Bluejay THERAPEUTICS

Advancing Liver Science to Change Lives

43rd Annual J.P. Morgan Healthcare Conference
January 13, 2025

Our Mission

We are dedicated to developing life-changing and potentially curative treatments for serious viral and liver diseases

How we get there

- **We are shifting the treatment paradigm**
  - By developing a potentially life-changing treatment for chronic hepatitis D (CHD)
  - By pursuing a functional cure for chronic hepatitis B (CHB) a reality
- **Our team combines decades of experience in virology, immunology and liver diseases with scientific integrity and a personal commitment to improve the lives of patients**

Bluejay overview

Fast-to-market strategy for Brelovitug in CHD

Highly potent mAb with compelling interim phase 2 data and regulatory path with EMA PRIME and Orphan designations in the most severe form of viral hepatitis

Combination therapy targeting high rate of functional cure in CHB

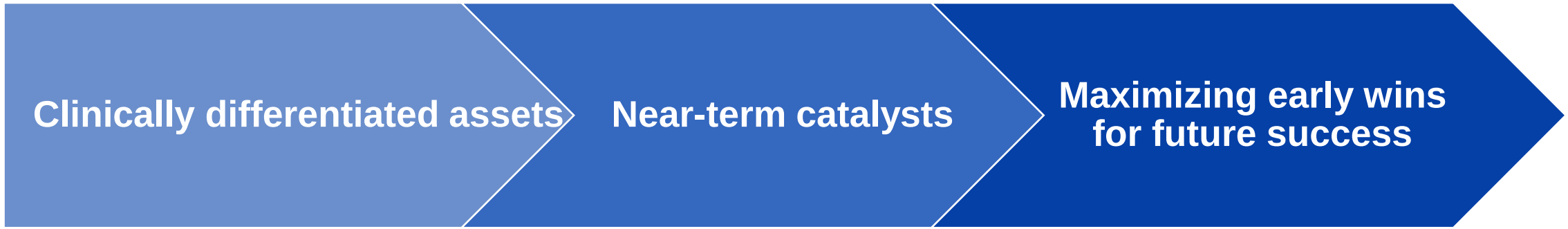
Promising combination strategy with Brelovitug + other proprietary assets aimed at achieving high functional cure rates in CHB

Expand and advance pipeline for other liver diseases

Leverage our Liver Targeting Platform (L-TAP) designed to optimize potency and safety for liver diseases with urgent unmet medical needs.

Build a fully-integrated global biopharma company

Our expert team has a solid track record to build a successful global biopharma



Proven leadership with deep expertise in virology, liver diseases

Keting Chu

M.D., Ph.D.

Founder, CEO & Chairman

ATP Apple Tree Partners · CHIRON · Leukemia & Lymphoma Society · LYFE Capital · mission therapeutics · FivePrime · NOVARTIS

Hassan Javanbakht

Ph.D.

Chief Scientific Officer

Roche · GILEAD · HARVARD MEDICAL SCHOOL

Nancy Shulman

M.D.

Chief Medical Officer

abbvie · Genentech A Member of the Roche Group · Stanford Medicine · Roche

Melissa Koomey

Chief Commercial Officer

GILEAD · Pfizer · NOVARTIS

Peter Garcia

Chief Financial Officer

ALX ONCOLOGY · MARINA BIOTECH · LINEAGE Cell Therapeutics · PDL BioPharma · AMGEN

Roland Gendron

SVP, Head of Business Development

GILEAD · CytomX THERAPEUTICS · Seagen

Involved in 11 NDA approvals and 8 product launches

Our Pipeline: Four clinical programs

PROGRAM	TARGET	THERAPEUTIC AREA	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3
Brelovitug monoclonal antibody	HBsAg	HDV	PRIME and Orphan designations (EMA)			Pivotal Trial Initiation 1H 2025
		HBV				
Cavrotolimod	TLR9 agonist	HBV				
BJT-628 Transcript inhibitor	PAPD5/7	HBV				
Undisclosed	Undisclosed	Liver disease				
Undisclosed	Undisclosed	Liver disease				

TLR9=Toll-like receptor 9 PAPD5/7 = Noncanonical poly(A) polymerases PAPD5 and PAPD7

