2 $\log_{10}$ IU/mL decline from baseline.
ALT, alanine aminotransferase; **BLV**, bulevirtide; **DT**, delayed treatment; **EOT**, end of treatment; **FU24**, follow-up at 24 weeks after EOT (week 168); **HDV**, hepatitis delta virus.

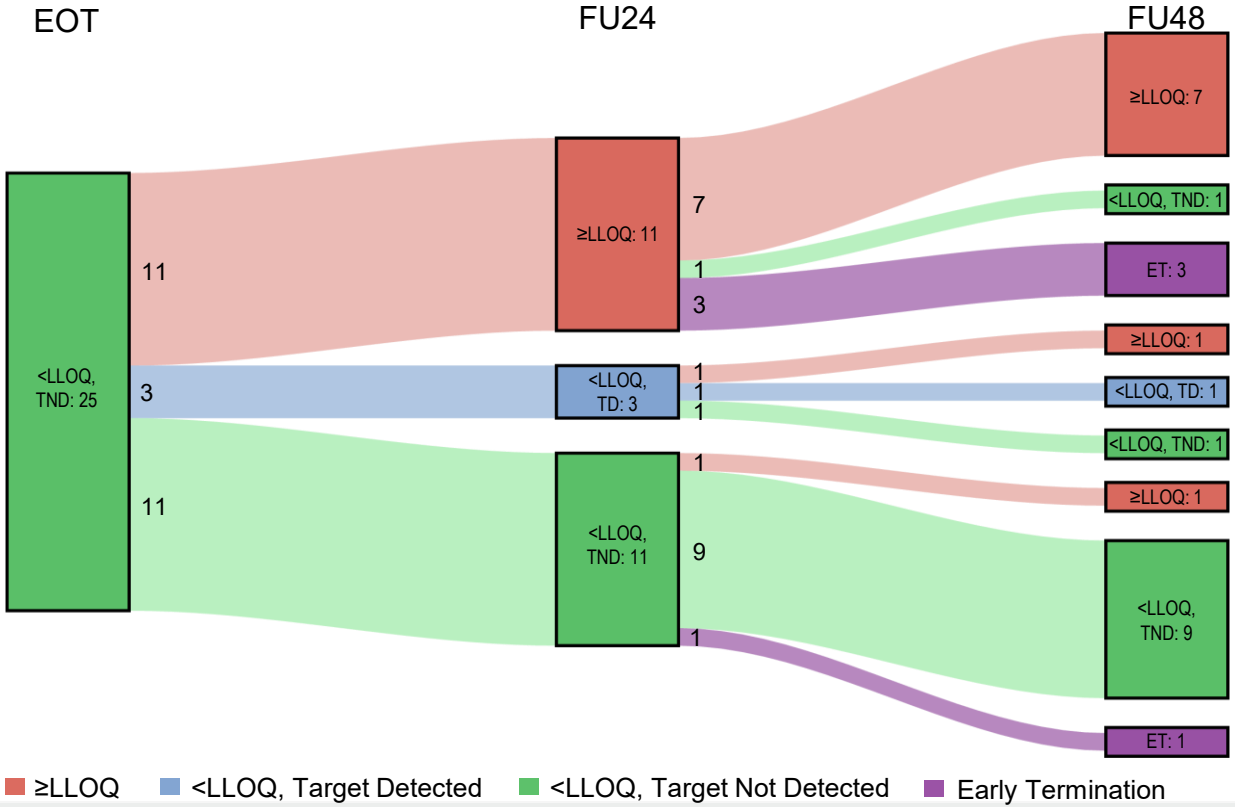
Virologic Relapse by FU48 in Patients With Undetectable HDV RNA at EOT, BLV 2 mg Group



- In the BLV 2 mg group, 7 of 14 patients who were HDV RNA undetectable at EOT were undetectable at both FU24 and FU48

Relapse was defined as detectable HDV RNA during follow-up after undetectable HDV RNA at EOT.
BLV, bulevirtide; **ET**, early termination; **EOT**, end of treatment; **FU24**, follow-up at 24 weeks after EOT (week 168); **FU48**, follow-up at 48 weeks after EOT (week 192); **HDV**, hepatitis delta virus; **LLOQ**, lower limit of quantitation; **TD**, target detected; **TND**, target not detected.

