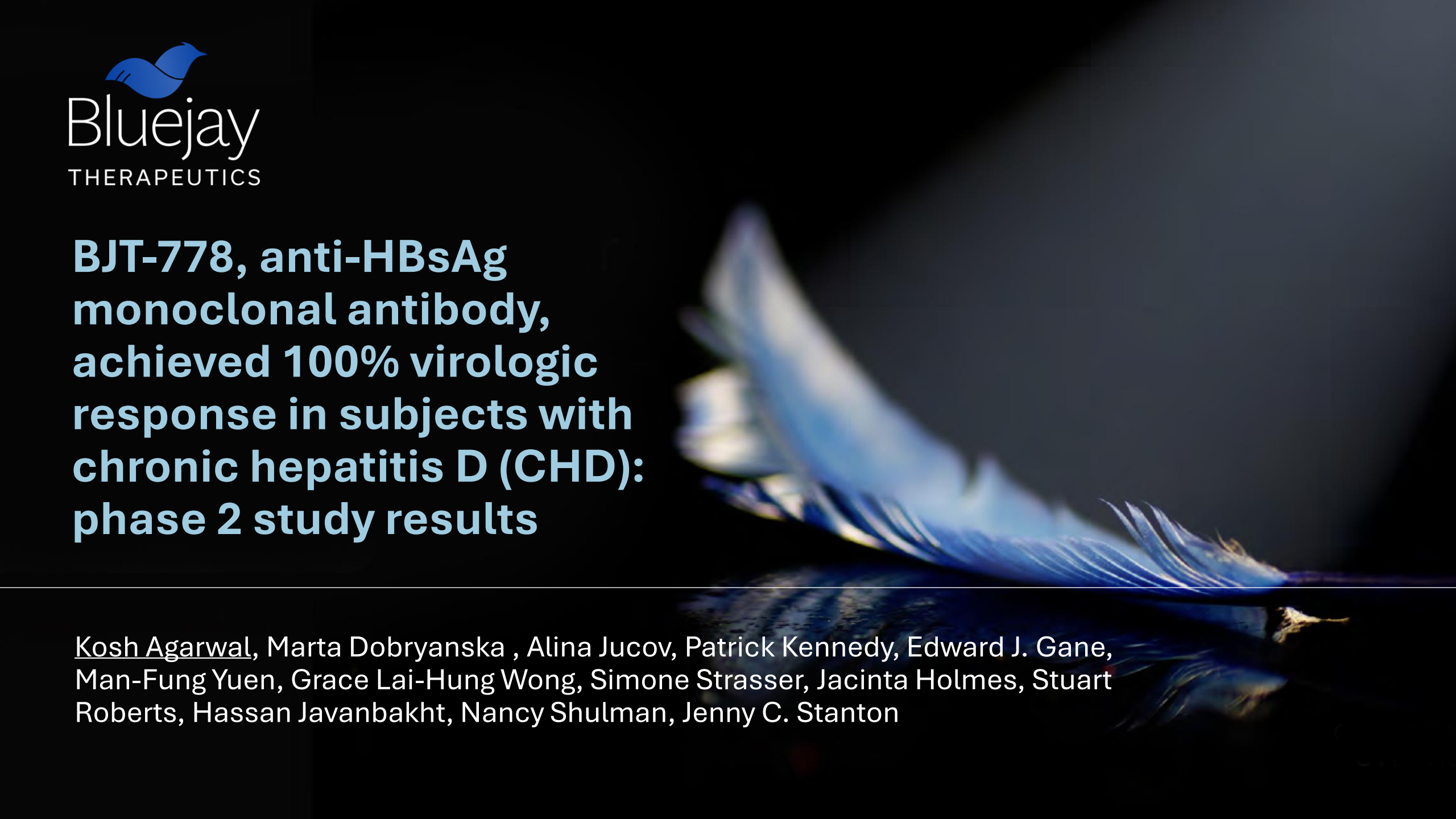

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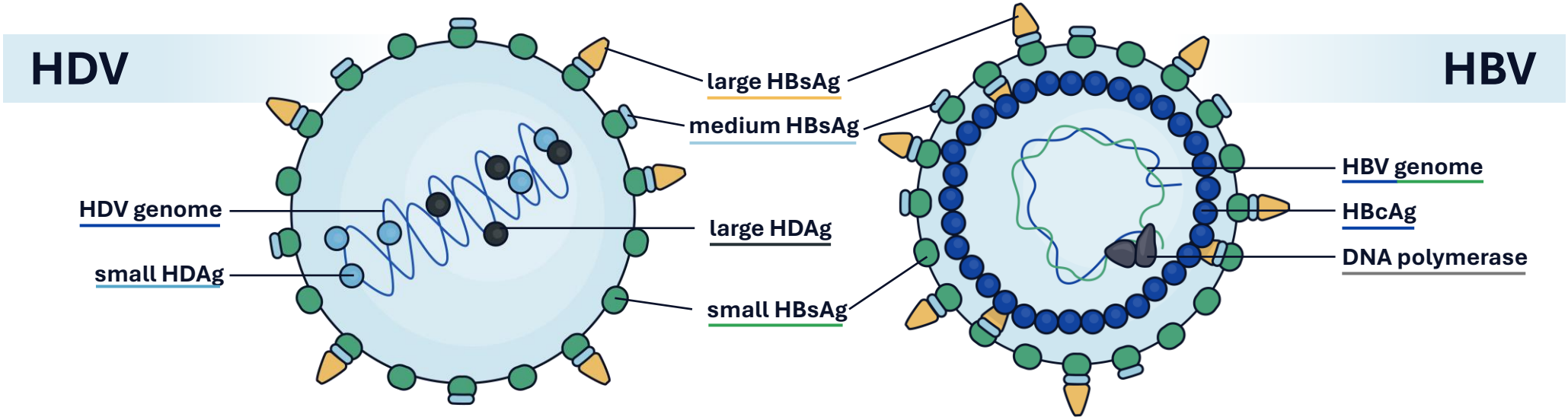
# BJT-778, anti-HBsAg monoclonal antibody, achieved 100% virologic response in subjects with chronic hepatitis D (CHD): phase 2 study results

Kosh Agarwal, Marta Dobryanska , Alina Jucov, Patrick Kennedy, Edward J. Gane, Man-Fung Yuen, Grace Lai-Hung Wong, Simone Strasser, Jacinta Holmes, Stuart Roberts, Hassan Javanbakht, Nancy Shulman, Jenny C. Stanton

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

- CHD affects >12 million people worldwide[1].
- It is the most severe form of viral hepatitis with the majority of patients developing cirrhosis within 5-10 years[2].
- 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.

