

POWERING THE IMMUNE SYSTEM
TO TRANSFORM LIVES

AASLD Late Breaking Data Update Call

November 13, 2023

Introductions



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AASLD Insights

Marianne De Backer, M.Sc., Ph.D., MBA, Vir's Chief Executive Officer



Vir's Approach to Achieving a Chronic Suppressive Therapy for Chronic Hepatitis Delta

Phil Pang, M.D., Ph.D., Vir's Chief Medical Officer

Hepatitis Delta: Background



- Liver virus that occurs only in those with HBV
 - Requires the HBV surface antigen to be infectious
- Rapidly progressive liver disease: of those with cirrhosis, ~50% develop HCC, liver decompensation, require transplantation or die within 5 years¹
 - In Europe, more people are transplanted for CHD than CHB
- ▼ Prevalence: ~12 Million worldwide, with ~300,000 in US and EU4+UK

Chronic Hepatitis Delta: Limited Options





The NEW ENGLAND
JOURNAL of MEDICINE

A Glimmer of Hope for an Orphan Disease

Marc G. Ghany, M.D., M.H.Sc.

- 45% Achieved Composite Response*
- Bulevirtide requires daily reconstitution and injection
- Not approved in the United States

"On the basis of surrogate end points used for other chronic viral infections, sustained suppression of HDV viremia should represent the best marker of treatment efficacy. If undetectable HDV viremia is required for clinical benefit, then only 12% of patients in the 2-mg group and 20% of patients in the 10-mg group had a clinical benefit [after 48 weeks of therapy]."

Hepatitis Delta: Robust Biological Rationale for Vir **Candidates**



VIR-3434

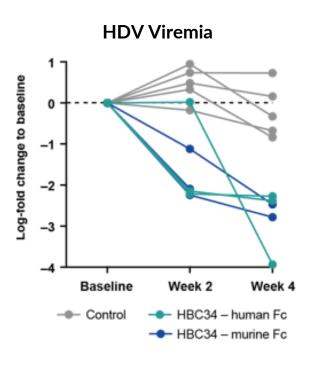
VIR-2218

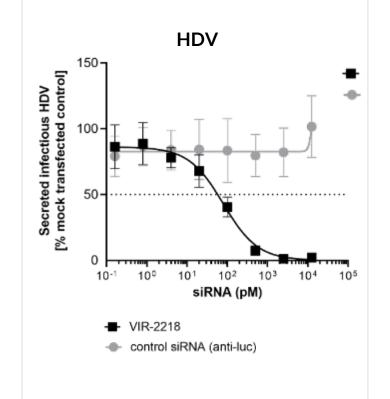
VIR-3434 + VIR-2218

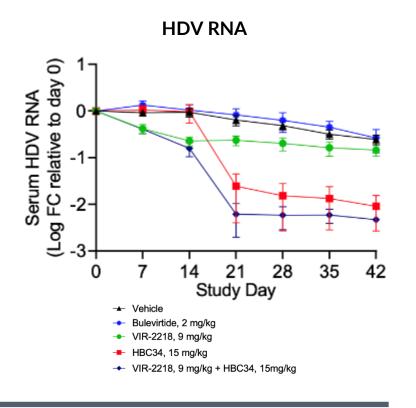
Lowering HDV RNA in vivo*

Lowering infectious HDV in vitro*

Combination efficacy in vivo**







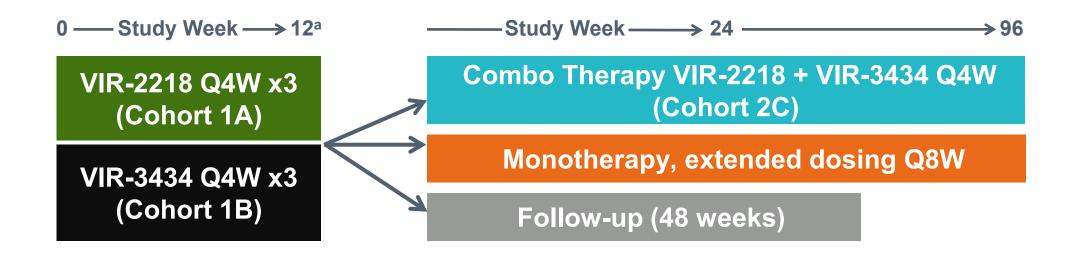


TO TRANSFORM LIVES

The monoclonal antibody VIR-3434 and siRNA VIR-2218 for the treatment of chronic Hepatitis D Virus: preliminary results from the Phase 2 SOLSTICE trial

SOLSTICE Trial Design – First Cohorts





- Participants achieving combined endpoint at Week 12 transition to extended dosing (Q8W) monotherapy.
- Participants not achieving ALT normalization and virologic response at Week 12 can transition to combination therapy or follow up.

