

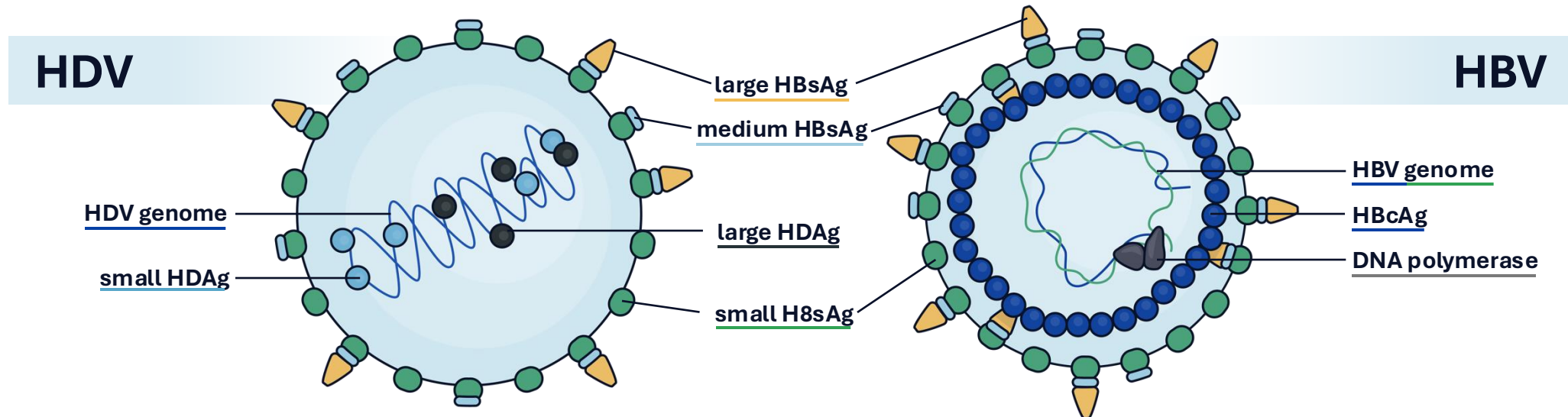


**BJT-778, anti-HBsAg
monoclonal antibody,
achieved 100% virologic
response in subjects with
chronic hepatitis D (CHD):
phase 2 study results**

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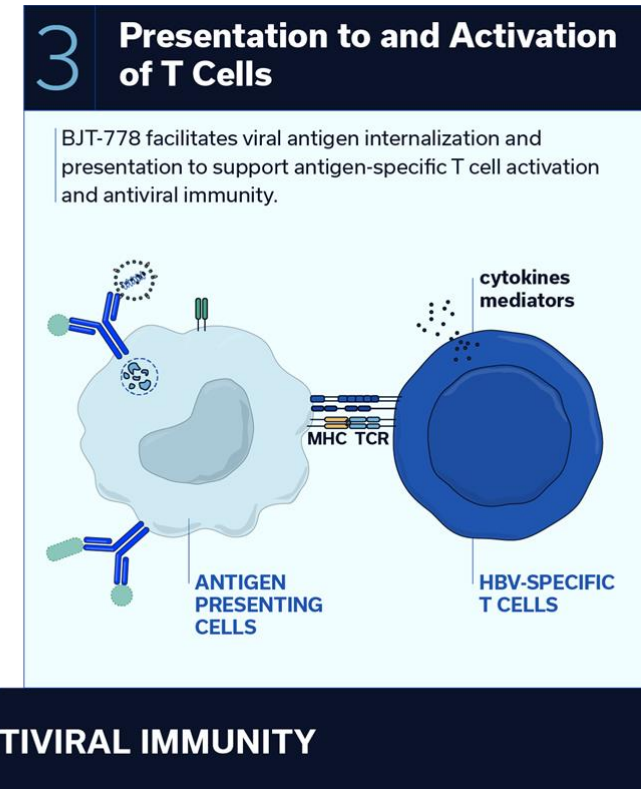
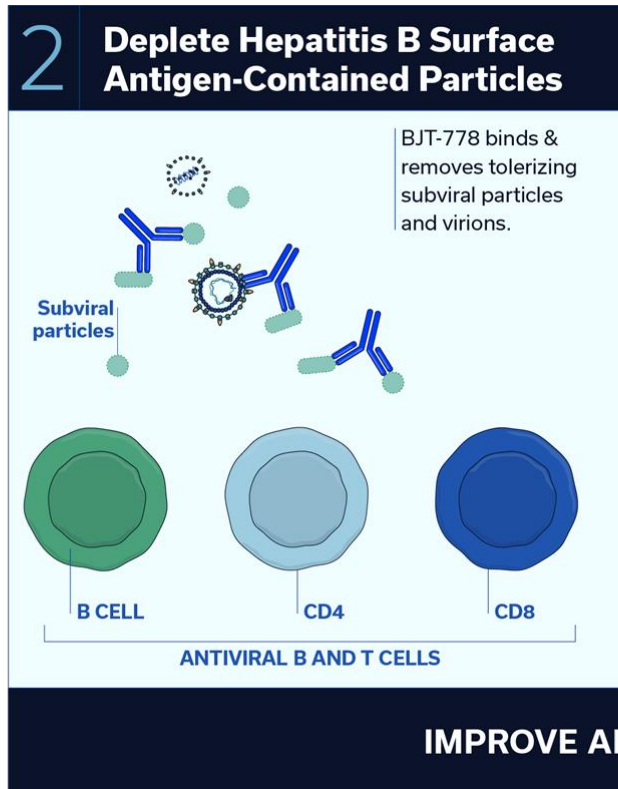
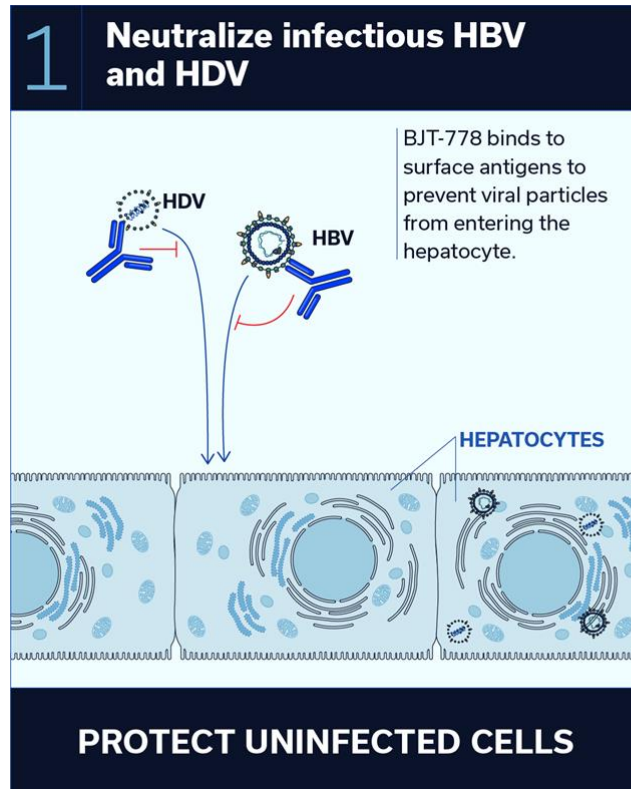
Chronic Hepatitis Delta (CHD) is a Significant Global Health Challenge