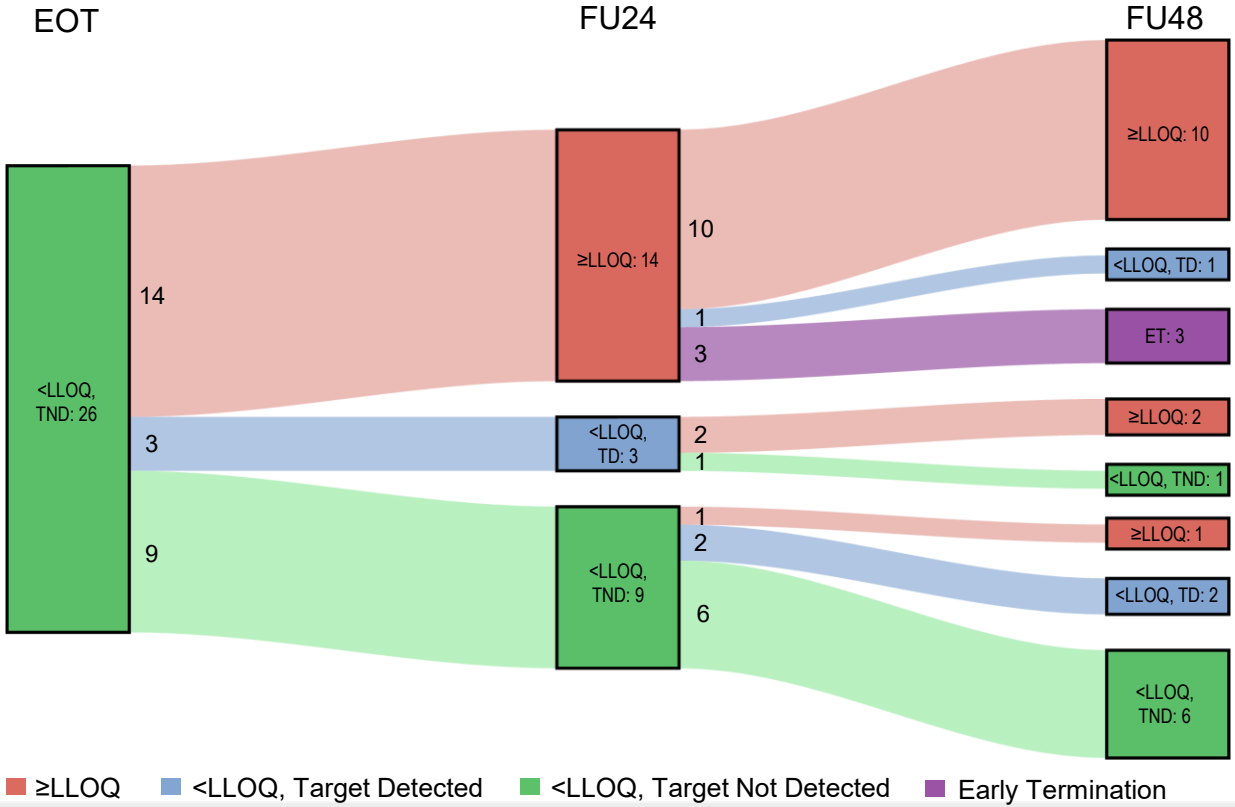
Virologic Relapse by FU48 in Patients With Undetectable HDV RNA at EOT, BLV 10 mg Group



- In the BLV 10 mg group, 9 of 25 patients who were HDV RNA undetectable at EOT were HDV RNA undetectable at both FU24 and FU48

Relapse was defined as detectable HDV RNA during follow-up after undetectable HDV RNA at EOT.
BLV, bulevirtide; **ET**, early termination; **EOT**, end of treatment; **FU24**, follow-up at 24 weeks after EOT (week 168); **FU48**, follow-up at 48 weeks after EOT (week 192); **HDV**, hepatitis delta virus; **LLOQ**, lower limit of quantitation; **TD**, target detected; **TND**, target not detected.