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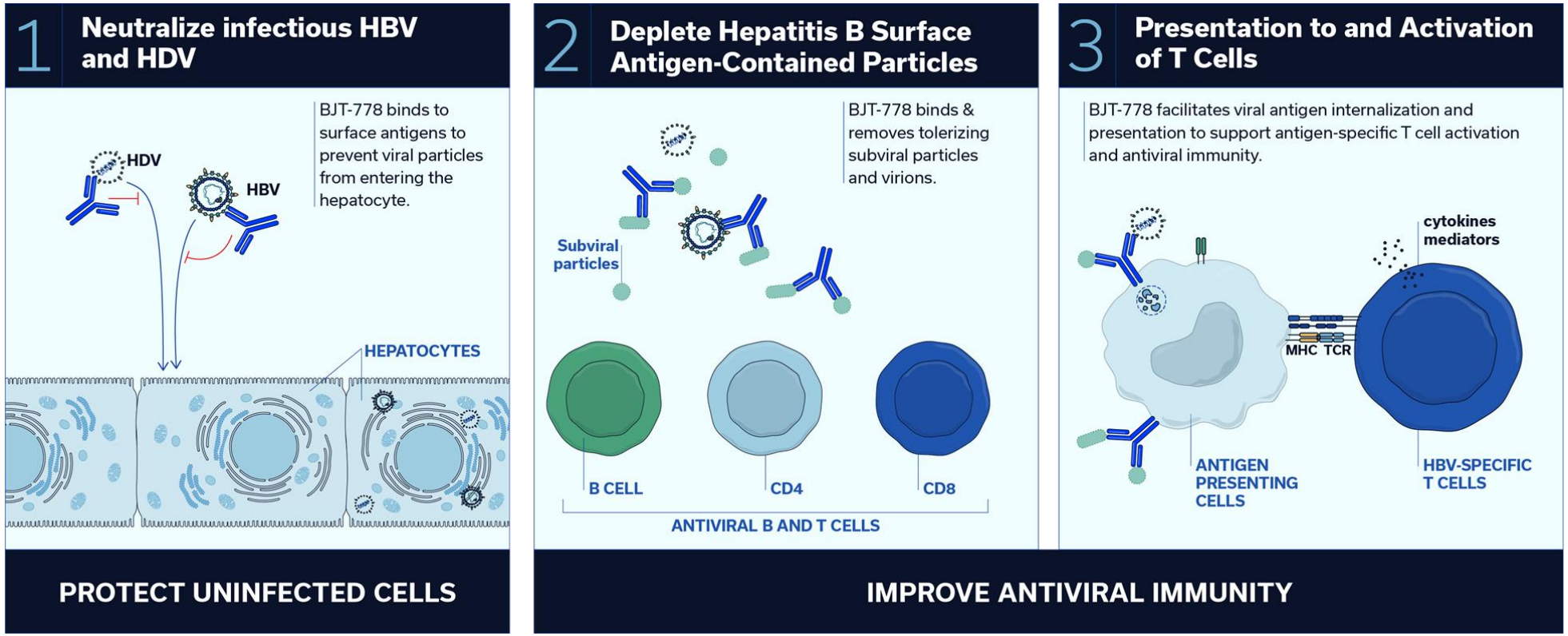
[1]Stockdale 2020 J Hepatol; [2]Romeo 2009 Gastroenterology

# 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

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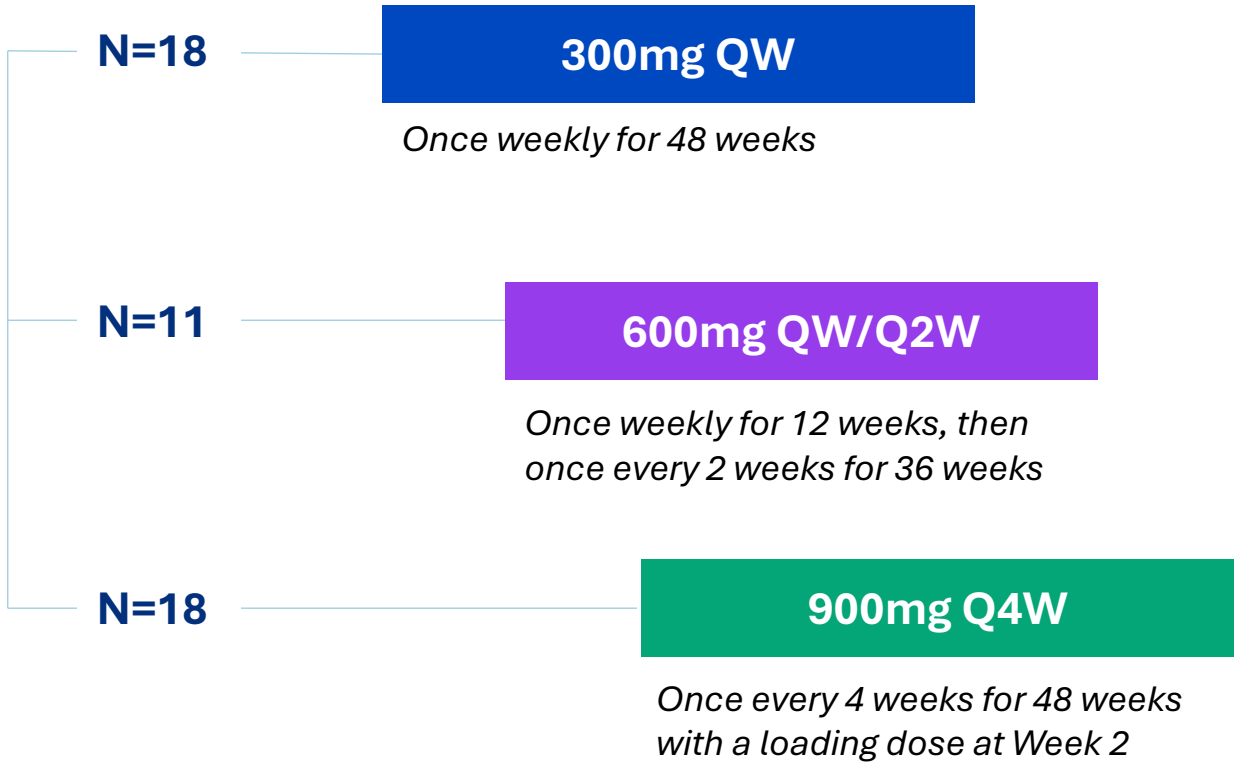
AASLD 2024 Poster # 1406