Lead Asset Brelovitug

- Fully human IgG1 monoclonal antibody, targets HBV surface antigen (HBsAg) with pan-genotypic activity[1]
- Potent anti-viral, picomolar, rapid HDV RNA reduction
- Convenient, long-half life, infrequent SC injection (i.e., Q1-4 weeks)
- Phase 2 testing in both CHD and CHB
- **CHD: Demonstrated efficacy, durable response and safety in phase 2 clinical trial**

Brelovitug

Multiple Mechanisms of Action

1. Potently binds to surface antigen to neutralize HDV and HBV, preventing new infection

2. Rapidly Clears HDV and HBV virions and subviral particles

3. Immunomodulatory activity antigen-specific T cell activation and antiviral immunity

[1] Pan-genotypic, expected to cover >95% of all the sequences and variants.

Strategies and Goals for Development Programs

Chronic Hepatitis D

→ Chronic Therapy

Treatment Goals: Undetectable HDV RNA or ≥ 2 log Decline HDV-RNA + ALT Normalization*

Monotherapy

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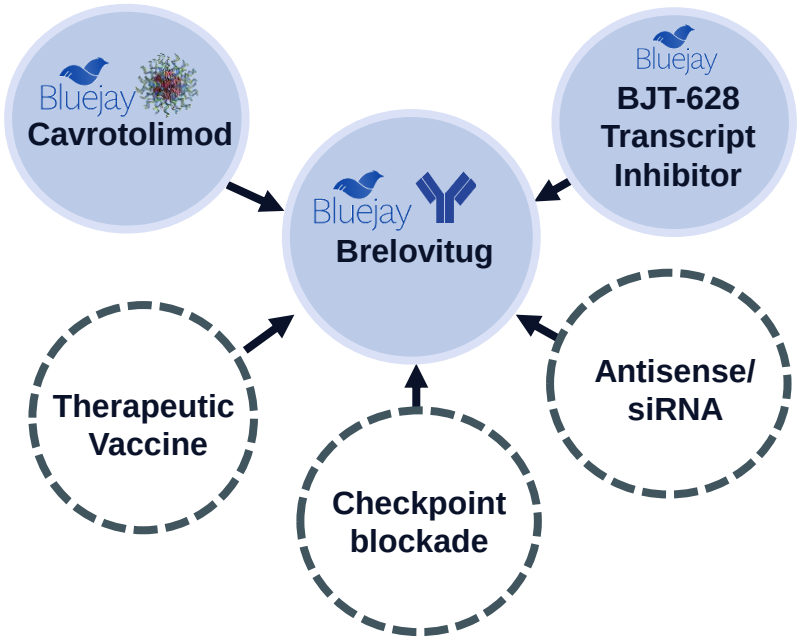
Brelovitug

Chronic Hepatitis B

→ Functional Cure

Treatment Goals: Sustained suppression (6 months or longer) of HBV DNA off-treatment with HBsAg loss*

Combination Therapy



Liver Targeted Platform

→ Improved Benefit-Risk

Treatment Goals: Optimize small molecule therapy with liver targeting to improve efficacy, safety