- CHD affects >12 million people worldwide¹.
- It is the most severe form of viral hepatitis with the majority of patients developing cirrhosis within 5-10 years².
- New therapies are needed to prevent disease progression in these individuals.
- HDV is a defective virus that requires HBV to replicate and spread by using HBsAg as its envelope protein.

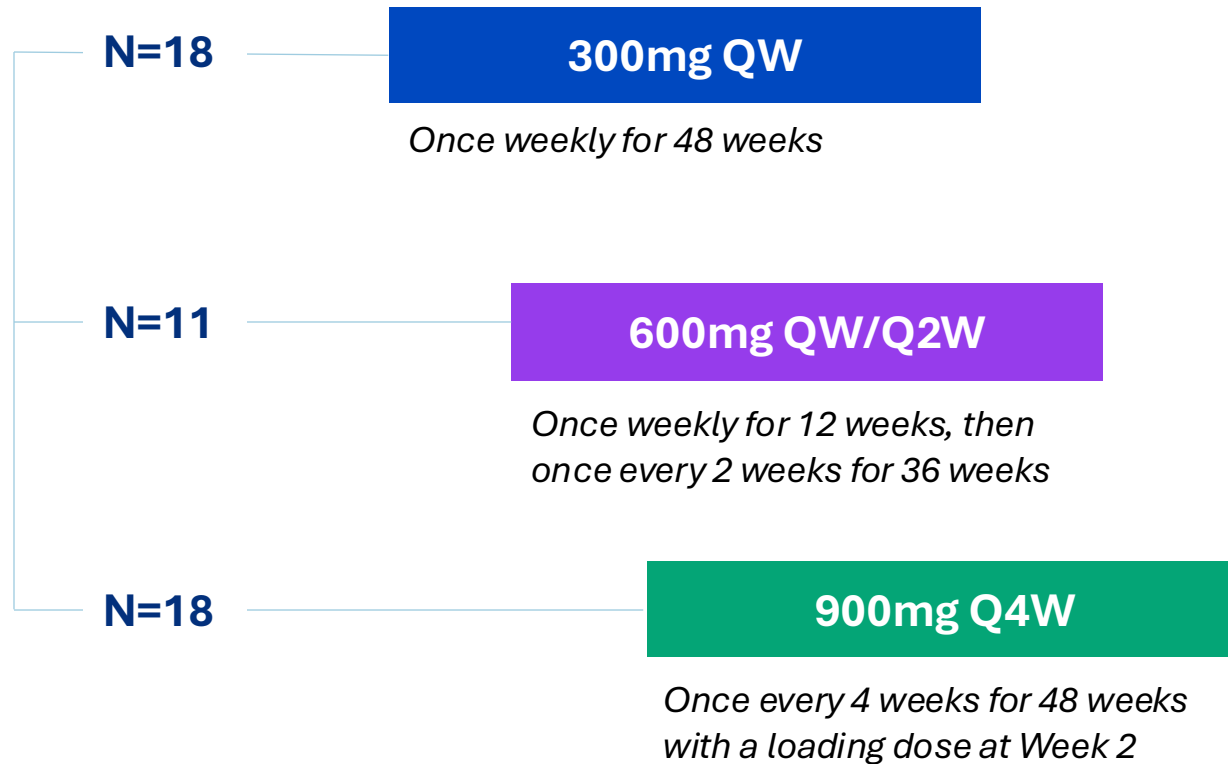


Rationale for BJT-778 Treatment for CHD

- Fully human high-affinity (pM) anti-HBsAg monoclonal antibody with pan-genotypic activity
- Targets the antigenic domain of the Hepatitis B surface antigen (HBsAg)
- Removes HDV from blood and prevents HDV from infecting new hepatocytes by binding HBsAg



BJT-778-001 Phase 2 in CHD: Study Design



*HDV RNA Quantification performed at VIDRL, Melbourne, AUS
LLOQ <10 IU/mL
LLOD <5 IU/mL – ‘Target not detected’

Key Entry Criteria

- Adults with chronic HDV
- Quantifiable HDV RNA
- HBV DNA <100 IU/mL on NUCs
- Compensated liver disease
- PLT >100 K/mm³
- ALT ≤ 10x ULN
- Well-controlled HIV allowed