^aVIR-2218 200 mg SC and VIR-3434 300 mg SC

Week 12 Preliminary Results



	VIR-2218 Q4W (Cohort 1A) N = 5	VIR-3434 Q4W (Cohort 1B) N = 6	VIR-2218+3434 Q4W (Cohort 2C) N = 6 ^a
HDV Virologic Response ^b , n (%)	1 (20)	3 (50)	5 (100)
Reduction from Baseline in HDV RNA (log ₁₀ IU/mL), Median (IQR)	-1.39 (-1.51, -1.04)	-1.98 (-2.82, -0.94)	-4.29 (-5.47, -3.93)
HDV RNA < LLOQ ^c , n (%)	1 (20)	2 (33)	5 (100)
HDV RNA < LOD ^d , n (%)	1 (20)	1 (17)	4 (80)
Reduction from Baseline in HBsAg (log ₁₀ IU/mL), Median (IQR)	-1.35 (-1.52, -1.27)	-0.18 (-0.35, -0.09)	-3.88 (-4.03, -3.88)
ALT normalization ^e , n (%)	2 (40)	2 (33)	1 (20)
ALT (U/L), Mean (SD)	118.8 (145.5)	44.0 (19.5)	42.6 (7.5)
Combined Endpoint ^f , n (%)	0	1 (17%)	1 (20)

^a Cohort 2C has 6 total participants enrolled with 5 participants reaching at least 12 weeks.

^b Undetectable or ≥ 2 log₁₀ decrease in HDV RNA.

[°]LLOQ <63 IU/mL, supplied by Robogene® 2.0 Assay was used to assess HDV RNA, supplied and analyzed by Viroclinics-DDL™.

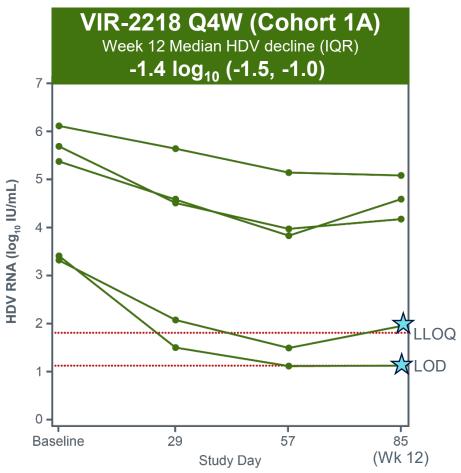
^d LOD <14 IU/mL, supplied by Robogene® 2.0 Assay was used to assess HDV RNA, supplied and analyzed by Viroclinics-DDL™.

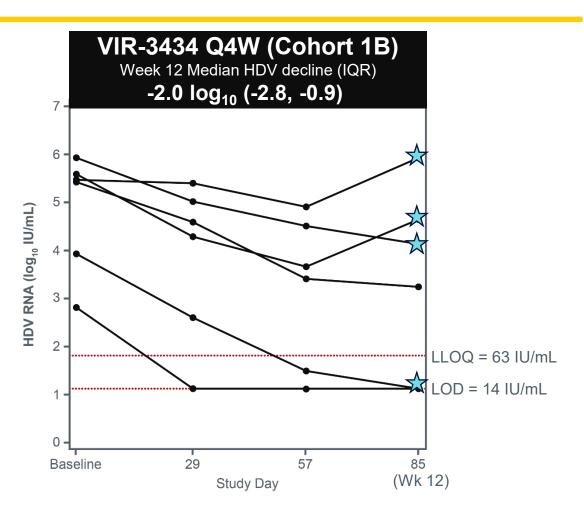
e ALT ≤ ULN: Female = 33 U/L; Male ULN = 40 U/L.

f Combined Endpoint = undetectable or ≥ 2 log_{10} decrease in HDV RNA + ALT normalization.