# 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

## Key Entry Criteria

- Adults with chronic HDV
- Quantifiable HDV RNA
- HBV DNA <100 IU/mL on NUCs
- Compensated liver disease
- PLT >100 K/mm$^3$
- 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

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# 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, log10 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, log10 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 |

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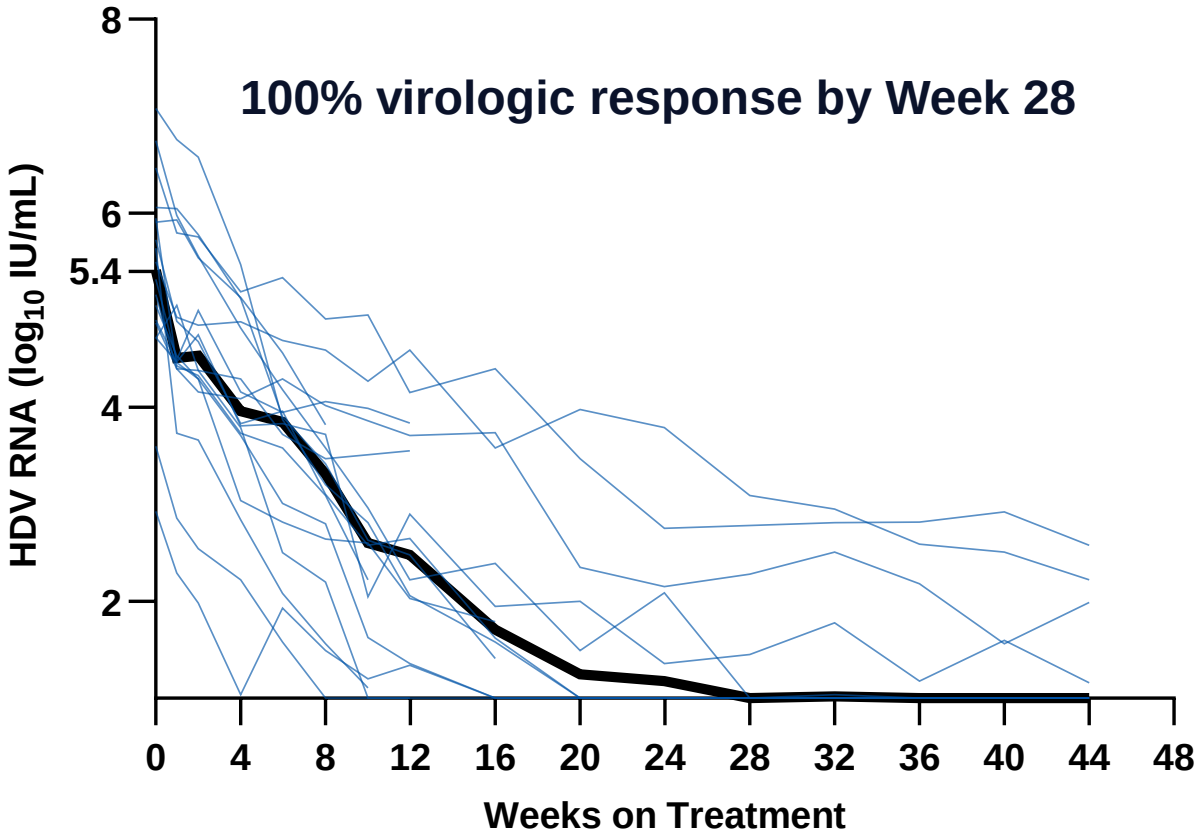
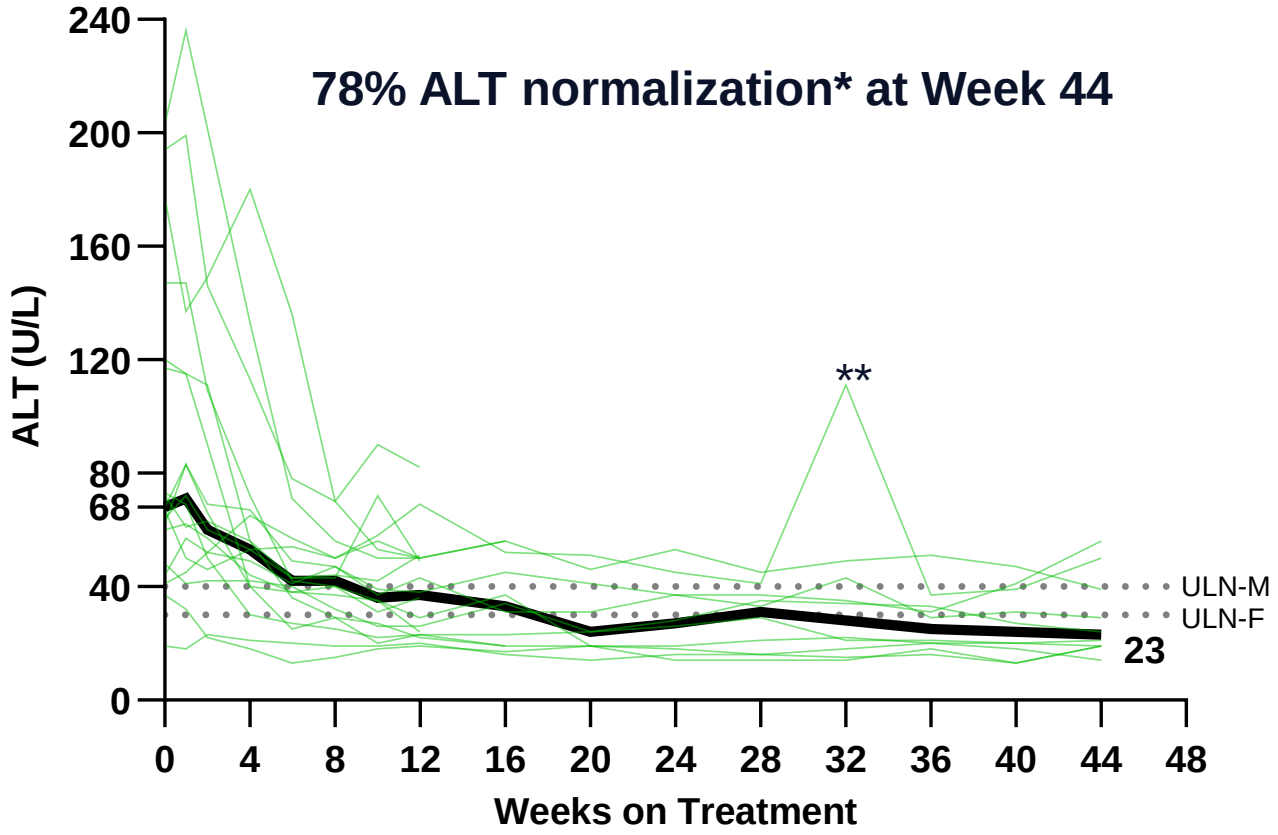
*entry criteria initially did not require abnormal ALT