Monotherapy

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Undisclosed Small molecule

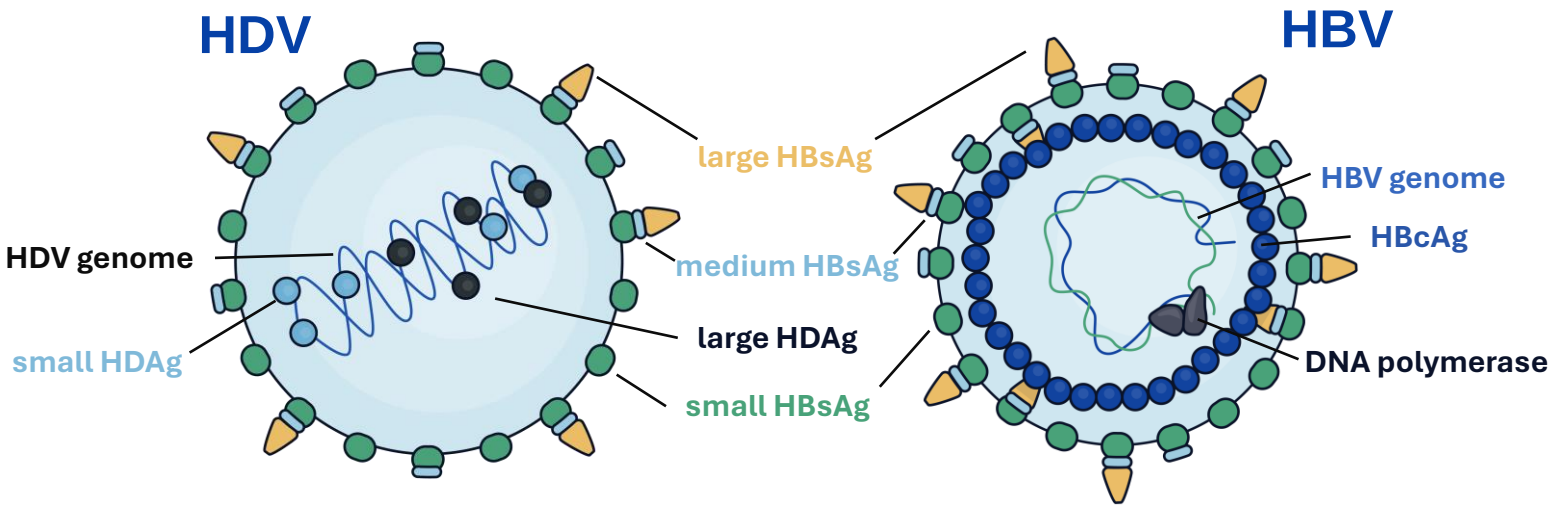
*Approvable endpoints; 2018 FDA Draft Guidance for Industry – HBV development; 2019 FDA Draft Guidance for Industry – HDV development

Brelovitug for Chronic Hepatitis Delta (CHD)

Developing a life-changing therapy

High unmet need and large market opportunity in CHD the most severe form of viral hepatitis[1]

- People with chronic hepatitis B can become infected with HDV - CHD
- A **severe disease**: Accelerated progression to cirrhosis, liver failure, liver cancer and liver-related death in CHD is 2-3x that of CHB alone[3]



HDV requires HBsAg as its envelope protein to replicate and spread

>7 MM globally with active hepatitis delta virus[2]

~100,000 in the US and EU

>50% progress to liver-related death ≤10 years of diagnosis[3]

No approved treatment in the US and most countries around the world

[1.] Romeo 2009 Gastroenterology. [2.] Stockdale, A., et al 2020. Journal of Hepatology. 73: 523-532. [3.] Negro, F. and Lok, A. 2023. Hepatitis D: A review. JAMA. 2023;220(24):2376-2387.

Fast-to-market strategy for Brelovitug in CHD: clear regulatory path

No FDA-approved therapies for CHD

- Brelovitug's **EMA PRIME and Orphan designations** anticipated to accelerate development
- BTD pending in the FDA
- Current standard of care in the US is off-label use of peg-IFN-α
  - Low functional cure rate and high discontinuation rates due to side effects
- Gilead's bulevirtide available only in EU, UK, Switzerland, Australia; received Complete Response Letter from US FDA

Clear path to FDA approval

FDA Draft Guidance for Industry (2019) outlines composite primary surrogate endpoint

Virologic Response	+	ALT Normalization
Serum HDV RNA target not detected (TND) or ≥2 log^{10} IU/mL decrease from baseline		ALT decreases from baseline to ≤ upper limit of normal (ULN)

FDA. 2019. Chronic Hepatitis D Virus Infection: Developing Drugs for Treatment. DRAFT Guidance for Industry.

Global Burden of CHD: 7 Million People with Active Viremia at Increased Risk of Liver Cancer, Liver Failure and Death