VIR-2218 or VIR-3434 Monotherapy Antiviral Activity



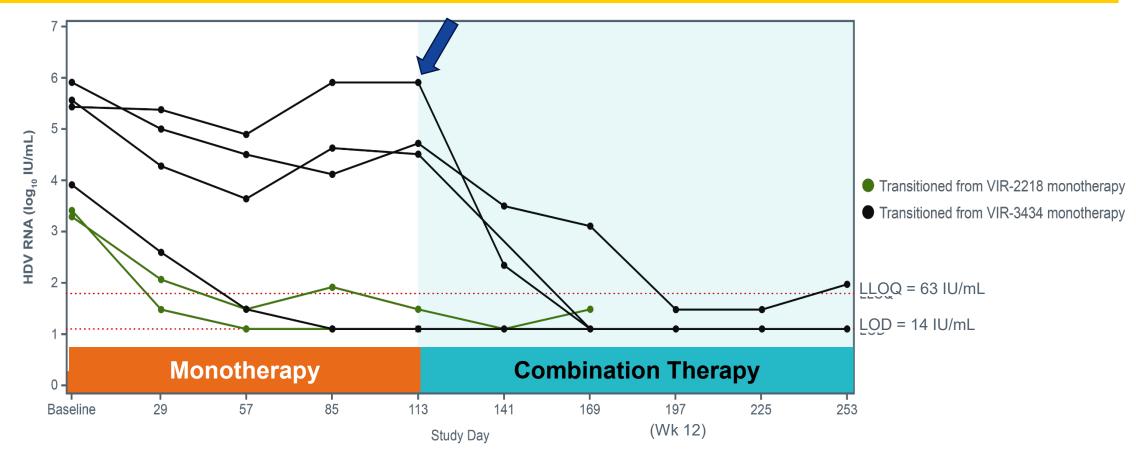




Transitioned to combination for not achieving either virologic response or ALT normalization. Baseline is the most recent non-missing measurement before the initial study intervention. LLOQ, lower limit of quantification; values below LLOQ but above LOD are shown as 31 IU/mL. LOD, limit of detection; values below LOD are reported as 13 IU/mL.

Antiviral Activity of Combination VIR-2218 and VIR-3434 Therapy





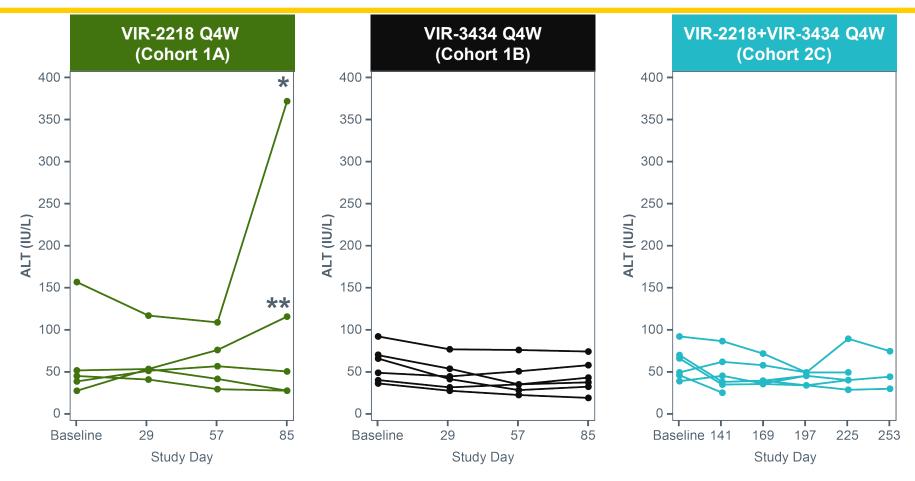
Baseline is the most recent non-missing measurement before the initial study intervention.

Participants not achieving ALT normalization and virologic response at Week 12 of monotherapy can transition to combination therapy or follow-up.

From the 5 participants who have reached at least Week 16, 4 participants achieved HDV RNA < LOD at Week 16. One of six participants has not reached Week 12 in the Combination therapy. LLOQ, lower limit of quantification; values below LLOQ but above LOD are shown as 31 IU/mL.

LOD, limit of detection; values below LOD are reported as 13 IU/mL.