Key Endpoints

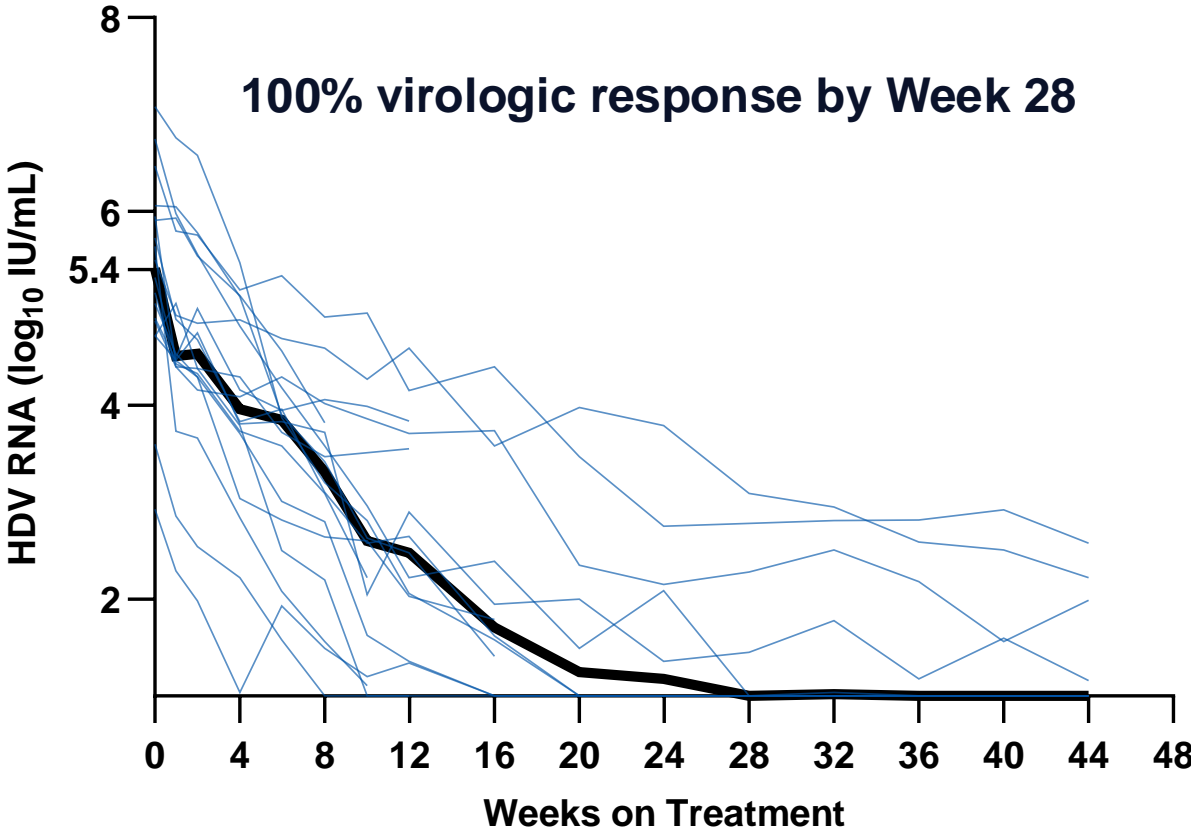
- **Safety** and tolerability
- **Virologic response:** ≥2 log₁₀ HDV RNA IU/ml reduction from baseline or HDV RNA TND*
- **ALT normalization** in subjects with abnormal at baseline
- **Combined response:** virologic + ALT normalization

Demographics and Baseline Characteristics

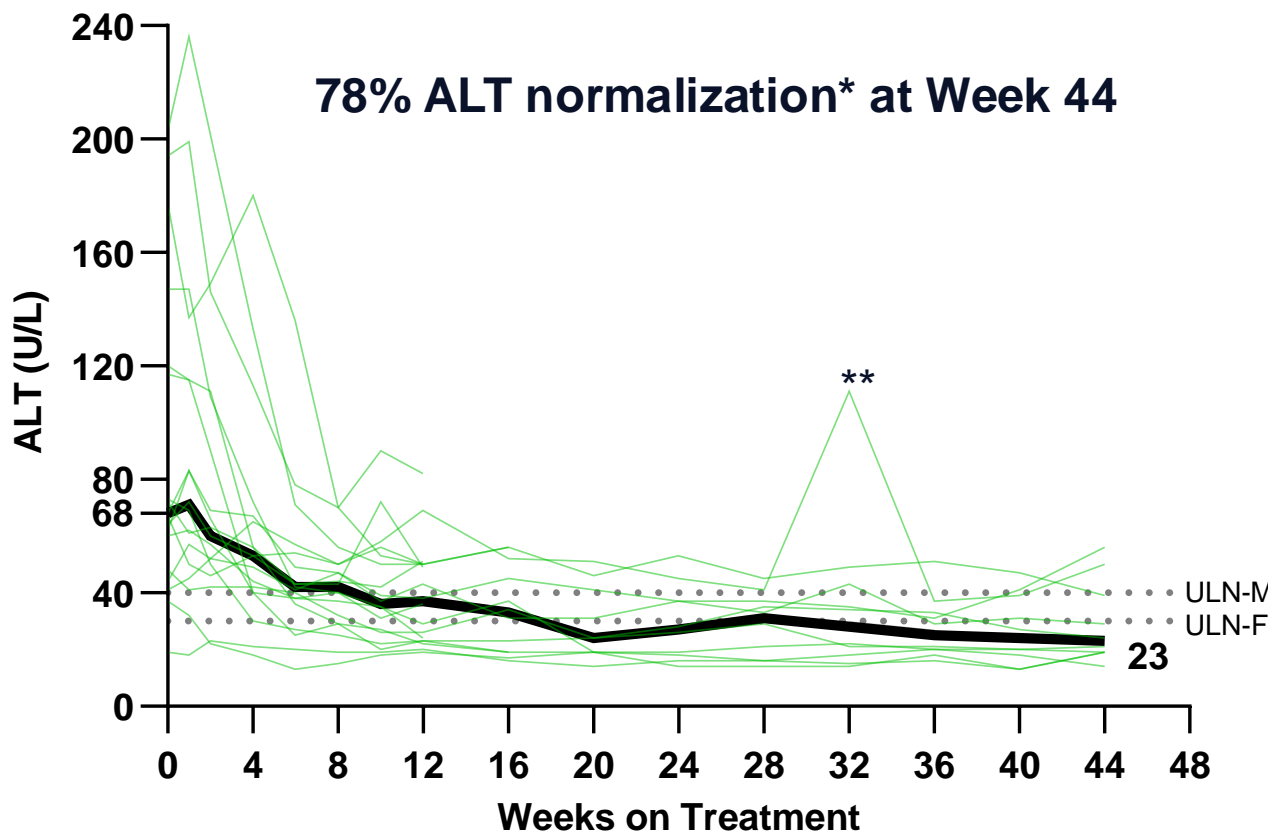
	300 mg QW N=18	600 mg QW/Q2W N=11	900 mg Q4W N=18
Age, years, median (range)	44 (31 – 62)	42 (20 – 53)	49 (36 – 68)
Men, n (%)	12 (67%)	6 (55%)	8 (44%)
White, n (%)	18 (100%)	9 (82%)	17 (94%)
Cirrhosis, n (%)	4 (22%)	1 (9%)	8 (44%)
Liver stiffness, kPa, median (range)	9.9 (5.4 – 25.1)	7.4 (5.9 – 13.8)	10.3 (4.5 – 46.4)
ALT, U/L, mean (range)	68 (19 – 203)	36 (19 - 55)	63 (15 – 242)
Baseline abnormal ALT, n (%)	17 (94%)	4 (36%)*	17 (94%)
HBsAg, log ₁₀ IU/ml, median (range)	4.1 (3.6– 4.9)	4.4 (3.5 – 5.1)	4.0 (1.7 – 4.6)
HBeAg+, n (%)	1 (6%)	1 (9%)	3 (17%)
HIV-coinfection	0	0	1 (6%)
HDV RNA, median, log ₁₀ IU/ml (range)	5.4 (2.9 – 7.1)	4.8 (3.3 – 7.1)	5.4 (1.3 – 7.4)
HDV genotype 1, n (%)	18 (100%)	10 (91%)	18 (100%)
HDV genotype 5, n (%)	0	1 (9%)	0

