

Phase 3 *D-LIVR* Week 48 Topline Data – Investor Call



## Forward Looking Statements

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# Opening Remarks

David Cory – President and CEO



## Phase 3 *D-LIVR* Topline Data - Clinical

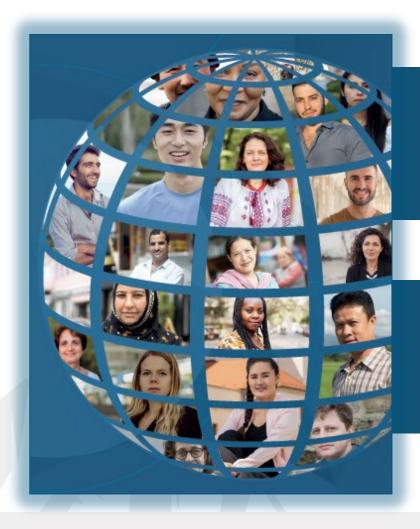
#### David Apelian, MD, PhD

- Former Executive Medical Officer, Eiger
- Member of the Board of Directors, Eiger



#### What Does a Win Look Like for HDV Patients?

#### CONSISTENT WITH FDA GUIDANCE ON DEVELOPMENT OF TREATMENTS FOR HDV\*

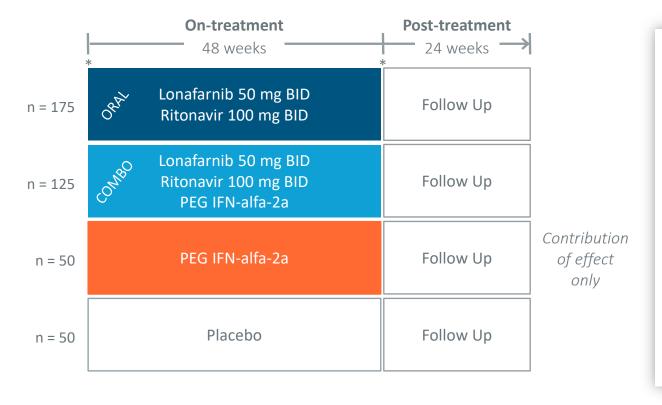


- Reduction in HDV Viral Load
- Improvement in Liver Inflammation (ALT)