ALT Profiles



Baseline is the most recent non-missing measurement before the initial study intervention. ULN Male = 40 U/L; Female = 33 U/L

^{*}Baseline HBsAg 21,547 IU/mL; Baseline HDV RNA 241,993 IU/mL; Baseline ALT 157 U/L; Peak ALT 5.8x baseline at Week 16. ALT 1.3x baseline 44 weeks after last dose of VIR-2218 **Baseline HBsAg 21,897 IU/mL; Baseline HDV RNA 487,809 IU/mL; Baseline ALT 28 U/L; Peak ALT 9.7x baseline at Week 24. ALT 4.5x baseline 28 weeks after last dose of VIR-2218

Conclusion & Key Takeaways

Early data demonstrate tolerability and potent antiviral activity after 12 weeks of VIR-2218 + VIR-3434 combination therapy

- At week 12, VIR-2218 and VIR-3434 monotherapy Q4W achieved median HDV RNA reductions of -1.4 log₁₀ and -2.0 log₁₀, respectively
- Combination therapy achieved the greatest (-4.3 log₁₀) and fastest decline in HDV RNA observed with any therapy to date
- No SAEs have occurred to date; majority of AEs were transient and grade 1 or 2
- ALT elevations occurred in 2 participants receiving siRNA monotherapy, both with baseline HBsAg > 10,000 IU/mL
- No clinically significant increases from baseline ALT observed through Week 20 with VIR-3434 monotherapy or VIR-2218+VIR-3434 combination therapy regardless of baseline HBsAg or HDV RNA

Key Takeaway

These early results from SOLSTICE are unprecedented, with **80% of participants being undetectable at Week 12** of combination therapy," said
Tarik Asselah, M.D., Ph.D., Professor of Hepatology at the Hôpital Beaujon,
APHP, Clichy, France, and at the University of Paris, and Head of Viral
Hepatitis at INSERM UMR1149, France. "If this result can be reproduced in a
much larger group of participants, I believe this potentially **once monthly therapy** could be transformative for patients."

Vir's Approach to Achieving a Potential Functional Cure for Chronic Hepatitis B

Phil Pang, M.D., Ph.D., Vir's Chief Medical Officer

Hepatitis B: In Pursuit of a Functional Cure



Unmet Need

~300M

people in the world live with chronic hepatitis B¹

~40%

of patients experience significant clinical consequences (HCC, cirrhosis, etc.)² <7%

functional cure* rates with available treatments³

Vir Solution

Multiple combination regimens to **STOP** the virus and **CLEAR** the infection

VIR-3434

a neutralizing mAb engineered for immune engagement **VIR-2218**

HBV-targeted siRNA as a potential "backbone"

MARKET LEADERSHIP OPPORTUNITY:

Our goal: 1st to achieve

≥30% functional cure rate

Evaluating in

3 unique patient segments

^{1 -} www.who.int/news-room/fact-sheets/detail/hepatitis-b

^{2 -} https://www.nejm.org/doi/full/10.1056/NEJM200205303462202

^{3 -} Marcellin, Gastroenterology 2016;150:134-144

Hepatitis B: Progress in Our Pursuit



VIR-2218-1001 TRIAL

24 Weeks following End of Treatment*

Sustained HBsAg loss

16% (N=5 of 31)

VIR-2218

+ (IFN α

200 mg x6 or x13 Q4W

180 μg ≤44 weeks

Cohorts 4&5 (N=31)

End of Treatment**

Log HBsAg decline

≥2.7

VIR-3434 +

VIR-2218

18 or 75 mg

200 mg

Cohort 1-3 (N=40)

MARCH TRIAL PART A

^{*}Safety and efficacy of VIR-2218 with or without pegylated interferon alfa in virally-suppressed participants with chronic hepatitis B virus infection: post-treatment follow-up (presentation #LBO-02). Yuen et al., EASL 2023