* entry criteria initially did not require abnormal ALT

BJT-778 300 mg Once Weekly: 100% Virologic Response and Parallel Declines in ALT



18 18 18 17 12 10 10 10 10 10 10 # of subjects



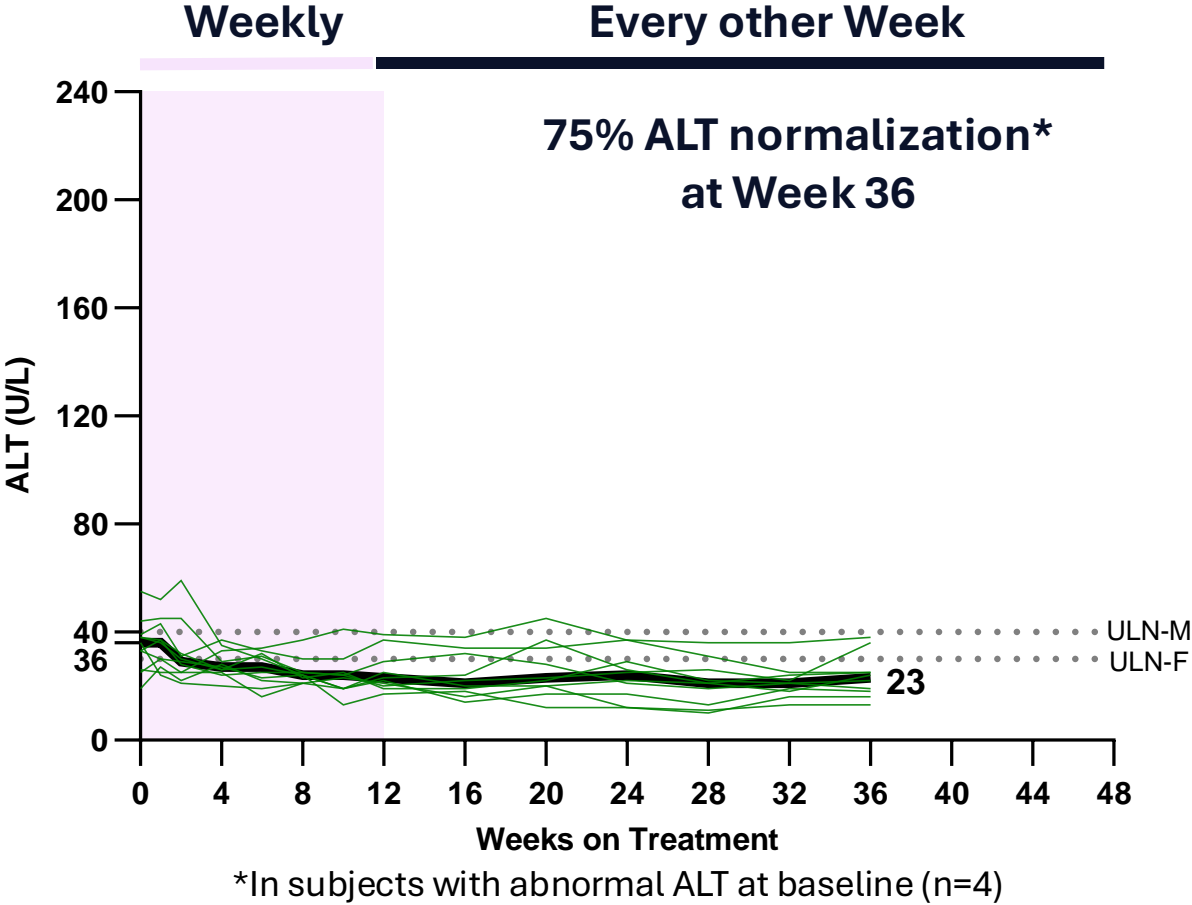
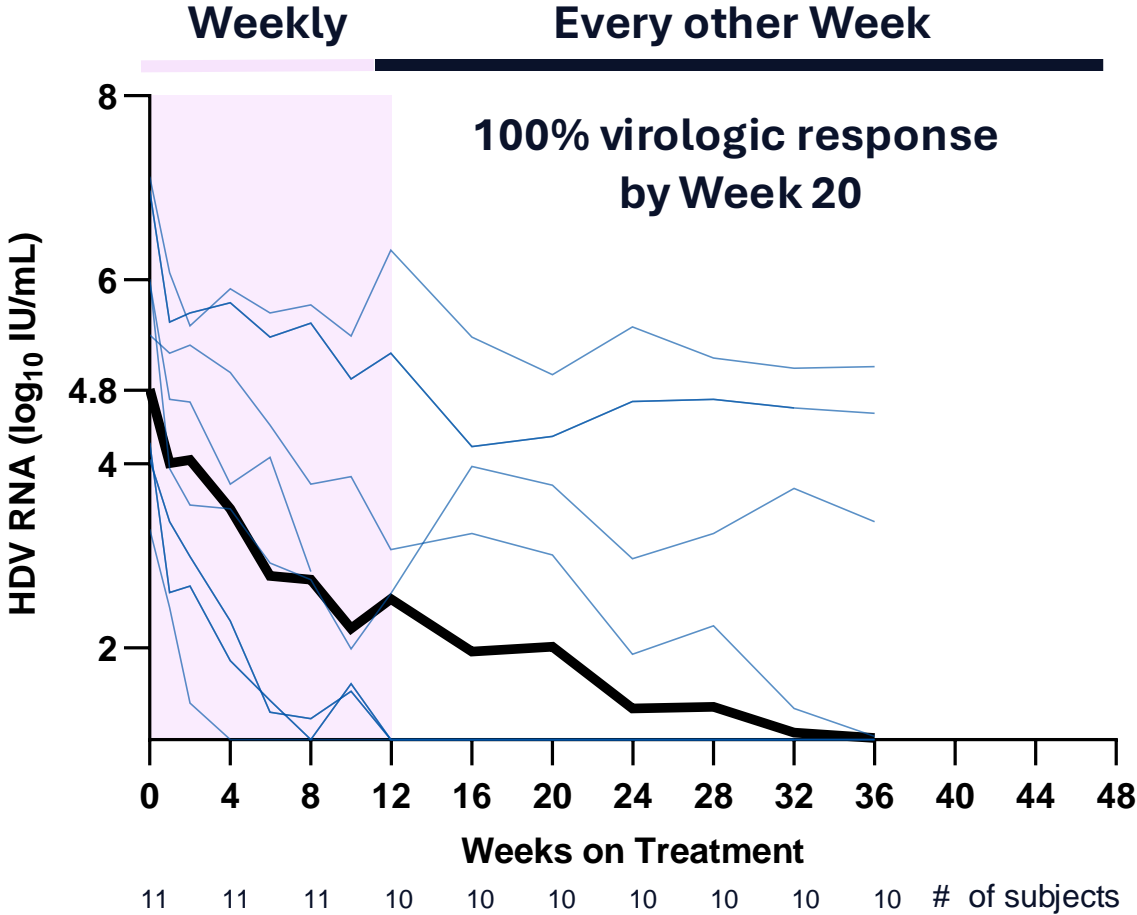
*In subjects with abnormal ALT at baseline
**Isolated asymptomatic G2 ALT increase during holiday festivities with ↑↑ alcohol consumption