Virologic Relapse by FU48 in Patients With Undetectable HDV RNA at EOT, DT/BLV 10 mg Group



- In the DT/BLV 10 mg group (after 96 weeks on BLV), 6 of 26 patients who were HDV RNA undetectable at EOT remained undetectable at both FU24 and FU48
- Overall, among all groups, most virologic relapses occurred during the first 24 weeks after EOT

Relapse was defined as detectable HDV RNA during follow-up after undetectable HDV RNA at EOT.
BLV, bulevirtide; **DT**, delayed treatment; **ET**, early termination; **EOT**, end of treatment; **FU24**, follow-up at 24 weeks after EOT (week 168); **FU48**, follow-up at 48 weeks after EOT (week 192); **HDV**, hepatitis delta virus; **LLOQ**, lower limit of quantitation; **TD**, target detected; **TND**, target not detected.

HBsAg Loss and Liver-Related Clinical Outcomes

Number of Patients, n/N	BLV 2 mg (n = 49)		BLV 10 mg (n = 50)		DT/BLV 10 mg (n = 50)	
Time point	**BL to EOT**	**FU24**	**BL to EOT**	**FU24**	**W48 (DT) to EOT**	**FU24**
HBsAg loss[a]	0/49	1/49	0/50	0/50	1/50	1/50
Liver-related clinical outcomes[b]	0/49	0/46	0/50	0/47	1/50	1/49

- Hepatitis B surface antigen (HBsAg) loss was rare at EOT and during posttreatment follow-up
- Liver-related clinical outcomes were rare
  - — On treatment: 1 case of mild ascites in the DT/BLV 10 mg group
  - — Posttreatment through FU24: 1 case of mild ascites in the DT/BLV 10 mg group

[a]HBsAg loss was defined as HBsAg positive at BL and HBsAg negative at the visit. [b]Liver-related clinical outcomes included but were not limited to development of cirrhosis; liver decompensation, including development or worsening of jaundice, coagulopathy, ascites, hepatic encephalopathy, bleeding from varices, and liver failure; hepatocellular carcinoma; liver transplant; and liver-related death. Missing values remained missing. Posttreatment events were those that started after the last BLV dose date.
DT, delayed treatment; **BL**, baseline; **BLV**, bulevirtide; **EOT**, end of treatment; **FU24**, follow-up at 24 weeks after EOT (week 168); **HBsAg**, hepatitis B surface antigen; **W**, week.

Overall Safety Summary

	BLV 2 mg		BLV 10 mg		DT/BLV 10 mg	
Patients, n (%)	**EOT (n = 49)**	**EOT to FU24 (n = 46)**	**EOT (n = 50)**	**EOT to FU24 (n = 47)**	**W48 (DT) to EOT (n = 51)**	**EOT to FU24 (n = 49)**
Any AE	48 (98)	25 (54)	48 (96)	26 (55)	46 (92)	25 (51)
Any grade 3 or 4 AE	12 (24)	5 (11)	10 (20)	5 (11)	5 (10)	9 (18)
Any AE leading to withdrawal of BLV	0	N/A	0	N/A	0	N/A
Any SAE	3 (6)	2 (4)	6 (12)	3 (6)	3 (6)	4 (8)
ALT >10 × ULN after EOT[a]	N/A	5/46 (11)	N/A	4/46 (9)	N/A	3/48 (6)
Cirrhosis at BL	N/A	4/5 (80)	N/A	3/4 (75)	N/A	2/3 (67)
HDV rebound[b]	N/A	3/5 (60)	N/A	4/4 (100)	N/A	2/3 (67)
Posttreatment total bilirubin increase[c]	N/A	2/5 (40)	N/A	1/3 (33)	N/A	1/2 (50)
Death	0	0	0	0	1 (2)[d]	0