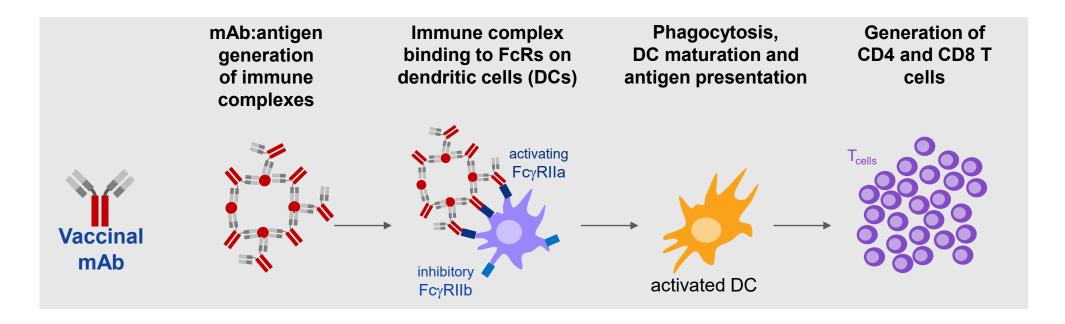
^{**}Preliminary data from the ongoing open-label Phase 2 MARCH trial evaluating the safety, tolerability and antiviral activity of VIR-2218 in combination with VIR-3434 in virally suppressed participants with chronic HBV infection who received continuous NRTI therapy for two months or more. All participants are virally suppressed on NRTIs.

Gane et al. AASLD 2022

VIR-3434 Questions:



- When VIR-3434 is given for 24 weeks as part of a cocktail with VIR-2218 +/- peginterferon alpha:
 - Does VIR-3434 enhance the end of treatment response rates?
 - Are there indications that VIR-3434 is immunostimulatory (vaccinal effect?)



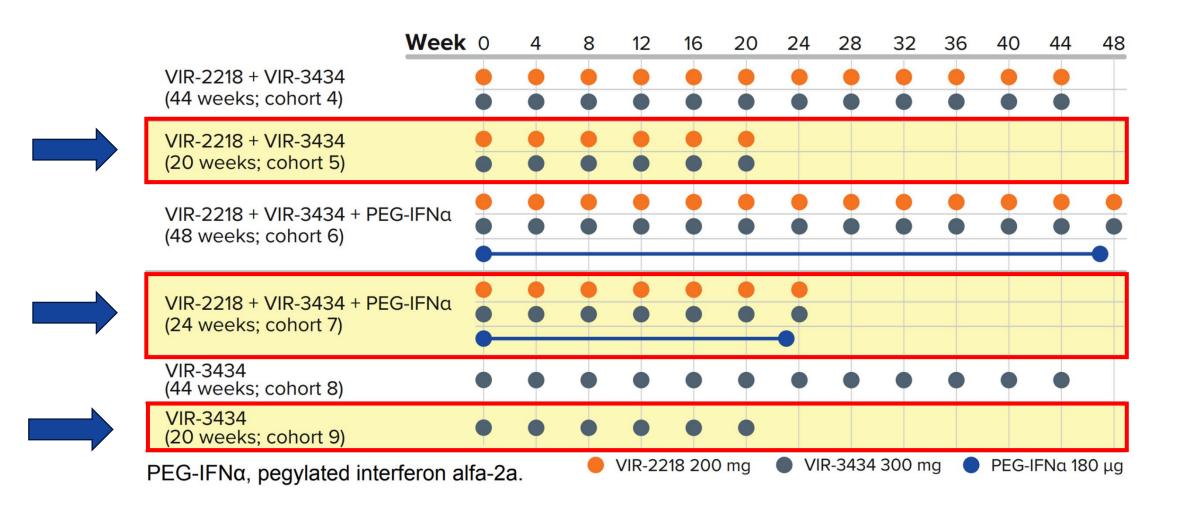


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VIR-2218 and VIR-3434 With or Without Pegylated Interferon Alfa-2A for the Treatment of Chronic HBV Infection: End of Treatment (EOT) Results After 24 Weeks of Therapy (March Study Part B)

MARCH Part B Study Design





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Participant Baseline Characteristics

Parameter	VIR-3434 20 Weeks n = 10	VIR-2218 + VIR-3434 20 Weeks n = 20	VIR-2218 + VIR-3434 + PEG-IFNα 24 Weeks n = 21
HBsAg (log ₁₀ IU/mL),	2.91	3.14	2.98
median (range)	(0.79, 3.96)	(1.29, 4.50)	(-0.35, 4.45)
Baseline HBsAg, n (%) < 100 IU/mL 100 to < 1,000 IU/mL 1,000 to < 10,000 IU/mL > 10,000 IU/mL	2 (20.0)	1 (5.0)	3 (14.3)
	5 (50.0)	6 (30.0)	8 (38.1)
	3 (30.0)	9 (45.0)	7 (33.3)
	0	4 (20.0)	3 (14.3)
HBeAg-negative, n (%)	7 (70.0)	15 (75.0)	12 (57.1)