Bold lines are median values

Virologic response = ≥ 2 \log_{10} HDV RNA IU/ml reduction from baseline or HDV RNA TND; Upper Limit Normal

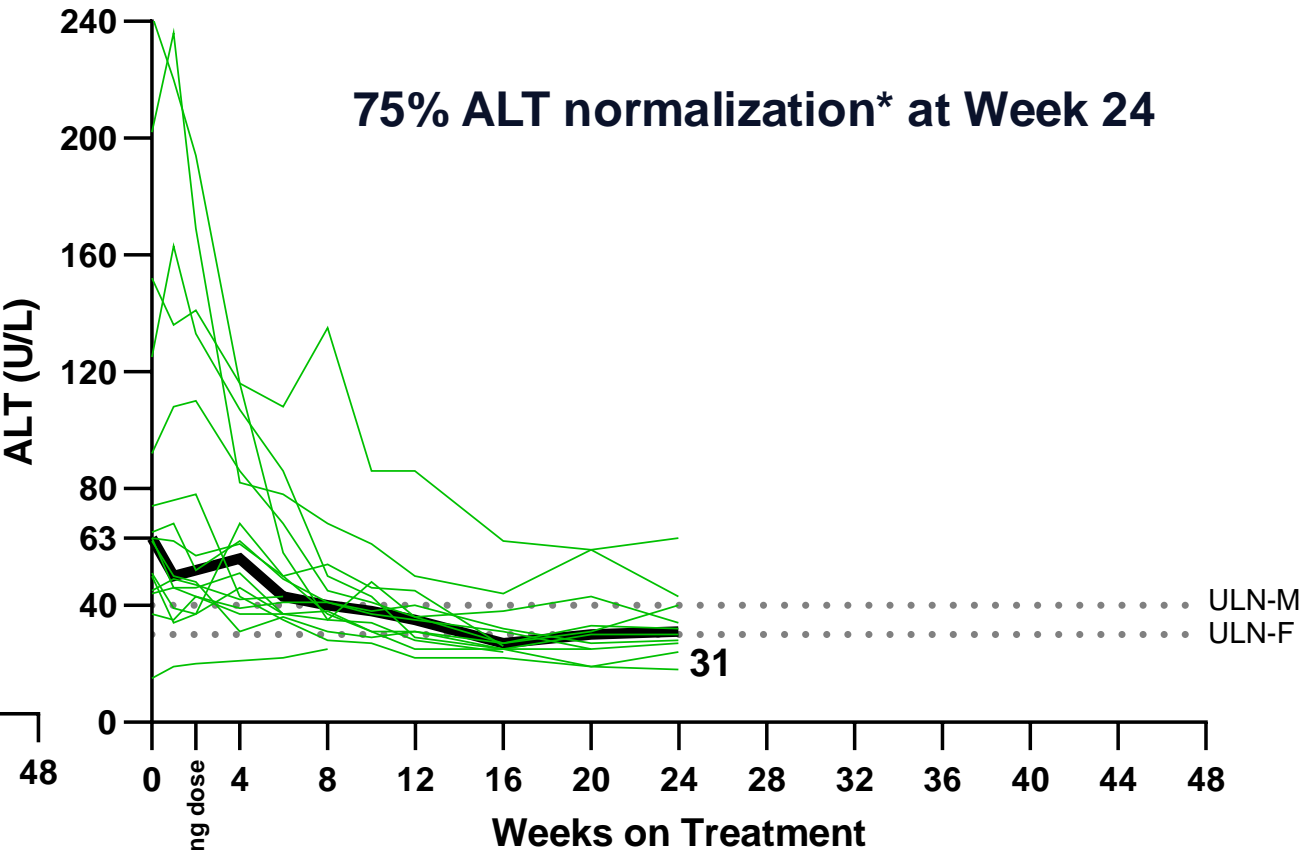
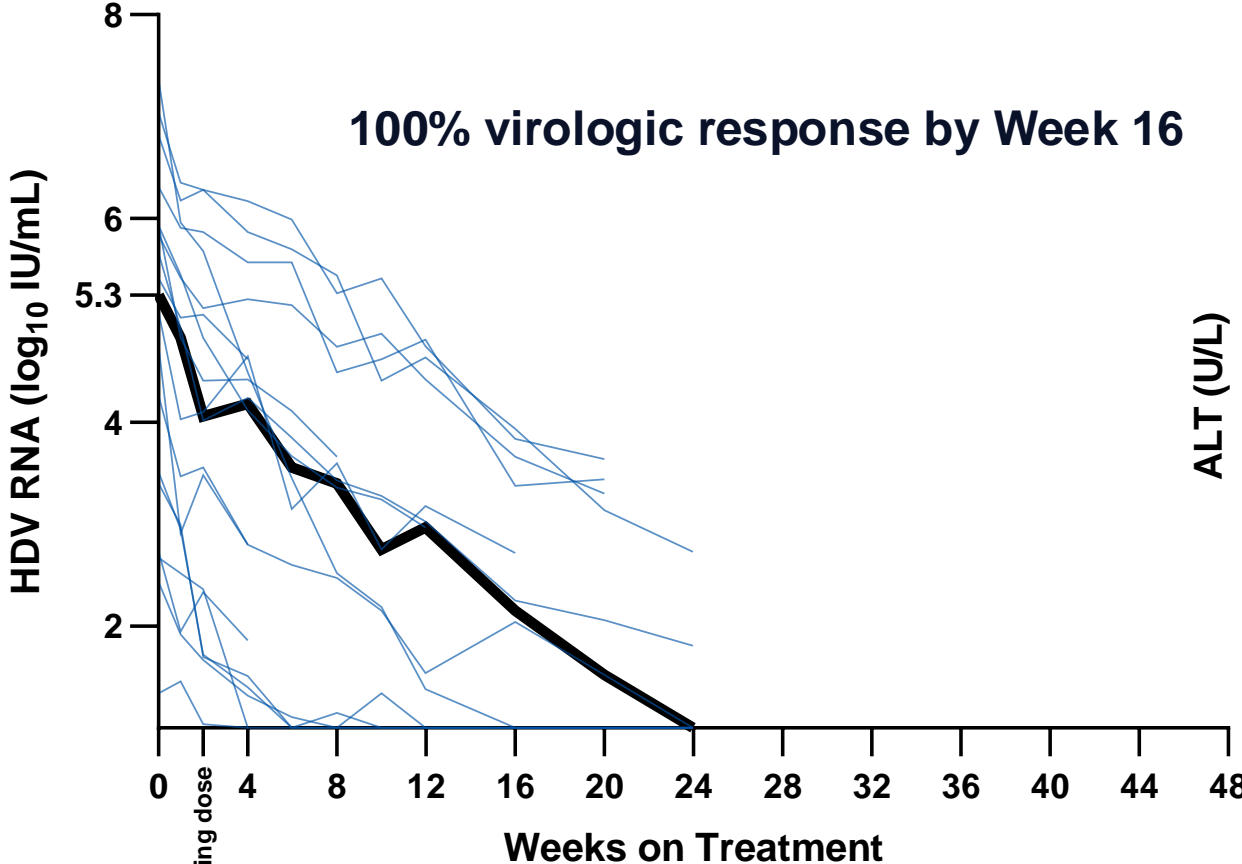
BJT-778 600 mg SC QW for 12 Weeks Followed by Q2W