Addressable CHD patient population

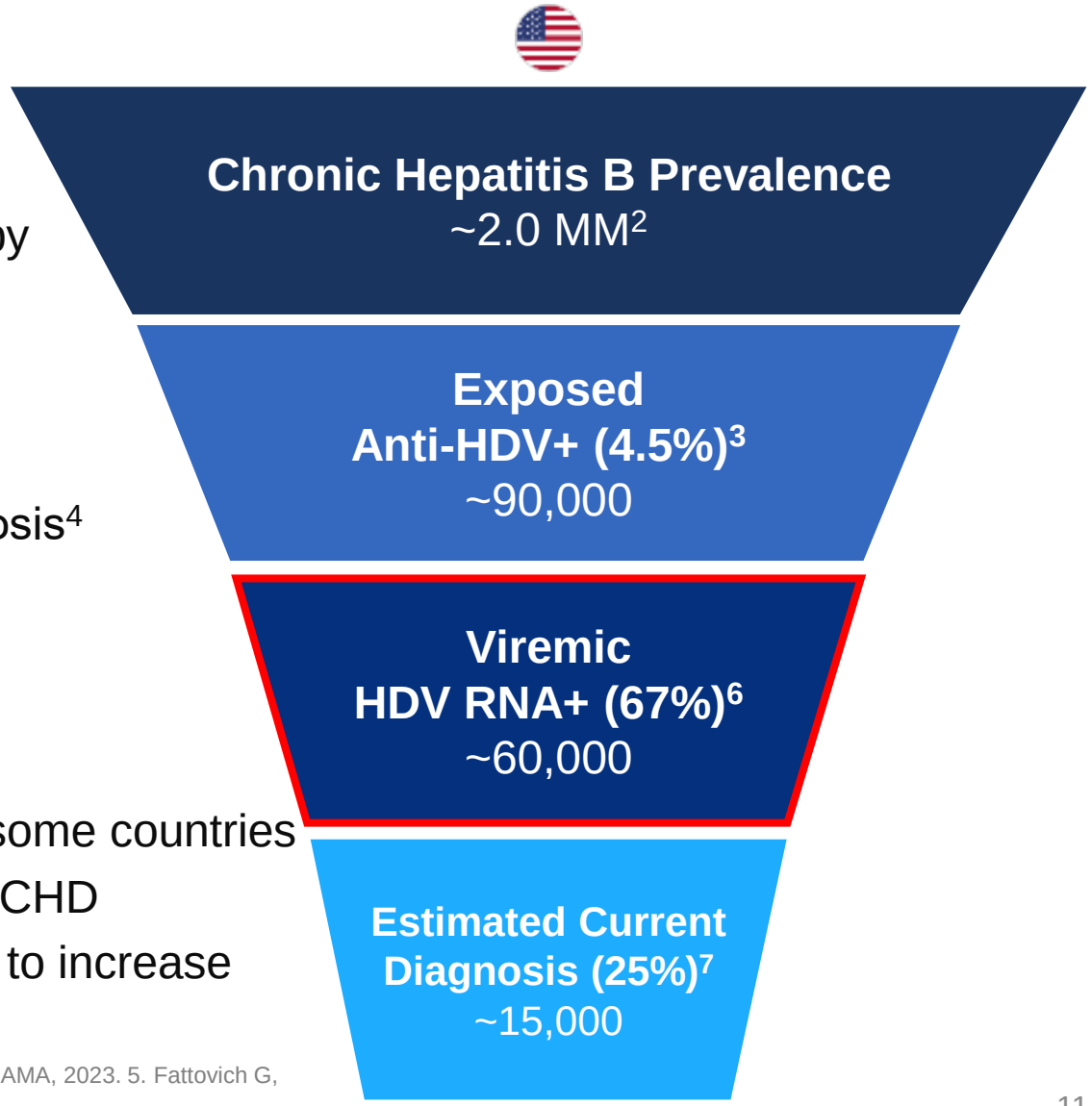
- >12 MM people worldwide have experienced HDV infection; ~4.5% of people with CHB[1]
- >7 MM are viremic and are candidates for antiviral therapy
- Prevalence varies by country

Serious, costly clinical outcomes

- **>50%** progress to liver-related death ≤10 years of diagnosis[4]
- **3x** risk of liver cancer vs. HBV alone[5]

Urgent unmet need for effective treatment

- No FDA-approved therapy; only bulevirtide available in some countries
- With no treatment available, little incentive to screen for CHD
- Underdiagnosed: New treatment introductions expected to increase awareness, screening and diagnosis of CHD



1. Stockdale, *Journal of Hepatology*,2020. 2. Wong R, *Liver International*, 2024. 3. Gish R, *Hepatology*, 2024. 4. Negro F, JAMA, 2023. 5. Fattovich G, *Gut* 2000. 6. The Polaris Observatory Investigators, Journal of Hepatology 2024. 7. Company estimate