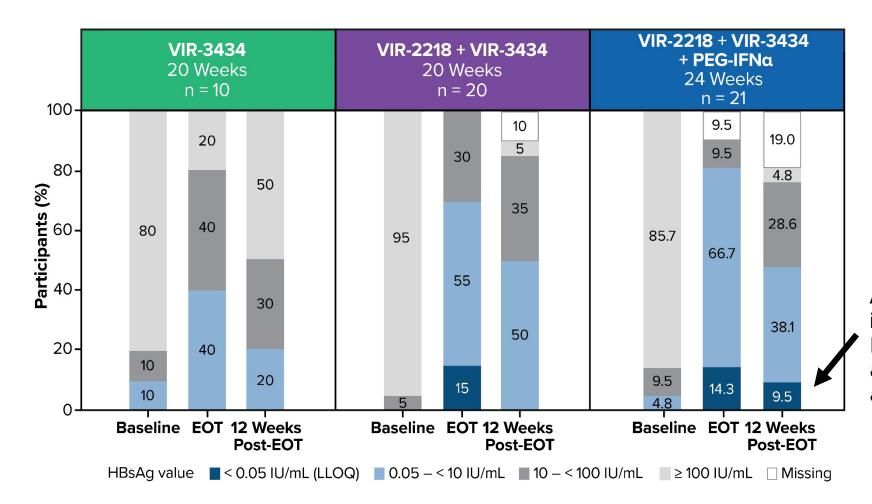
HBeAg, hepatitis B e antigen; HBsAg, hepatitis B surface antigen; PEG-IFNα, pegylated interferon alfa-2a.

VIR-3434 Enhances the Rate of HBsAg Loss at EOT

	12 Weeks		20–24 Weeks		— 24 Weeks —		
	Previously Reported		MARCH Part B			Previously Reported	
Participants with HBsAg Loss, n (%)	VIR-2218 + VIR-3434 12 weeks ^a (n = 19)	VIR-2218 + PEG-IFNα 12 weeks ^b (n = 5)	VIR-2218 + PEG-IFNα 24 weeks ^b (n = 18)	VIR-3434 20 weeks (n = 10)	VIR-2218 + VIR-3434 20 weeks (n = 20)	VIR-2218 + VIR-3434 + PEG-IFNα 24 weeks (n = 21)	VIR-2218 + PEG-IFNα 48 weeks ^b (n = 13)
At EOT	0 (0)	0 (0)	1 (5.6)	0 (0)	3 (15.0)	3 (14.3)	4 (30.8)
Baseline HBsAg < 3,000 IU/mL	0 / 17 (0)	0 / 2 (0)	1 / 9 (11.1)	0 / 8 (0)	3 / 13 (23.1)	3 / 16 (18.8)	2 / 6 (33.3)
Baseline HBsAg ≥ 3,000 IU/mL	0 / 2 (0)	0 / 3 (0)	0 / 9 (0)	0 / 2 (0)	0 / 7 (0)	0 / 5 (0)	2 / 7 (28.6)

- ~3x increase in EOT response rates with addition of VIR-3434
- An IFN-free regimen can achieve HbsAg loss at EOT

HBsAg Distribution: Baseline, EOT, and 12 Weeks Post-EOT



At 12 weeks post-EOT, 2 participants in the VIR-2218 + VIR-3434 + PEG-IFNα cohort maintained HBsAg loss; all other participants with HBsAg loss at EOT experienced a rebound