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



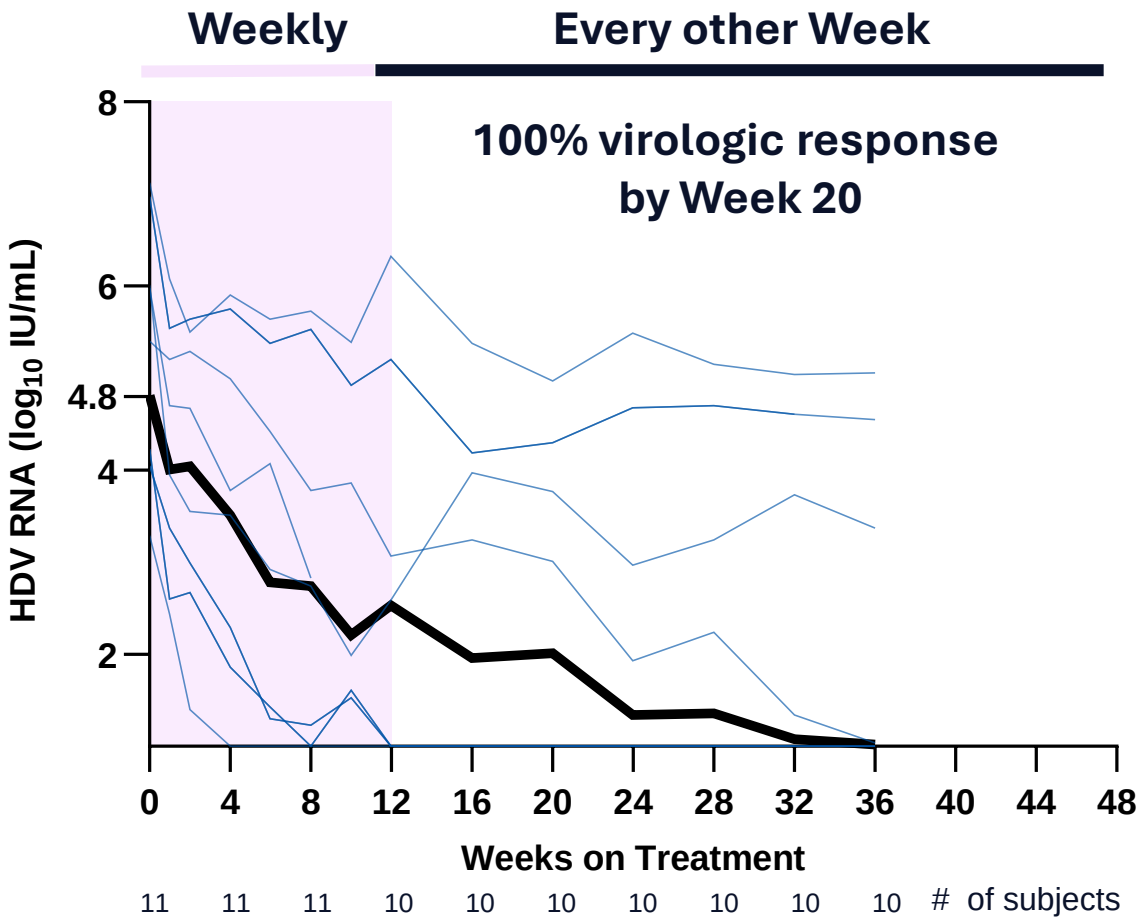



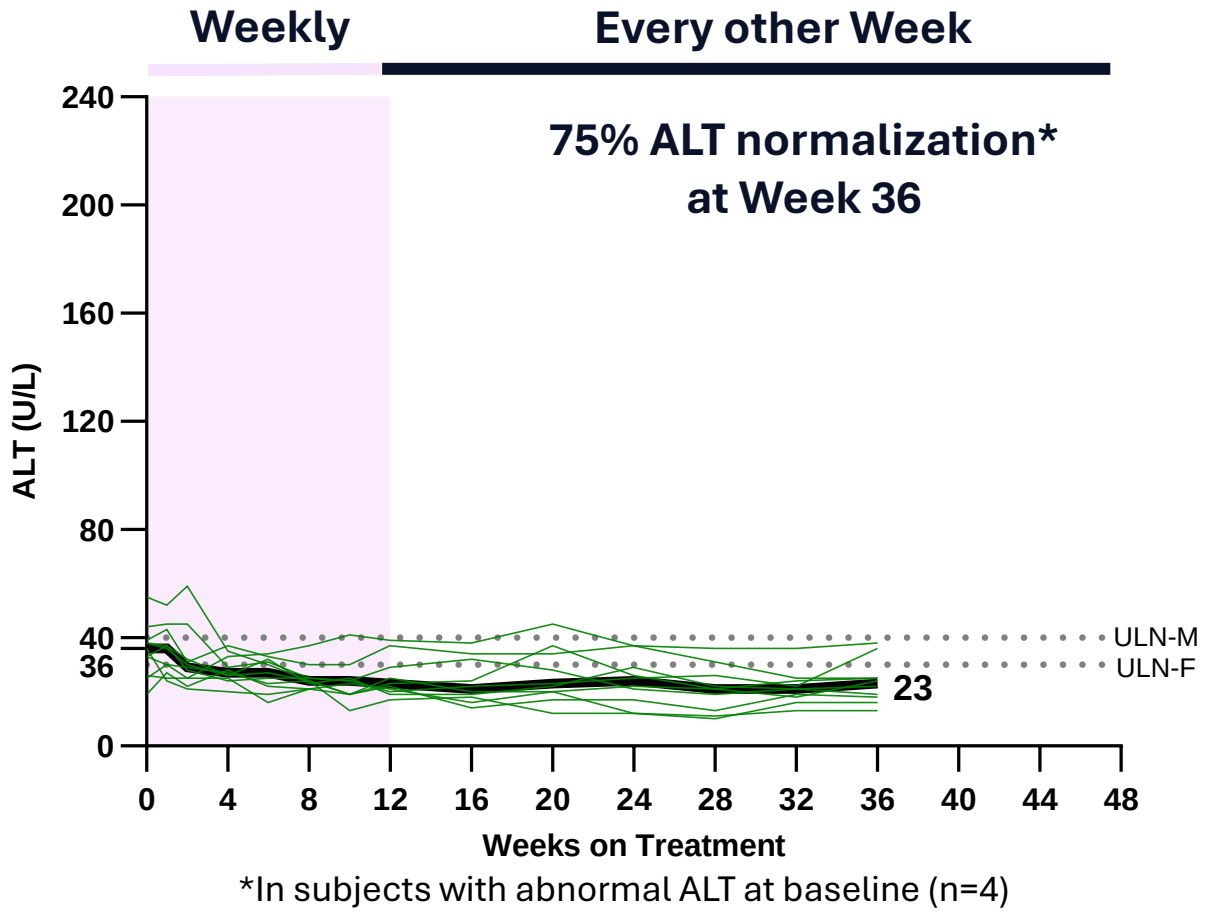

*In subjects with abnormal ALT at baseline
**Isolated asymptomatic G2 ALT increase during holiday festivities with ↑↑ alcohol consumption

**Bold lines are median values**

Virologic response = ≥2 log10 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