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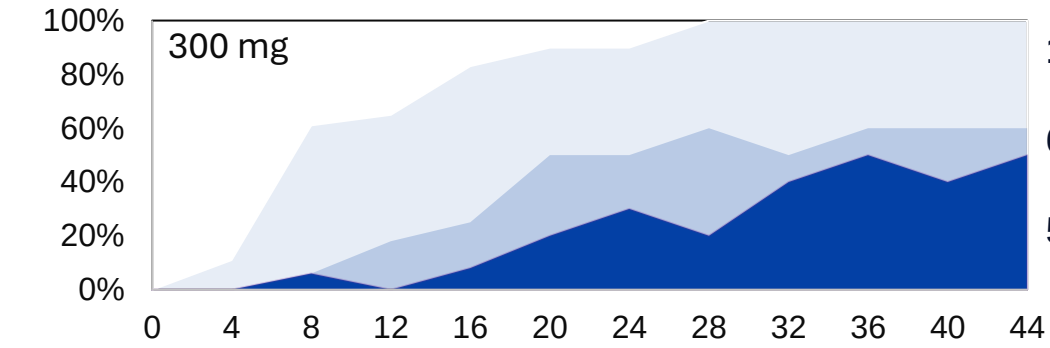
Oral presentation at
The Liver Meeting ® of AASLD
November 18th, 2024

BJT-778 (Brelovitug), 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

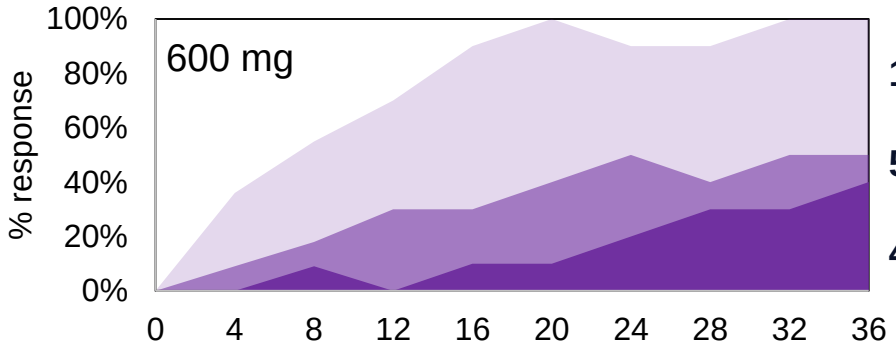
100% Virologic Response Across All Dose Arms



100% Virologic Response (10/10)

60% LLOQ (<10 IU/mL) (6/10)

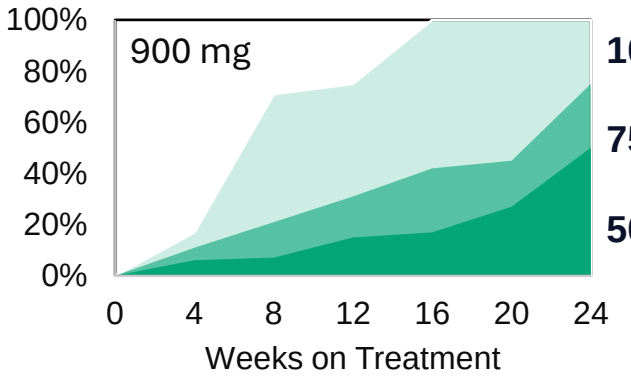
50% TND (5/10) (no amplification)



100% Virologic Response (10/10)

50% LLOQ (<10 IU/mL) (5/10)

40% TND (4/10) (no amplification)