- 1 subject from the Ukraine site discontinued the study after Week 8 due to an urgent move out of the country with >3 log reduction from baseline at and a normal ALT at Week 8

Virologic response = ≥ 2 log₁₀ HDV RNA IU/ml reduction from baseline or HDV RNA TND; ULN: Upper Limit Normal

BJT-778 900 mg Q4W: 100% Virologic Response and Parallel Declines in ALT

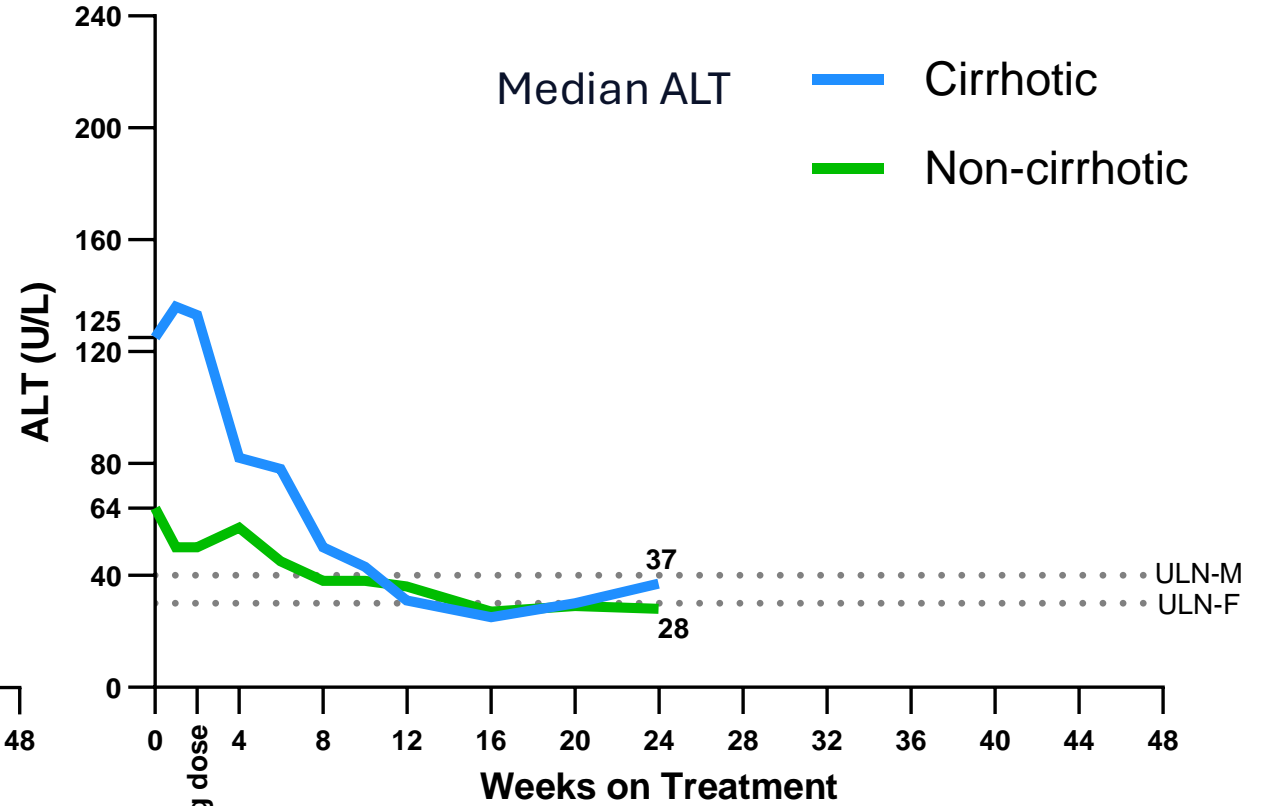
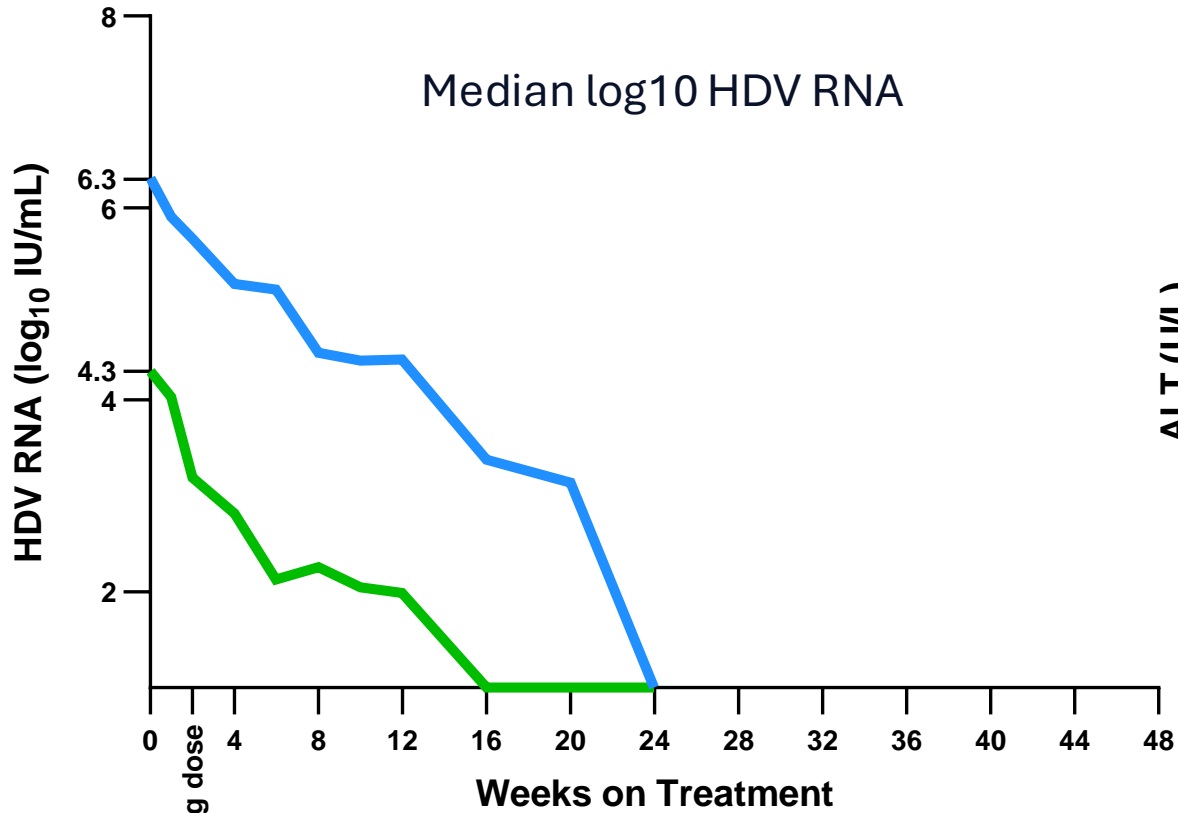