- Slows Disease Progression
- Improves Liver Histology
- Improves Survival



# D-LIVR Phase 3 Global Study



## Primary Endpoint at Week 48

≥ 2 log decline in HDV RNA +

#### Normalization of ALT

## Secondary Endpoint at Week 48

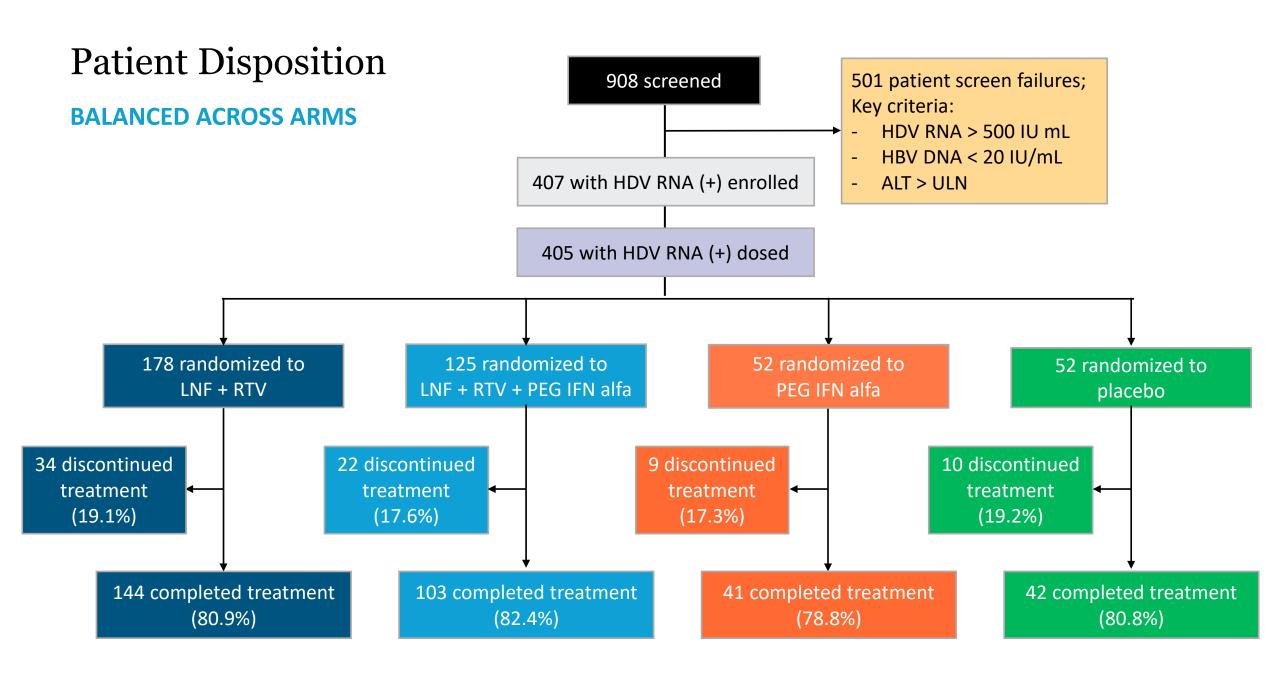
No worsening in fibrosis

≥ 2-point in Ishak HAI Score

All patients will be maintained on background HBV nucleoside therapy.



<sup>\*</sup> Liver biopsy

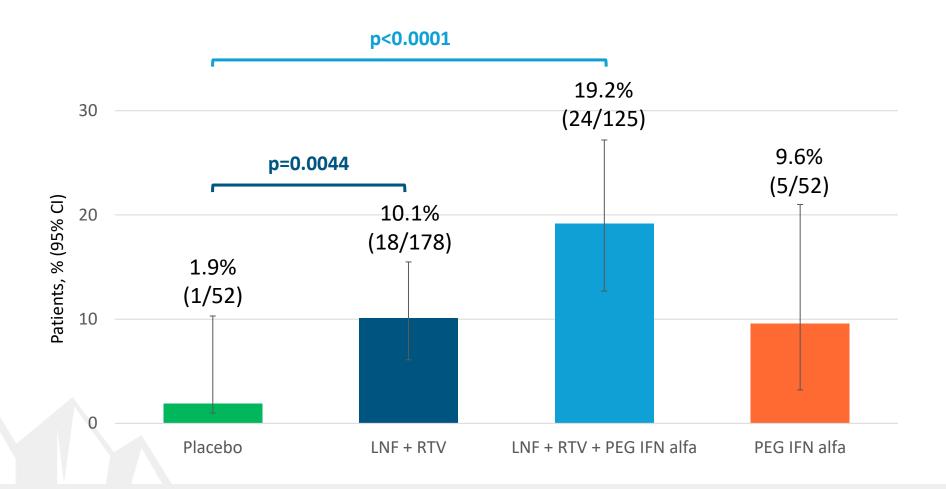


## **Baseline Characteristics**

		Placebo (n=52)	LNF + RTV (n=178)	LNF + RTV + PEG IFN alfa (n=125)	PEG IFN alfa (n=52)	Total (N=407)
Mean age, y (SD)		45.7 (10.9)	42.9 (10.8)	41.4 (11.5)	42.3 (11.0)	407
Men, n (%)		39 (75)	126 (71)	84 (67)	33 (64)	282 (69)
Race, n (%)	White	42 (81)	130 (73)	85 (68)	41 (79)	298 (73)
	Asian	10 (19)	40 (23)	35 (28)	10 (19)	95 (23)
	Black	0	3 (2)	3 (2)	0	6 (2)
	Other/no reported	0	5 (3)	1 (1)	1 (2)	7 (2)
Region	Asia	6 (12)	25 (14)	21 (17)	7 (14)	59 (15)
	Europe	43 (83)	127 (71)	92 (74)	41 (79)	303 (74)
	North America	1 (2)	14 (8)	9 (7)	2 (4)	26 (6)
	Other	2 (4)	12 (7)	3 (2)	2 (4)	19 (5)
Mean ALT, U/L (SD)		122 (83)	100 (69)	99 (73)	82 (47)	407
Mean HDV RNA, log IU/mL (SD)		4.97 (1.12)	4.94 (1.13)	5.14 (1.17)	4.88 (1.19)	406
HDV ganatuna n (%)	1	47 (90)	174 (98)	118 (94)	52 (100)	391 (96)
HDV genotype, n (%)	4/5/8/not reported	1 (2) / 0 / 0 / 4 (8)	0 / 1 (0.6) / 0 / 3 (2)	0/0/1(1)/6(5)	0/0/0/0	16 (4)
Median HBsAg, log IU/mL (range)		3.92 (2.18, 4.75)	3.83 (2.11, 4.75)	3.91 (1.16, 4.75)	3.92 (2.22, 4.63)	407
Cirrhosis, n (%)		15 (29)	47 (26)	32 (26)	14 (27)	108 (27)