[a]Includes 2 additional patients who met criteria for ALT >10 × ULN, based on laboratory data reported in the Gilead global safety database. [b]Increase in HDV RNA ≥2 $\log_{10}$ IU/mL from LLOQ (if HDV RNA was less than LLOQ at EOT) or an increase of ≥2 $\log_{10}$ IU/mL from the EOT value. [c]The 2 additional patients from the safety database were not included in analysis. Includes increases in the total bilirubin category per the Child-Turcotte-Pugh scoring system after EOT. [d]Due to plasma cell myeloma, considered not related to BLV. **AE**, adverse event; **ALT**, alanine aminotransferase; **BL**, baseline; **BLV**, bulevirtide; **DT**, delayed treatment; **EOT**, end of treatment; **FU24**, follow-up at 24 weeks after EOT (week 168); **HDV**, hepatitis delta virus; **LLOQ**, lower limit of quantitation; **N/A**, not applicable; **SAE**, serious adverse event; **ULN**, upper limit of normal; **W**, week.

Overall Safety Summary

- No AEs led to premature study drug discontinuation, and no treatment-related SAEs or treatment-related deaths were reported through EOT
- Most posttreatment ALT elevations >10 × ULN were observed at the follow-up visit at 12 weeks after EOT
  - — Of the 12 patients with ALT elevations >10 × ULN, posttreatment SAEs were seen in 7 (all of which resolved during follow-up), 5 discontinued the study early, and BLV was restarted in at least 5

AE, adverse event; **ALT**, alanine aminotransferase; **BLV**, bulevirtide; **EOT**, end of treatment; **SAE**, serious adverse event; **ULN**, upper limit of normal.

Conclusions

- A subset of patients treated with BLV monotherapy for 2 to 3 years maintained virologic and biochemical responses 24 weeks after stopping BLV
- Virologic relapse occurred in over half of those patients who were HDV RNA undetectable at EOT and occurred most often in the first 24 weeks after EOT
- The rate of liver-related clinical outcomes while on BLV and through 24 weeks after treatment was low
- ALT increases occurred in a subset of patients after treatment discontinuation. Most of these patients had cirrhosis at baseline, associated HDV rebound, and SAEs (which resolved during follow-up)

ALT, alanine aminotransferase; **BLV**, bulevirtide; **EOT**, end of treatment; **HDV**, hepatitis delta virus; **SAE**, serious adverse event.

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- Correspondence: Soo Aleman, soo.aleman@ki.se