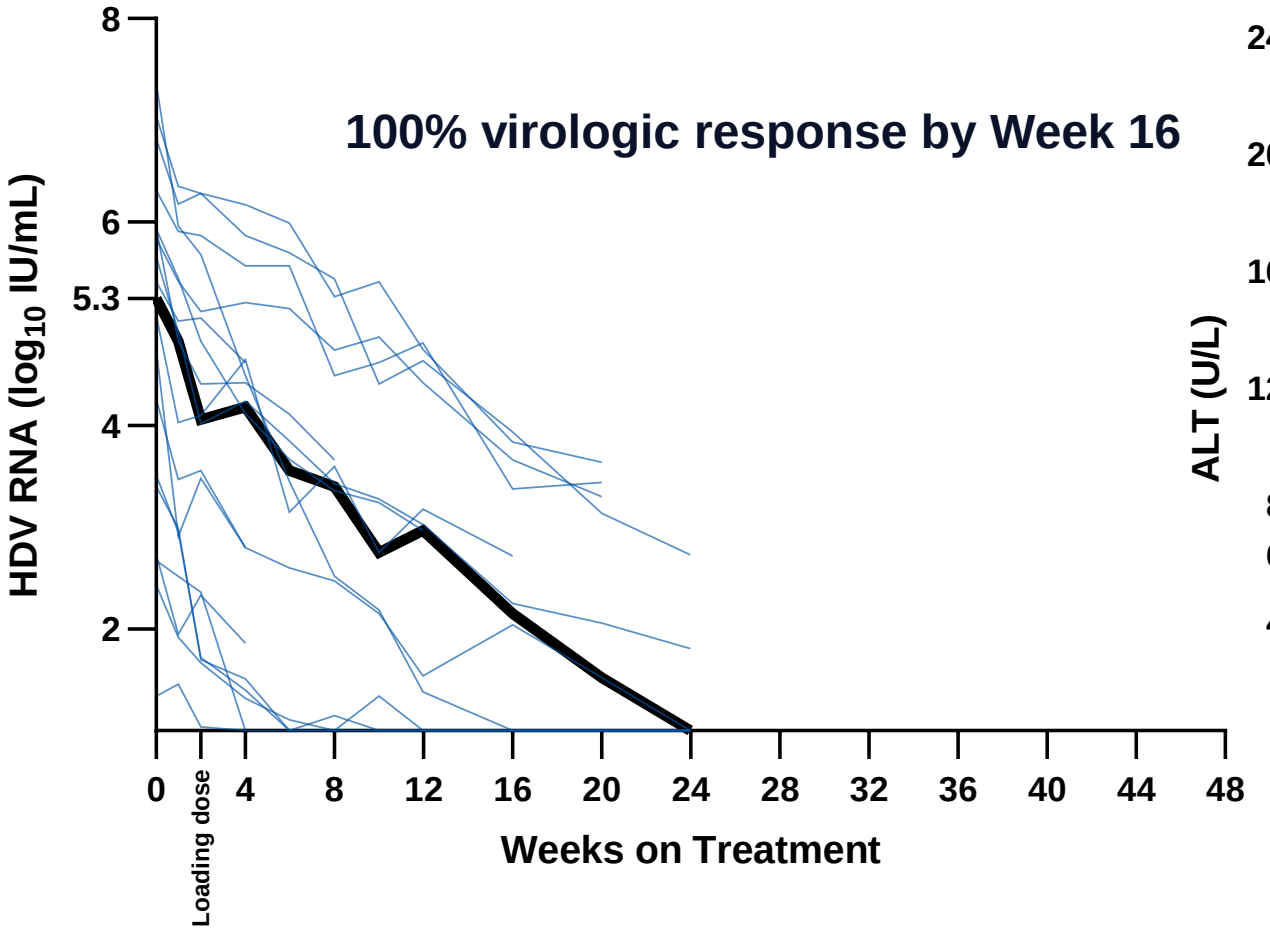



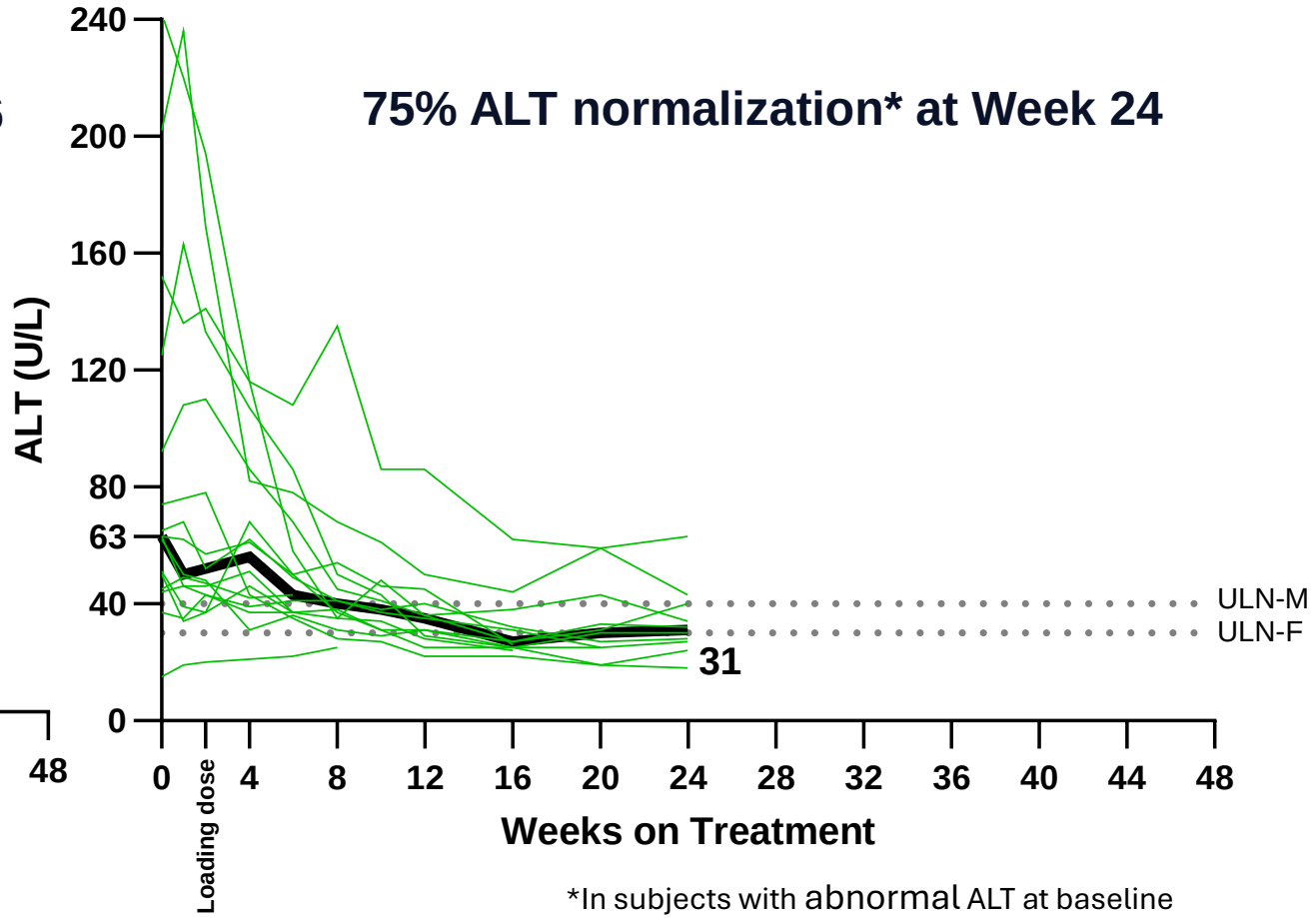

*In subjects with abnormal ALT at baseline (n=4)