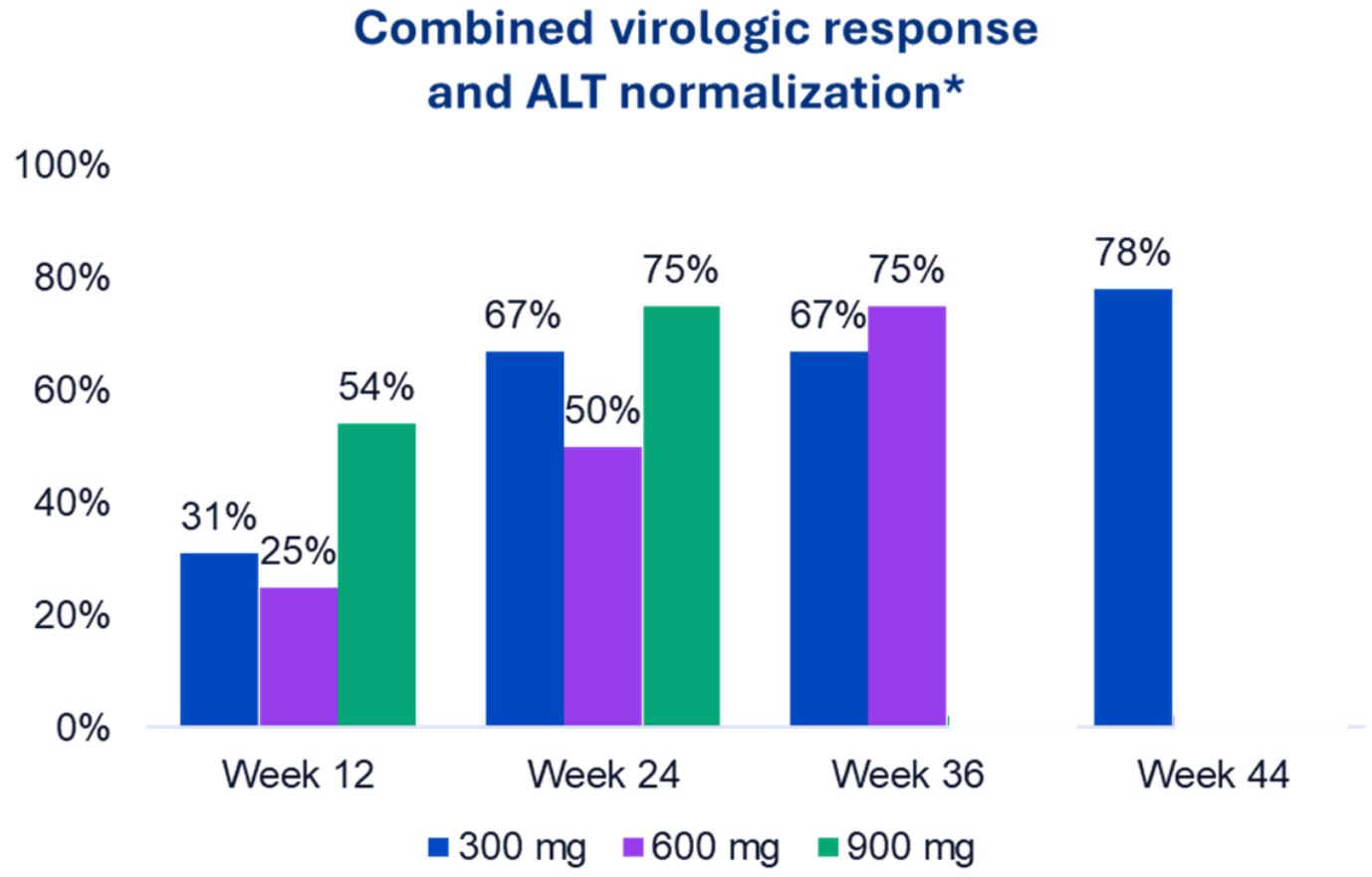
100% Virologic Response (8/8)

75% LLOQ (<10 IU/mL) (6/8)

50% TND (4/8) (no amplification)

Increasing rates of HDV RNA <10 IU/mL including Target-not-Detected (TND)

Up to 78% combined response:
the surrogate primary endpoint in FDA Guidance on Developing Drugs for Treatment of CHD



*In subjects with abnormal ALT at baseline

All Regimens Explored Were 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 Brelovitug, 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%)

*1 subject from the Ukraine site in the 600 mg arm discontinued the study after Week 8 due to an urgent move out of the country. She had >3 log reduction from baseline at Week 8 and a normal ALT.
**At least possibly related to treatment