Disclosures

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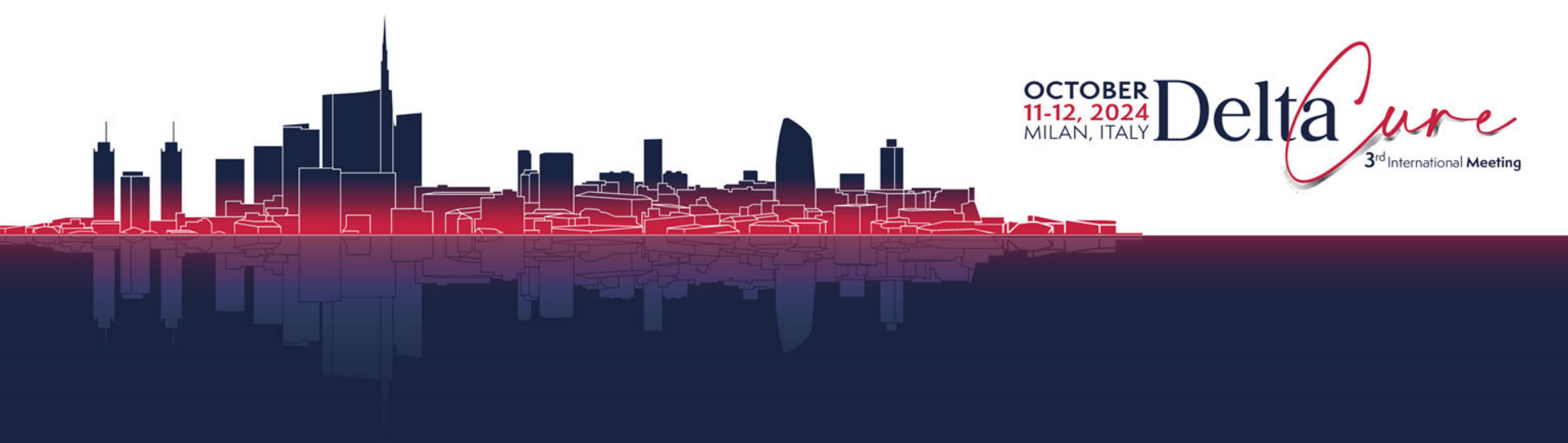
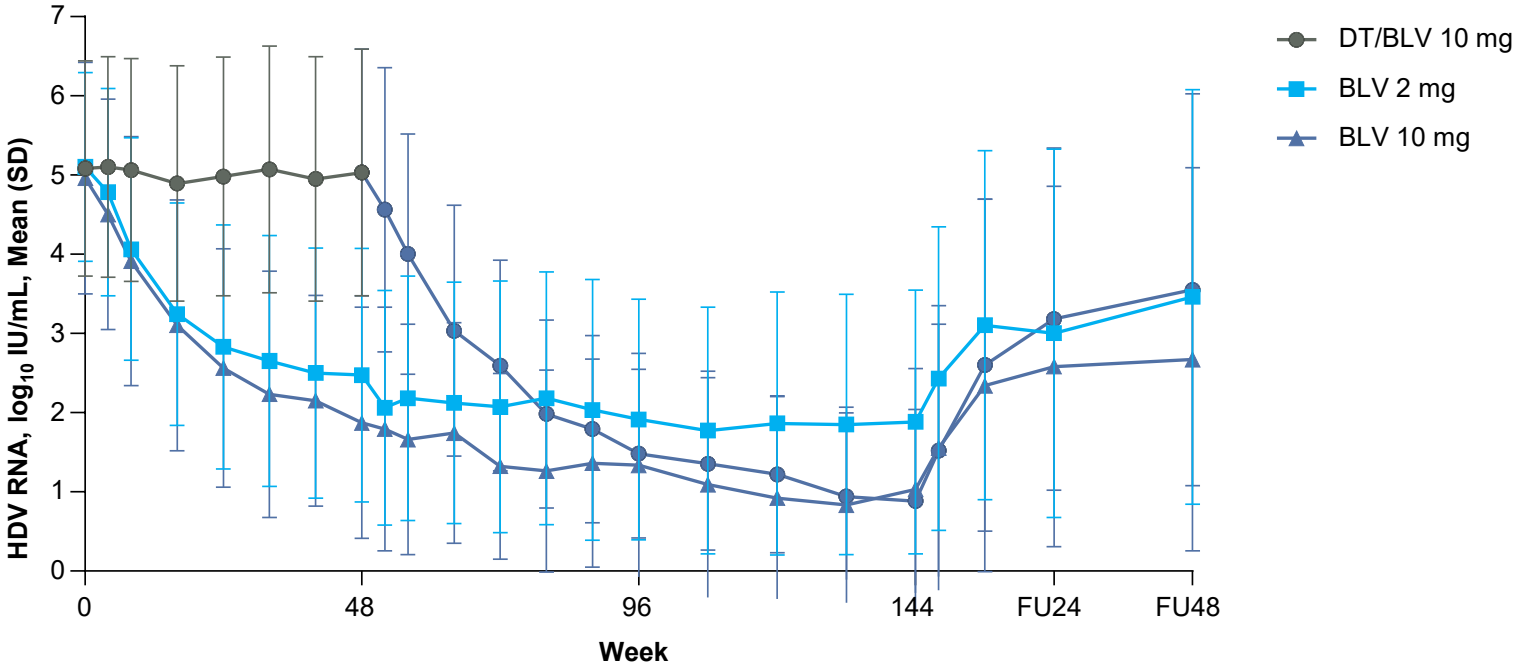