## Primary Endpoint Achieved with Significance in BOTH Arms

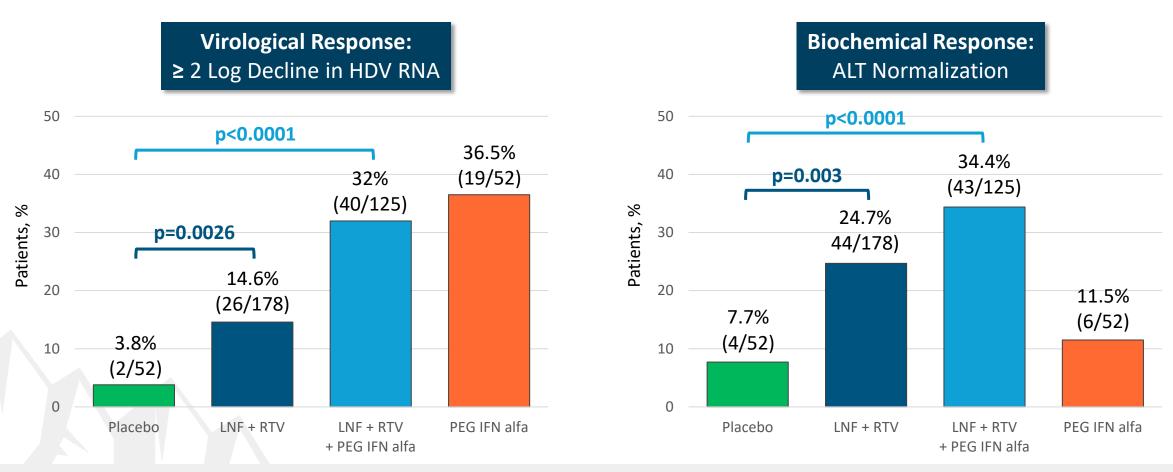
#### % PATIENTS ACHIEVING COMPOSITE ≥2 LOG DECLINE IN HDV RNA + ALT NORMALIZATION AT WEEK 48





## Key Secondary Endpoints Achieved in BOTH Arms with Significance

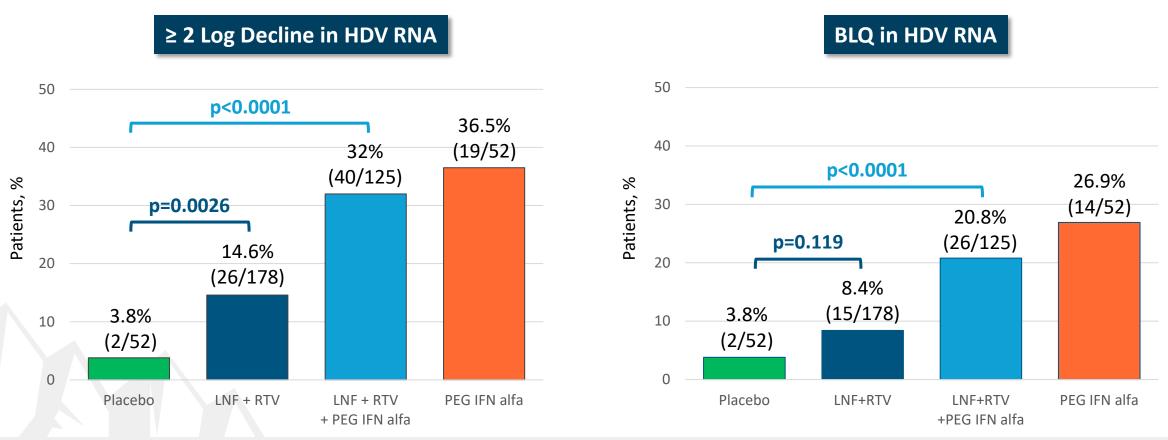
#### **COMPONENTS OF COMPOSITE PRIMARY ENDPOINT AT WEEK 48**