Response Rates of Brelovitug both Weekly or Monthly and Bulevirtide daily

24-week endpoints	Bulevirtide 2 mg daily	Brelovitug 300 mg weekly	Brelovitug 900 mg every 4 weeks
Virologic response (≥2 log ↓ in HDV RNA or target not detected (TND)	27/49 (**55%**)	9/10 (**90%**)	8/8 (**100%**)
HDV RNA TND	3/49 (**6%**)	3/10 (**30%**)	4/8 (**50%**)
ALT normalization	26/49 (**53%**)	6/9 (**67%**)	6/8 (**75%**)
Combined surrogate endpoint (FDA)	18/49 (**37%**)	6/9 (**67%**)	6/8 (**75%**)
TND + ALT normalization	(**≤6%***)	2/9 (**22%**)	2/8 (**25%**)

*Based on TND alone

Source: Buleveritide: Wedemeyer, et al. EASL 2021

Note: These data are not based on head-to-head or comparator trials. Differences exist between trial designs and subject characteristics, and caution should be exercised when comparing data across trials.

Response Rates of Brelovitug Monotherapy and VIR Combination

24-week endpoints	Tobevibart plus Elebsiran every 4 weeks	Brelovitug 300 mg weekly	Brelovitug 900 mg every 4 weeks
Virologic response (≥2 log ↓ in HDV RNA or target not detected (TND)	32/32 (**100%**)	9/10 (**90%**)	8/8 (**100%**)
HDV RNA TND	13/32 (**41%**)	3/10 (**30%**)	4/8 (**50%**)
ALT normalization	15/32 (**47%**)	6/9 (**67%**)	6/8 (**75%**)
Combined endpoint (FDA)	15/32 (**47%**)	6/9 (**67%**)	6/8 (**75%**)
TND + ALT normalization	6/32 (**19%**)	2/9 (**22%**)	2/8 (**25%**)

Source: Tobevibart plus Elebsiran: Asselah, et al. AASLD 2024

Note: These data are not based on head-to-head or comparator trials. Differences exist between trial designs and subject characteristics, and caution should be exercised when comparing data across trials.

Brelovitug development in chronic HDV: Summary

Addressing the most severe form of viral hepatitis

~7MM affected globally, ~100K in EU/US. Risk of disease progression 2-3x that of CHB alone - 50% of patients die from liver-related causes within 10 years of diagnosis

Brelovitug is a pioneering monotherapy

Fully human mAb with picomolar potency, favirable safety profile and long half-life enables durable HDV RNA reduction and potentially infrequent dosing (weekly or monthly)

Positive results across dose arms in Phase 2 clinical study

Up to **78%** combined endpoint of virological response + ALT normalization – **FDA approvable primary surrogate endpoints**, strong safety profile and lack of DDIs make Brelovitug attractive for potential chronic therapy, even in more advanced disease

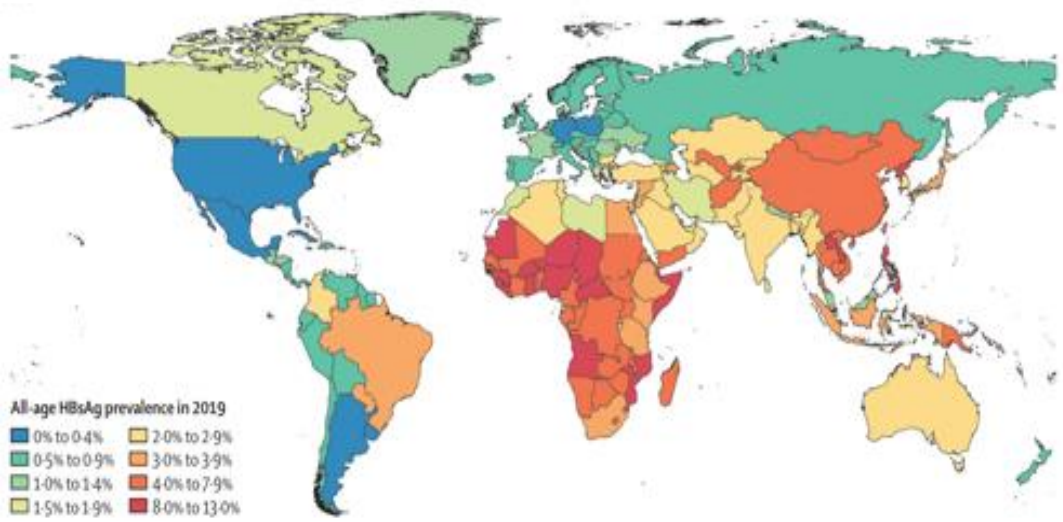
Accelerated development strategy

With PRIME and Orphan designation in the EU. Strong performance in FDA-approvable endpoints **Initiation of pivotal trial in 1H2025**