*In subjects with abnormal ALT at baseline

18 18 14 13 12 11 8 # of subjects

Virologic response = ≥ 2 \log_{10} HDV RNA IU/ml reduction from baseline or HDV RNA TND; ULN: Upper Limit Normal

Similar Efficacy in Subjects With Cirrhosis vs. No Cirrhosis – 900 mg Every 4 Weeks



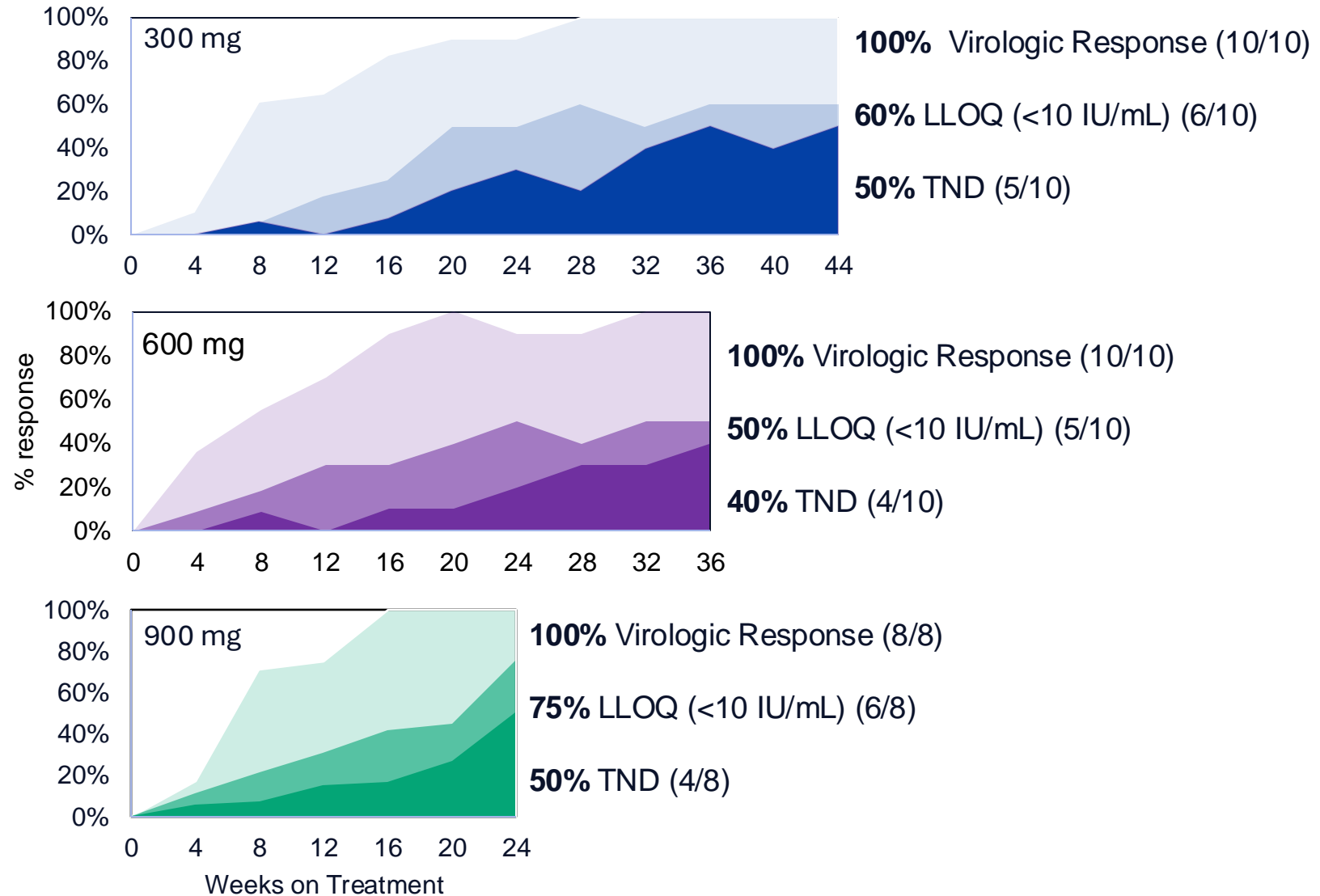
8 8 6 5 5 5 4 # Cirrhotic

10 10 8 8 7 6 4 # Non-cirrhotic

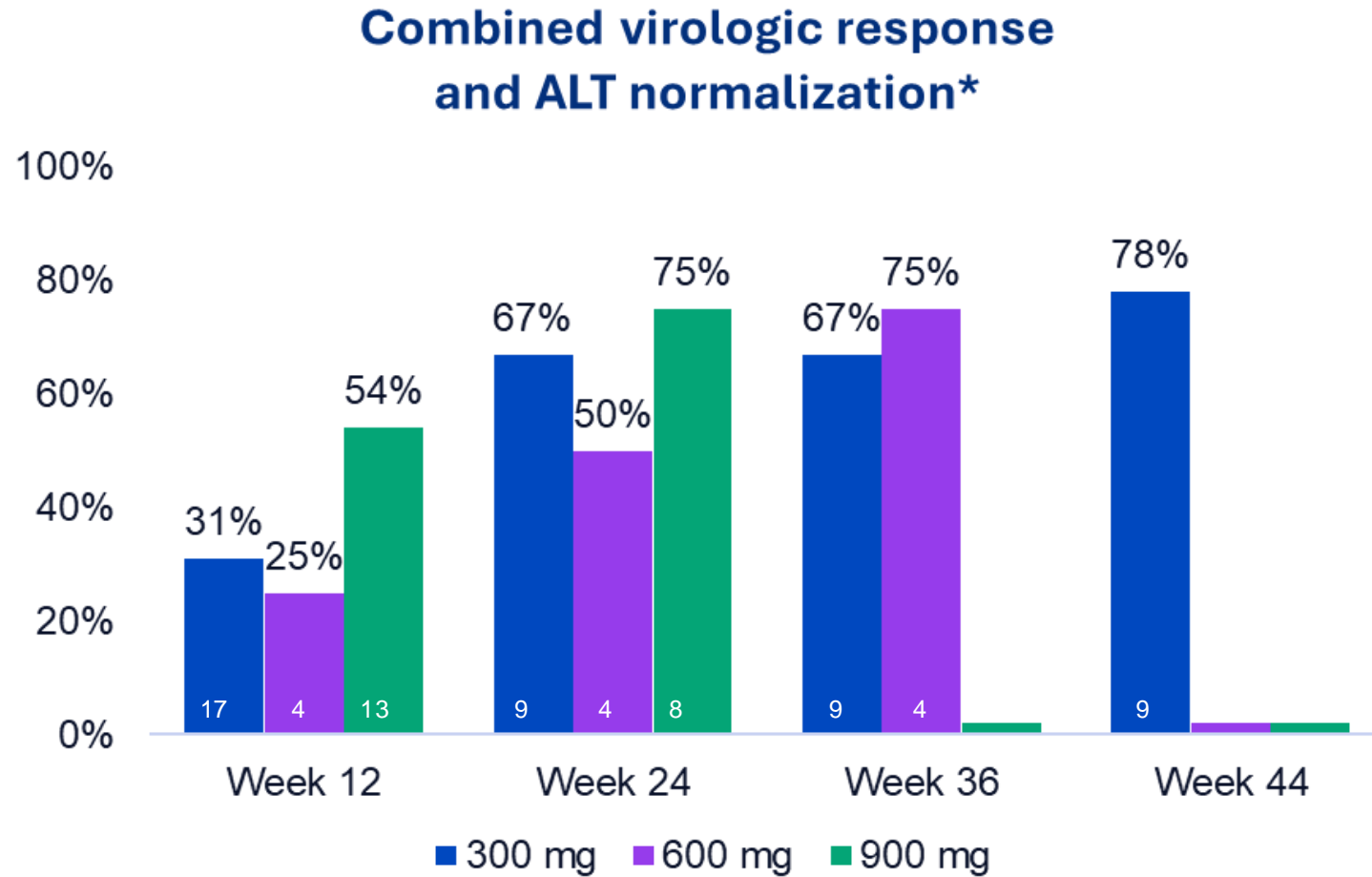


ULN: Upper Limit Normal

100% Virologic Response Across All Dose Arms: Increasing Rates of HDV RNA <10 IU/mL Including Undetectable



Up to 78% Combined Response with BJT-778 Monotherapy



*In subjects with abnormal ALT at baseline

All Regimens Explored Were Safe and Well Tolerated: No \geq Grade 3 AEs, SAEs or Discontinuations Due to AEs

	300 mg (n=18)	600 mg (n=11)	900 mg (n=18)
All AEs, n	24	28	28
AEs related to BJT-778, n	6	14	18
Subjects with any AE, n (%)	11 (61%)	11 (100%)	11 (61%)
Subjects with related* AE, n (%)	5 (28%)	8 (73%)	6 (33%)
Grade 3, 4, or 5 AEs	0	0	0
Serious AEs	0	0	0
Discontinuations due to AEs	0	0	0
Subjects with Related AEs (n >1) AEs, n (%)			
Injection site erythema	2 (11%)	5 (45%)	1 (6%)
Injection site pruritus	0	1 (9%)	1 (6%)