## Virologic Response at End of Treatment

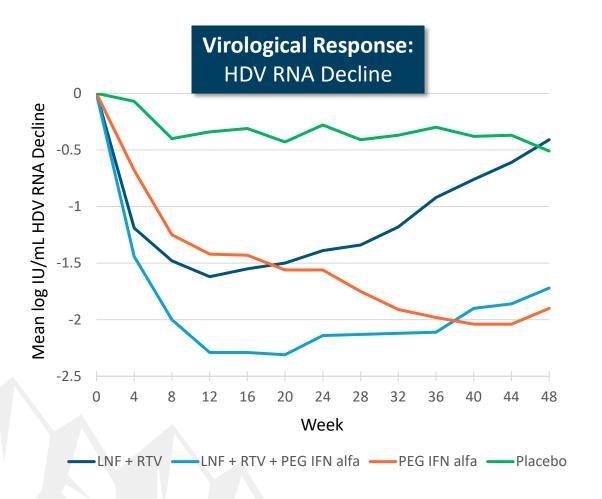
#### 20.8% OF PATIENTS IN COMBINATION ARM ARE BELOW LIMIT OF QUANTITATION\* (BLQ) AT WEEK 48

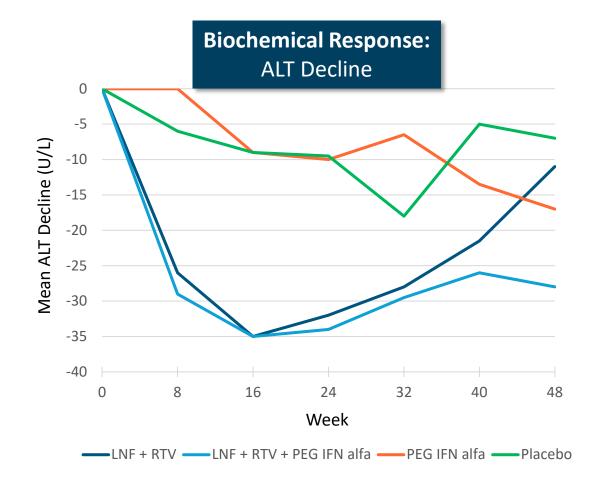




## Mean HDV RNA and ALT Decline Through End of Treatment

#### **INTENT TO TREAT (ITT) POPULATION (N=405)**







## Key Histological Secondary Endpoint

#### ≥ 2 POINT IMPROVEMENT IN ISHAK HISTOLOGY ACTIVITY INDEX AND NO WORSENING OF FIBROSIS

- Histologic improvement endpoint served as a basis for approval in multiple prior HBV registrational programs
- Histology evaluated by blinded assessment of paired liver biopsies collected at baseline and Week 48
- Dr. Zachary Goodman, *D-LIVR* pathologist
  - Director of hepatic pathology consultation and research at Inova Fairfax Hospital
  - Recognized expert in hepatobiliary pathology and liver biopsy interpretation
  - Lead pathologist for multiple clinical trials for the treatment of chronic viral HBV, HCV, and NASH



## Histology Response Rates at Week 48

#### PATIENTS WITH EVALUABLE PAIRED BIOPSIES (n=229)

	% (n)				
Response	Oral n=107	Combo n=66	PEG IFN alfa n=26	Placebo n=30	
Histologic Composite Endpoint	33% (35) (p=0.61)	53% (35) (p=0.0139)	38% (10) (p=0.46)	27% (8)	

- Histologic Composite Endpoint: ≥ 2-point improvement in HAI\* score + no worsening in Ishak fibrosis score
- Liver histology is the most direct way to assess improvements in:
  - Liver injury (necrosis and inflammation) measured by HAI score
  - Liver scarring (fibrosis) measured by fibrosis score



## Additional Analyses

- No discernible benefit in any prespecified subgroup
  - Baseline viral load (≤ 4 log vs > 4 log)
  - Cirrhotic vs non-cirrhotic
- Additional sub-analysis for predictors of early response (on-going)
- Week 72, 24-week post-treatment follow up period (on-going)
  - Key secondary endpoints including durability of virologic, biochemical, and composite responses



## Phase 3 *D-LIVR* Topline Safety

#### Colin Hislop, MBBS

- Senior Vice President of Clinical & Development Operations, Eiger
- Phase 3 *D-LIVR* Study Medical Monitor