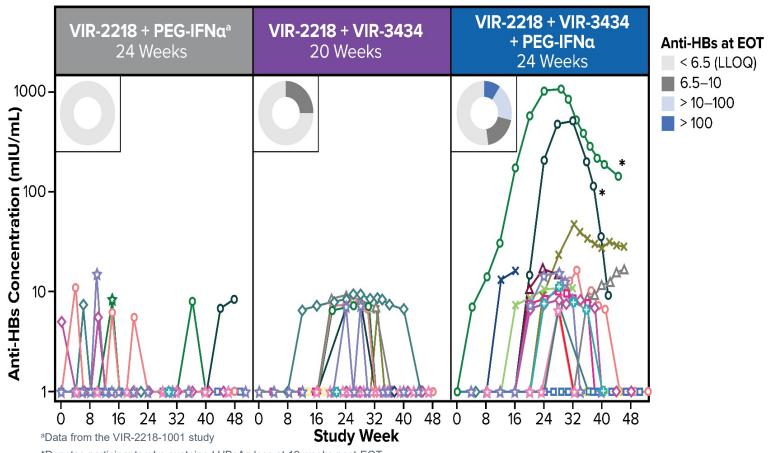
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EOT, end of treatment; HBsAg, hepatitis B surface antigen; LLOQ, lower limit of quantitation.

Data Suggests VIR-3434 Containing Regimen Stimulates **Anti-HBs Antibodies: Anti-HBs Concentrations by Cohort**

< 6.5 (LLOQ)

> 10–100



Anti-HBs antibody concentrations > 10 mIU/mL at EOT:

- VIR-2218 + VIR-3434 + PEG-IFNα: 11 of 21 (52.4%) participants at EOT
- VIR-2218 + PFG-IFNg treatment⁶· 2 of 18 (11.1%)

The highest anti-HBs concentrations were observed in the 2 participants in the VIR-2218 + VIR-3434 + PEG-IFNα cohort who maintained HBsAg loss through 12 weeks post-EOT.

Anti-hepatitis B surface antigen antibody (anti-HBs) concentrations in the VIR-2218-1001 and VIR-2218-1006 studies were determined using the Anti-HBs2 Assay IVD Kit on the Siemens ADVIA Centaur instrument and the Elecsys Anti-HBs II assay on the Roche Cobas instrument, respectively. The laboratory developed test using the Elecsys Anti-HBs II assay incorporated the addition of a VIR-3434 binding blocker (anti-idiotype Fab fragment) to the samples prior to analysis, preventing assay interference by VIR-3434.

Values <LLOQ were imputed as 1 mIU/mL

Anti-HBs, anti-hepatitis B surface antibody; LLOQ, lower limit of quantitation; PEG-IFNa, pegylated interferon alfa-2a

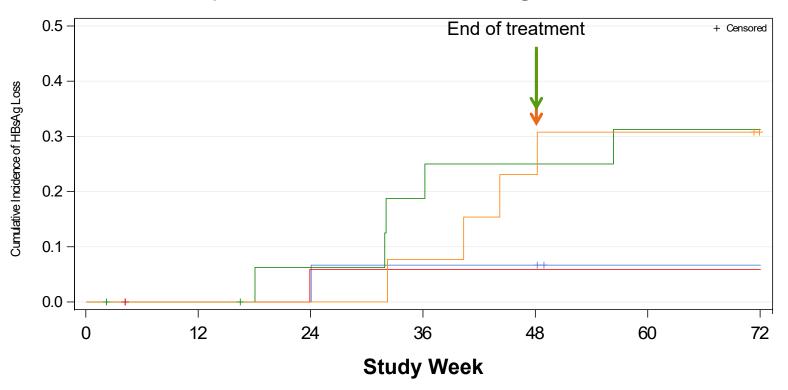
^{*}Denotes participants who sustained HBsAg loss at 12 weeks post-EOT

Summary

- VIR-3434 may play an important role in achieving a functional cure for chronic hepatitis B:
 - Increases EOT response rates (HbsAg Loss) from ~6% to ~15%
 - Evidence that VIR-3434 is capable of de novo immune activation (ie, a vaccinal effect)
- Data demonstrate the ability of VIR-2218 + VIR-3434, without PEG-IFN-α, to achieve HBsAg loss at EOT.
- ▼ Treatment with VIR-3434 monotherapy and the combination of VIR-3434 + VIR-2218 was generally well tolerated. No serious adverse events related to VIR-3434 or VIR-2218 were reported.
 - Of those treated with VIR-3434 + VIR-2218 + PEG-IFN-α, the majority of adverse events were consistent with the known effects of PEG-IFN-α.
- Data strongly support the potential of 48-week regimens of VIR-3434 + VIR-2218, with or without PEG-IFN-α, to result in meaningful rates of functional cure.