Injection site swelling	0	1 (9%)	1 (6%)
Flu-like illness	0	1 (9%)	1 (6%)
Pyrexia	1 (6%)	1 (9%)	1 (6%)
Chills	1 (6%)	1 (9%)	0
Headache	1 (6%)	1 (9%)	2 (11%)

*At least possibly related to treatment

Summary:

- Combined virologic + ALT normalization rates of up to 78% were achieved with BJT-778 monotherapy dosed every 1 to 4 weeks in patients with chronic HDV.
- 100% of subjects had virologic response.
- Declines in HDV RNA were observed in all subjects regardless of baseline HDV RNA or presence of cirrhosis and deepened over time.
- Parallel ALT declines were observed in subjects who had elevations at baseline.
- BJT-778 has been safe and well tolerated at all dosing regimens explored with no \geq Grade 3 AEs, SAEs or discontinuations due to AEs.
- BJT-778 900 mg every 4 weeks shows promising efficacy, by Week 24:
 - 75% combined response (ALT normalization + Virologic)
 - 100% virologic response
 - 75% LLOQ (<10 IU/ml)
 - 50% target not detected (TND)

Conclusions:

- BJT-778 is safe and effective as monotherapy for CHD with 100% virologic responses and combined responses >75%.
- Larger randomized controlled studies are planned.

Acknowledgements

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