## Overall Safety through Week 48

#### **BOTH LONAFARNIB-TREATMENT REGIMENS WERE WELL-TOLERATED**

	N (%)				
	Placebo (n=52)	LNF + RTV (n=178)	LNF + RTV + PEG IFN alfa (n=125)	PEG IFN alfa (n=50)	Total (N=405)
Patients ≥ 1 TEAE	37 (71)	168 (94)	120 (96)	48 (96)	373 (92)
Patient discontinuation due to LNF	1 (2)	16 (9)	10 (8)	1 (2)	28 (7)
Patient discontinuation due to RTV	1 (2)	15 (8)	10 (8)	1 (2)	27 (7)
Patient discontinuation due to PEG IFN alfa	0	0	12 (10)	1 (2)	13 (3)
Patients with serious TEAE	2 (4)	15 (8)	18 (14)	5 (10)	40 (10)
Patients with ≥ 1 TEAE leading to death	0	1 (1) <sup>1</sup>	0	1 (2) <sup>2</sup>	2 (1)



<sup>&</sup>lt;sup>1</sup>Deemed unrelated to treatment

<sup>&</sup>lt;sup>2</sup>Deemed related to treatment

### Dose Modifications

#### 33% OF PATIENTS DOSE REDUCED; ~50% SUBSEQUENTLY DOSE INCREASED

	N (%)				
	Placebo (n=52)	LNF + RTV (n=178)	LNF + RTV + PEG IFN alfa (n=125)	PEG IFN alfa (n=52)	Total (N=407)
Patients who dose reduced, n (%)	0	46 (26)	65 (52)	22 (44)	133 (33)
Patients who subsequently dose increased, n (%)	0	26 (57)	35 (54)	10 (46)	71 (53)
Patients with ≥ 1 dose interruption/missed dose, n (%)	14 (27)	76 (43)	64 (51)	27 (54)	181 (45)
Patients who subsequently restarted, n (%)	11 (79)	72 (95)	57 (89)	25 (93)	165 (91)
Reason for first dose interruption/missed dose					
Adverse Event, n (%)	2 (4)	19 (11)	34 (27)	10 (20)	65 (16)
Other (drug availability, etc) , n (%)	12 (23)	57 (32)	30 (24)	17 (34)	116 (29)

## Phase 3 *D-LIVR* Topline Data Summary

#### David Apelian, MD, PhD

- Former Executive Medical Officer, Eiger
- Member of the Board of Directors, Eiger





- Both lonafarnib arms achieve the composite primary endpoint vs PBO with statistical significance
- Secondary endpoints of virologic response and ALT normalization, separately, are also statistically significant
- Statistically significant improvement in histology in the combination arm
  - Further strengthens assessment of the potential utility/benefit of treatment
  - Could be predictive of improved long term clinical outcomes



## Clinician / Investigator Perspective

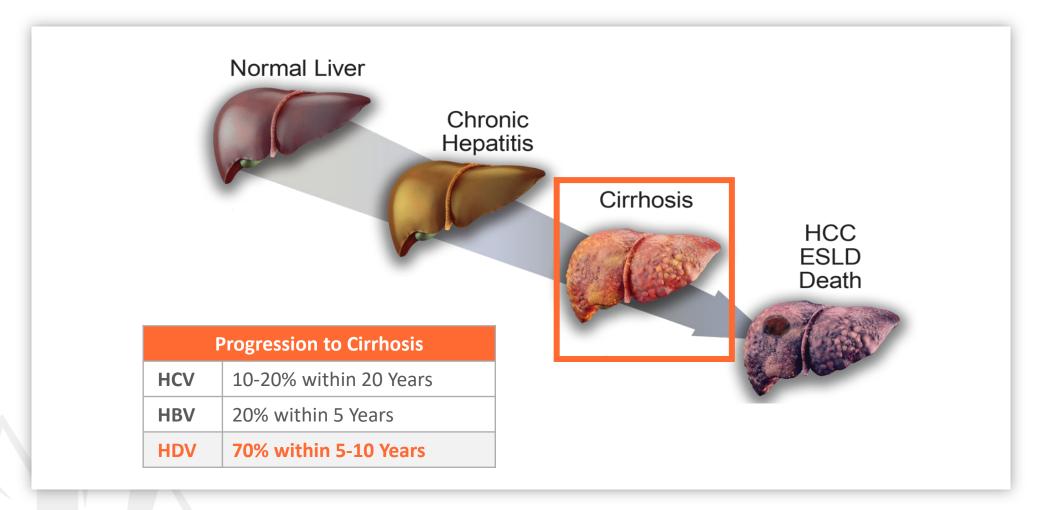
#### **Ohad Etzion, MD**

- Director of Gastroenterology and Liver Diseases, Soroka University Medical Center
- Phase 3 *D-LIVR* Study Co-Lead Investigator