HBsAg Loss Predominantly Occurs Between Week 24 to 48 of the Treatment Period with VIR-2218 + PEG-IFNα-Containing Regimens

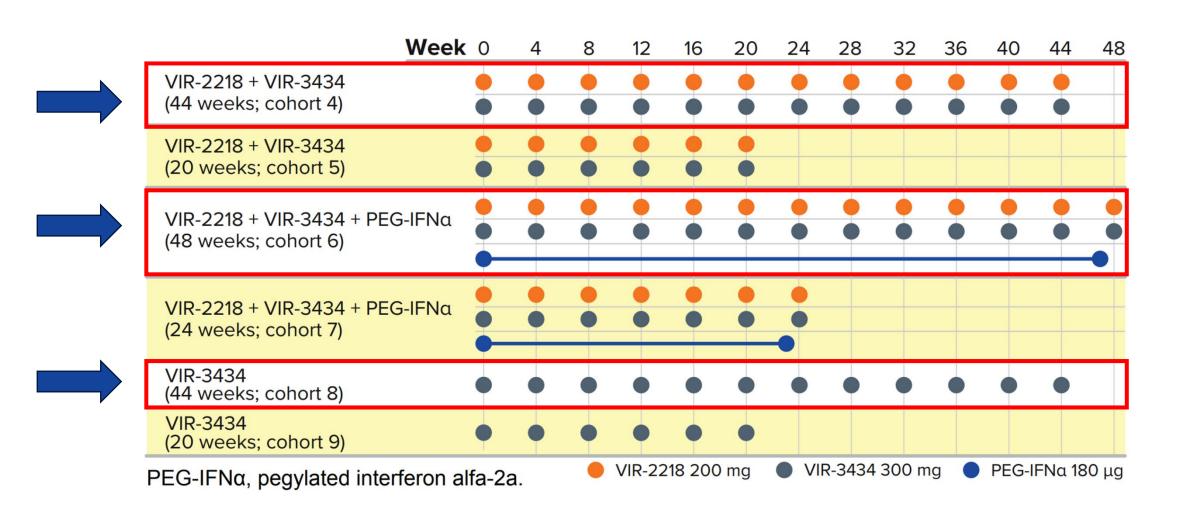
Kaplan Meier Estimate of HBsAg Loss



We hypothesize that immunostimulants may be more effective when given for >24 weeks

Cohort 1	Cohort 2	Cohort 3	Cohort 4	Cohort 5
(n = 15)	(n = 15)	(n = 18)	(n = 18)	(n = 13)
VIR-2218 x 6	VIR-2218 x 6 lead-in + PEG-IFNα x 12	VIR-2218 x 6 + PEG-IFNα x 24	VIR-2218 x 6 + PEG-IFNα x ≤48	

MARCH Part B Study Design – 48 Weeks





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Q&A

Multiple Anticipated CHD & CHB Data Catalysts



2023	Drug Candidates/Regimen	Catalyst	Timing
Hepatitis B	VIR-2218 (siRNA) + VIR-3434 (mAb) +/- PEG-IFN-α for 24 weeks	Phase 2: End of Treatment clinical data (MARCH Part B)	TODAY
Hepatitis Delta	VIR-3434 (mAb) monotherapy VIR-2218 (siRNA) monotherapy VIR-3434 (mAb) + VIR-2218 (siRNA) combo	Phase 2: Initial clinical data (SOLSTICE)	TODAY
2024	Drug Candidates/Regimen	Catalyst	Timing
Hepatitis B	VIR-2218 (siRNA) + VIR-3434 (mAb) +/- PEG-IFN-α for 24 weeks	Phase 2: 6-month post-treatment clinical data (MARCH Part B)	2Q
Hepatitis Delta	VIR-3434 (mAb) monotherapy VIR-2218 (siRNA) monotherapy VIR-3434 (mAb) + VIR-2218 (siRNA) combo	Phase 2: Additional clinical data (SOLSTICE)	2Q
Hepatitis B	VIR-2218 (siRNA) + VIR-3434 (mAb) +/- PEG-IFN- α for 48 weeks	Phase 2: End of Treatment clinical data (MARCH Part B)	4Q
Hepatitis B	VIR-2218 (siRNA) + VIR-3434 (mAb) +/- PEG-IFN- α in viremic patients for 48 weeks	Phase 2: End of Treatment clinical data (PREVAIL Platform – STRIVE/THRIVE sub-protocols)	4Q

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THANK YOU