Back-Up Slides

Mean HDV RNA Over Time



- Mean HDV RNA values decreased through EOT in all treatment groups but increased in the posttreatment period
- Follow-up HDV RNA values were lower than those observed at BL

Missing values were excluded from analysis.

BL, baseline; **BLV**, bulevirtide; **DT**, delayed treatment; **EOT**, end of treatment; **FU24**, follow-up at 24 weeks after EOT (week 168); **FU48**, follow-up at 48 weeks after EOT (week 192); **HDV**, hepatitis delta virus.

Posttreatment SAEs

Patients, n (%)	BLV 2 mg EOT to FU24 (n = 46)	BLV 10 mg EOT to FU24 (n = 47)	DT/BLV 10 mg EOT to FU24 (n = 49)
Any SAEs[a]	2 (4)	3 (6)	4 (8)
Hepatitis D	1 (2)	2 (4)	0
Hepatitis acute	1 (2)	0	0
Hepatitis function abnormal	0	0	1 (2)
Liver injury[b]	0	0	1 (2)
Transaminases increased	0	1 (2)	1 (2)
Chronic hepatitis B	0	0	1 (2)

- Of the 9 posttreatment SAEs, 8 were hepatic events associated with increases in ALT and HDV RNA
- The SAE of liver injury was attributed to tramadol/dexketoprofen

[a]Terms are from MedDRA. [b]Attributed to tramadol/dexketoprofen.
AE, adverse event; **ALT**, alanine aminotransferase; **BLV**, bulevirtide; **DT**, delayed treatment; **EOT**, end of treatment; **FU24**, follow-up at 24 weeks after EOT (week 168); **HDV**, hepatitis delta virus; **MedDRA**, Medical Dictionary for Regulatory Activities; **SAE**, serious adverse event.

Posttreatment SAEs, Additional Details

SAE PT (Reported Term)	Treatment Arm	ALT Increase	ALT Peak FU Day (U/L)	Onset/Resolution FU Day	HDV RNA at EOT log_{10} IU/mL	HDV RNA Peak EOT–FU24 log_{10} IU/mL	SAE Outcome	BLV Restarted	Comment
Hepatitis D (Acute hepatitis in HDV reactivation)	2 mg	10 × ULN	783[b] (44)	44/98	4.0	5.85	Resolved	Y	ED FU4
Hepatitis acute (Acute hepatitis)	2 mg	10 × ULN	1040[b] (110)	108/150	<LLOQ TND	6.08	Resolved	Y	ED (FU D135; unscheduled)
Transaminases increased (High transaminases)	10 mg	10 × ULN[a]	594[b] (141)	141/162	<LLOQ TND	5.16	Resolved	Y	-
Hepatitis D (Post treatment hepatitis D flare)	10 mg	10 × ULN	810 (90)	90/130	<LLOQ TND	4.80	Resolved	N	-
Hepatitis D (Acute hepatitis in HDV reactivation)	10 mg	10 × ULN	1240 (85)	85/140	<LLOQ TD	5.93	Resolved	Y	ED FU12
Chronic hepatitis B[c] (Exacerbation of chronic hepatitis B with a delta agent)	DT/10 mg	10 × ULN[a]	3912[b] (62)	58/90	<LLOQ TND	3.68	Resolved	N (TDF)	-
Liver injury[c] (Acute liver damage)	DT/10 mg	10 × ULN	1655[b] (76)	71/140	4.05	5.96	Resolved	Y	SAE attributed to tramadol/dexketoprofen
Transaminases increased (Increased aminotransferase)	DT/10 mg	5 × ULN	264 (163)	87/-	<LLOQ TD	5.12	Not resolved	Y	Post FU48 (FU D619)—resolution of SAE with normalisation of ALT/AST
Hepatic function abnormal[c] (Decreased liver function)	DT/10 mg	5 × ULN	351 (87)	163/-	<LLOQ TD	6.91	Not resolved	Y[b]	ED FU24 (ascites[d]; nonserious)