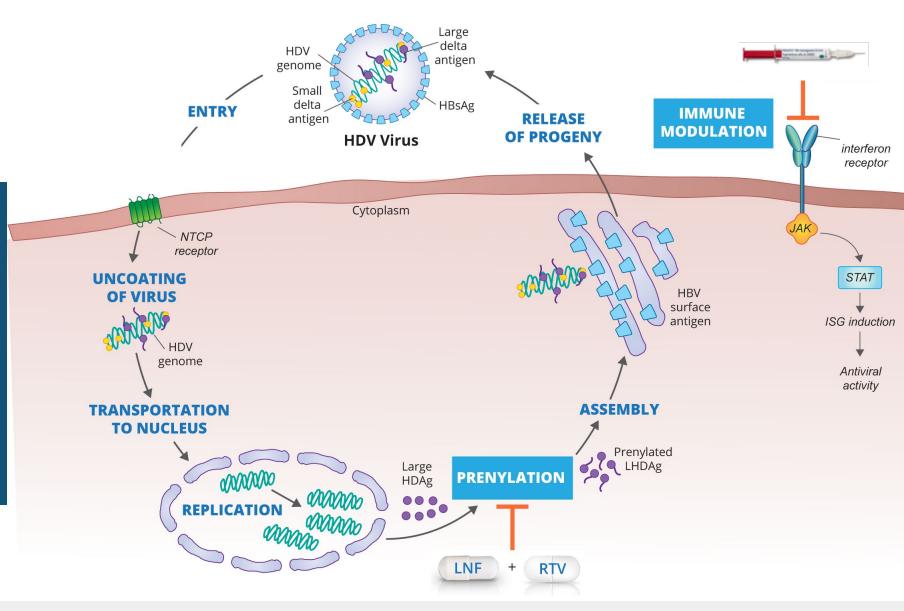
## HDV: Most Severe Form of Viral Hepatitis

#### **50% OF PATIENTS CIRRHOTIC AT DIAGNOSIS**





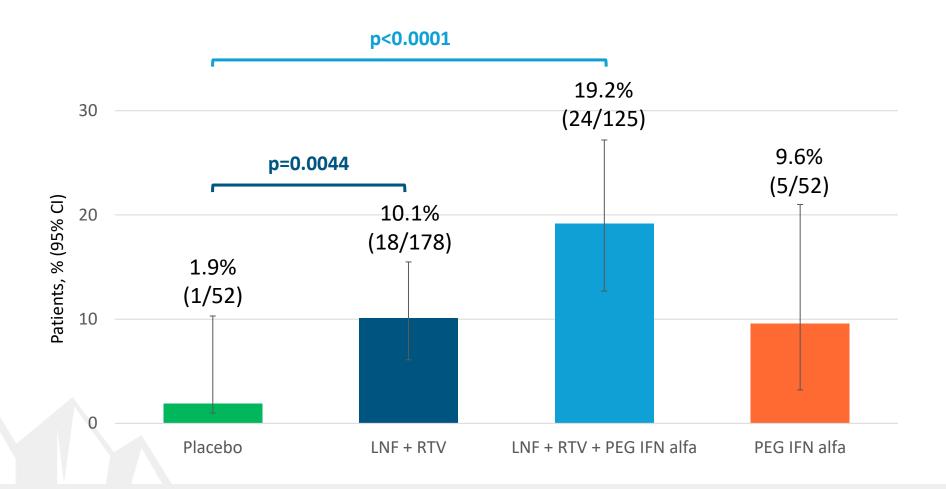
# Different Mechanisms of Action to Treat HDV





## Primary Endpoint Achieved with Significance in BOTH Arms

#### % PATIENTS ACHIEVING COMPOSITE ≥2 LOG DECLINE IN HDV RNA + ALT NORMALIZATION AT WEEK 48





## Histology Response Rates at Week 48

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	% (n)				
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Histologic Endpoint*	33% (35) (p=0.61)	53% (35) (p=0.0139)	38% (10) (p=0.46)	27% (8)	

- Histologic assessment is highly important
- Non-invasive tests used for disease staging in other forms of viral hepatitis show suboptimal performance in chronic HDV



<sup>\*</sup> Histologic Endpoint = ≥ 2 point improvement in Ishak histology activity index and no worsening of fibrosis at Week 48

# **Closing Remarks**

David Cory – President and CEO



# Q&A







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