- 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



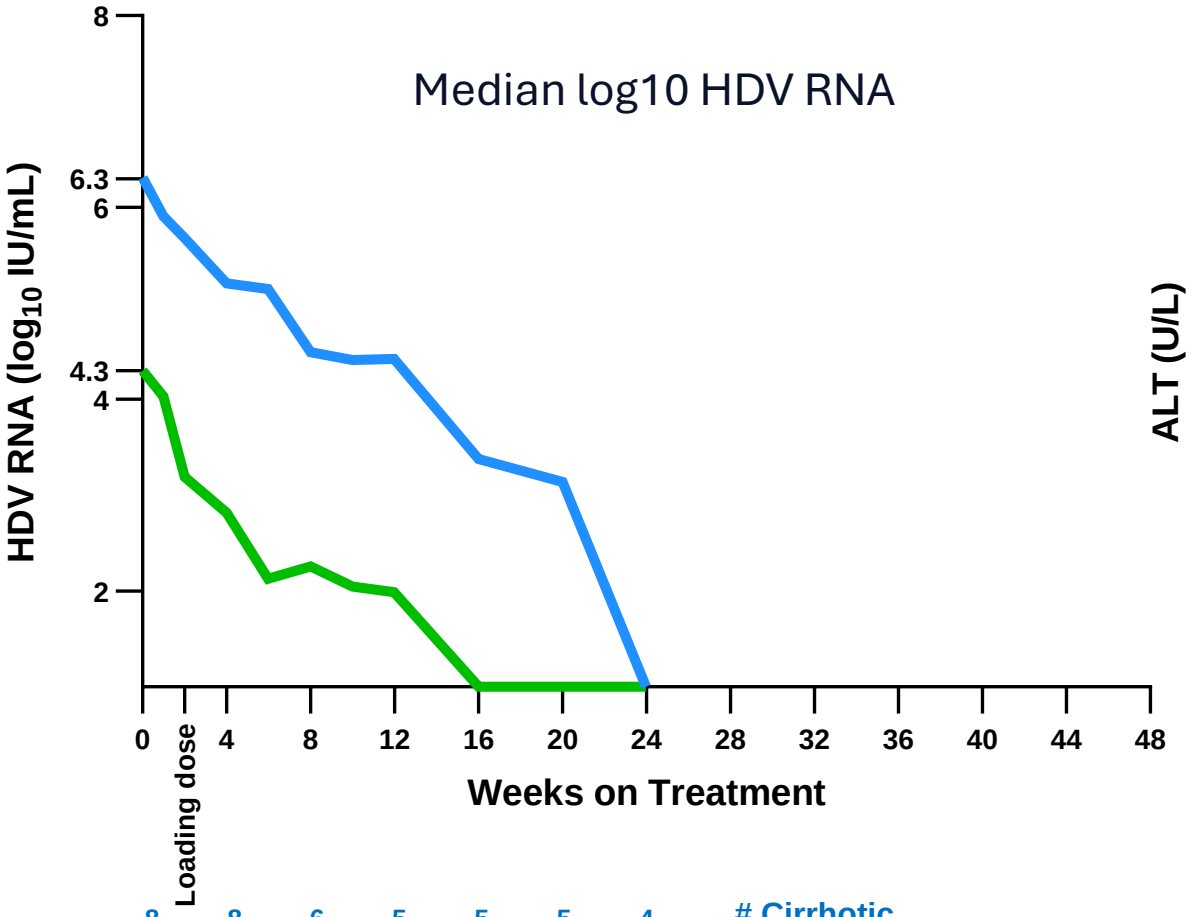



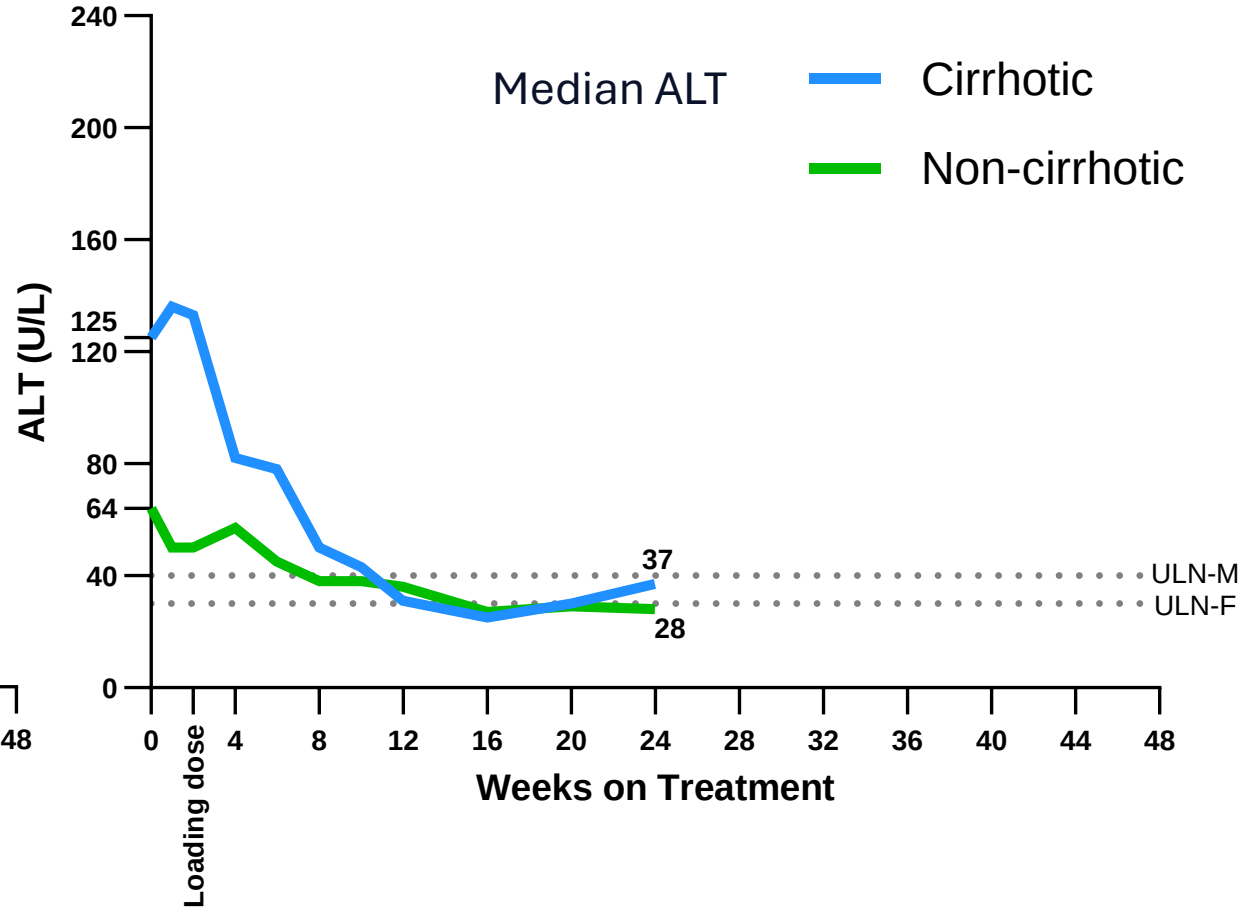

*In subjects with abnormal ALT at baseline

18 18 14 13 12 11 8 # of subjects

Virologic response = ≥2 log10 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