[a]Criteria met in safety database; clinical database ALT maximum >5 × ULN. [b]From the safety database. [c]Liver-related hospitalisation. [d]Liver-related clinical event.
ALT, alanine aminotransferase; **AST**, aspartate aminotransferase; **BLV**, bulevirtide; **D**, day; **DT**, delayed treatment; **ED**, early discontinuation; **EOT**, end of treatment; **FU**, follow-up; **FU4**, follow-up at 4 weeks after EOT (week 148); **FU12**, follow-up at 12 weeks after EOT (week 156); **FU24**, follow-up at 24 weeks after EOT (week 168); **FU48**, follow-up at 48 weeks after EOT (week 192); **HDV**, hepatitis delta virus; **LLOQ**, lower limit of quantitation; **PT**, preferred term; **SAE**, serious adverse event; **TD**, target detected; **TDF**, tenofovir disoproxil fumarate; **TND,** target not detected; **ULN**, upper limit of normal.

On-Treatment AEs by PT Occurring in >20% of Patients in Any Group

Patients, n (%)	BLV 2 mg BL to EOT (n = 49)	BLV 10 mg BL to EOT (n = 50)	DT/BLV 10 mg W48 to EOT (n = 50)
Any AEs[a]	48 (98)	48 (96)	46 (92)
Vitamin D deficiency	22 (45)	19 (38)	14 (28)
Headache	10 (20)	12 (24)	7 (14)
Leukopenia	10 (20)	9 (18)	7 (14)
Thrombocytopenia	10 (20)	8 (16)	7 (14)

[a]Terms are from MedDRA.
AE, adverse event; **BL**, baseline; **BLV**, bulevirtide; **DT**, delayed treatment; **EOT**, end of treatment; **MedDRA**, Medical Dictionary for Regulatory Activities; **PT**, preferred term; **W**, week.

Posttreatment AEs by PT Occurring in >10% of Patients in Any Group

Patients, n (%)	BLV 2 mg EOT to FU48 (n = 46)	BLV 10 mg EOT to FU48 (n = 47)	DT/BLV 10 mg EOT to FU48 (n = 49)
Any AEs[a]	31 (67)	34 (72)	30 (61)
ALT increased	16 (35)	8 (17)	17 (35)
AST increased	15 (33)	8 (17)	14 (29)
GGT increased	6 (13)	3 (6)	1 (2)
Thrombocytopenia	5 (11)	5 (11)	6 (12)
Lymphopenia	2 (4)	4 (9)	7 (14)
Transaminases increased	2 (4)	7 (15)	3 (6)
Fatigue	0	5 (11)	3 (6)

[a]Terms are from MedDRA.
AE, adverse event; **ALT**, alanine aminotransferase; **AST**, aspartate aminotransferase; **BLV**, bulevirtide; **DT**, delayed treatment; **EOT**, end of treatment; **FU48**, follow-up at 48 weeks after EOT (week 192); **GGT**, gamma glutamyltransferase; **MedDRA**, Medical Dictionary for Regulatory Activities; **PT**, preferred term.