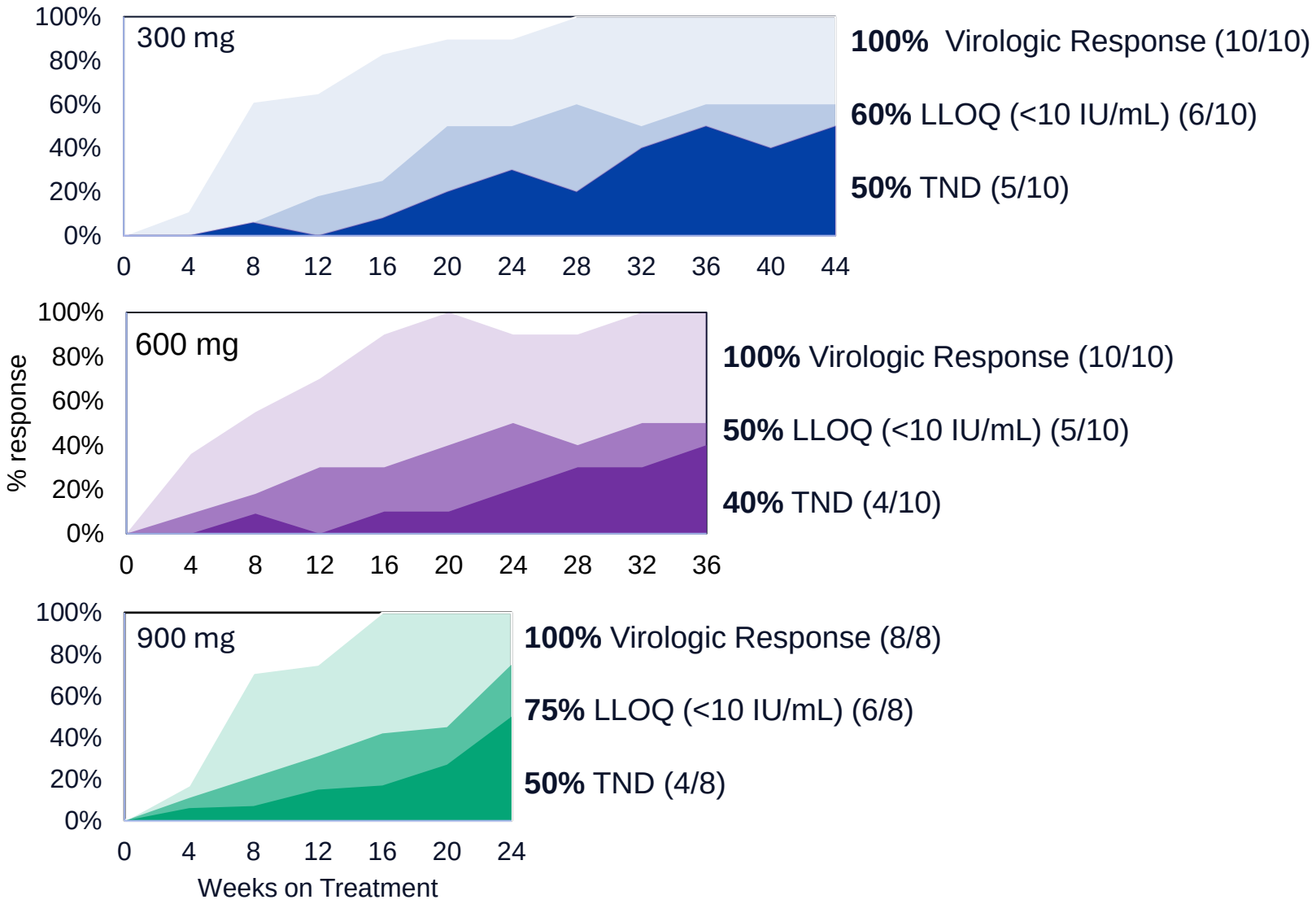



| | | | | | | | |
|---|---|---|---|---|---|---|---|
| 8 | 8 | 6 | 5 | 5 | 5 | 4 | # Cirrhotic |
| 10 | 10 | 8 | 8 | 7 | 6 | 4 | # Non-cirrhotic |

ULN: Upper Limit Normal

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

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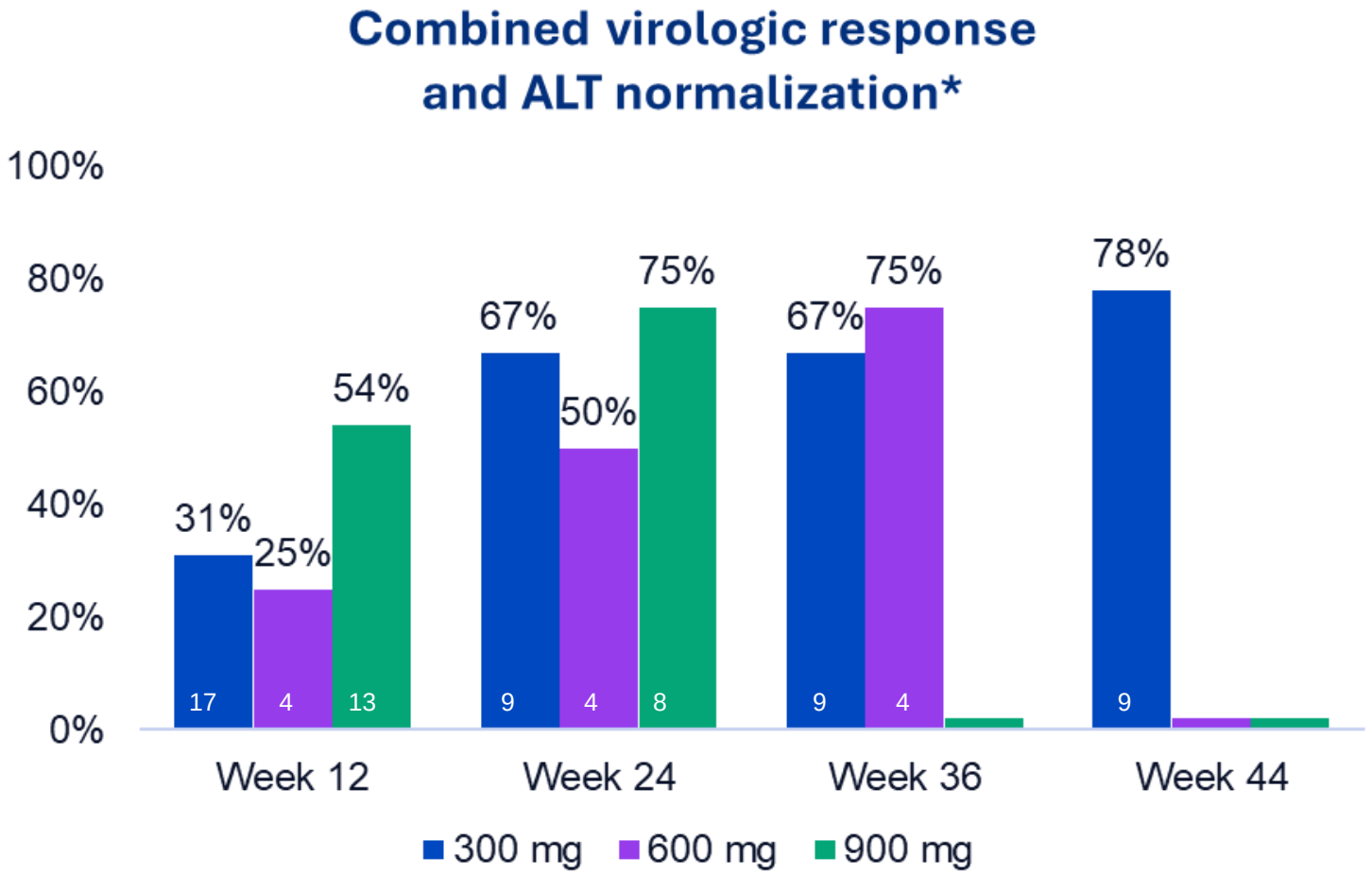
# Up to 78% Combined Response with BJT-778 Monotherapy




*In subjects with abnormal ALT at baseline

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# All Regimens Explored Were Safe and Well Tolerated: No ≥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

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# 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 ≥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)

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# 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.

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# Acknowledgements

**Thank you to all the subjects who participated in the trial and to the wonderful staff at the sites:**

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