Functional Cure for Chronic Hepatitis B

Combination Therapy Program

Chronic hepatitis B (CHB) is the most common liver disease globally



- HBV-infected individuals face an elevated risk of liver cirrhosis, liver failure and hepatocellular carcinoma (HCC)[1]
- CHB accounts for 30% of all deaths from cirrhosis and 40% of all deaths related to hepatocellular carcinoma globally[2]

~250 MM people with CHB globally[3]

~2 MM people with CHB in US[4]

~820 K global deaths annually[5]

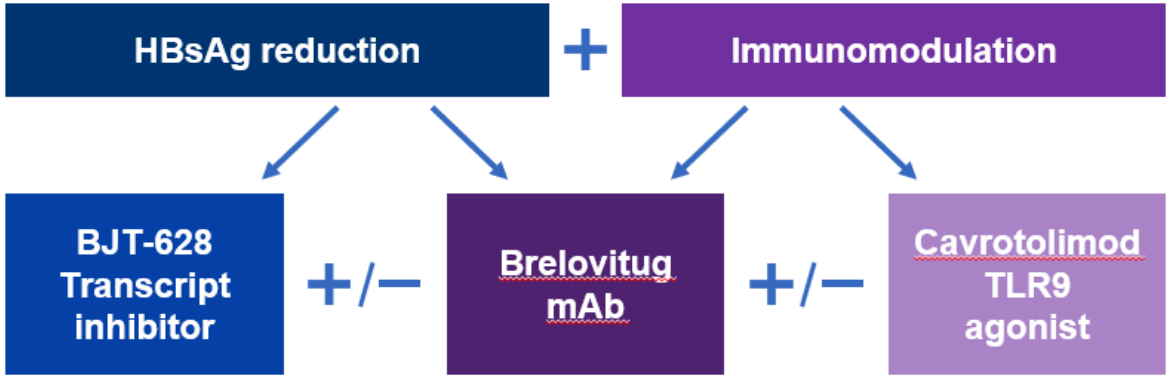
1. Polaris Observatory Collaborators (2023). Global prevalence, cascade of care and prophylaxis coverage of hepatitis B in 2022: a modeling study. Lancet Gastroenterol Hepatology. 2022; 7: 796–829 [2] Lin, C and Kao, J. (2023.) Develoment of hepatocellular carcinoma in treated and untreated patients with chronic hepatitis B virus infection. Clinical and Molecular Hepatology, 2023; 29(3):605-622. 3. https://www.who.int/news-room/fact-sheets/detail/hepatitis-b 4. Wong R et al. Hepatology 2021;74:607-26. 5. https://www.hepb.org/what-is-hepatitis-b/what-is-hepb/facts-and-figures

Goal of the industry in new drug development in CHB: finite treatment to achieve functional cure

Current: Lifelong Treatment with NUCs

- Long-term suppression of HBV
- Daily oral treatment with nucleos(t)ide analogs (NUCs) delivers effective HBV DNA undetectability but rarely (<5%) achieves functional cure
- NUC therapy is lifelong, with compliance issues and required monitoring for adverse events such as bone loss and kidney disease

Bluejay Approach: Finite Combination Therapy for Functional Cure



A combination strategy built on Brelovitug and two other Bluejay assets has the potential to increase functional cure rates

Functional cure defined as: Loss of HBsAg with or without seroconversion to anti-HBsAg while off treatment for at least 24 weeks

Bluejay L-TAP

Highly potent and safer therapies for liver diseases

LTAP Goals

Optimizing the benefit / risk profile of small molecules through liver targeting

Improve safety and tolerability

- Reduce the amount of drug that reaches other non-target organs; minimizing side effects

Improved efficacy

- Increase effective dose of drugs that are intended to act in the liver

Improved pharmacokinetics

- Improve DMPK of drugs that have poor solubility, low bioavailability, or rapid metabolism

Targeting specific liver cell types

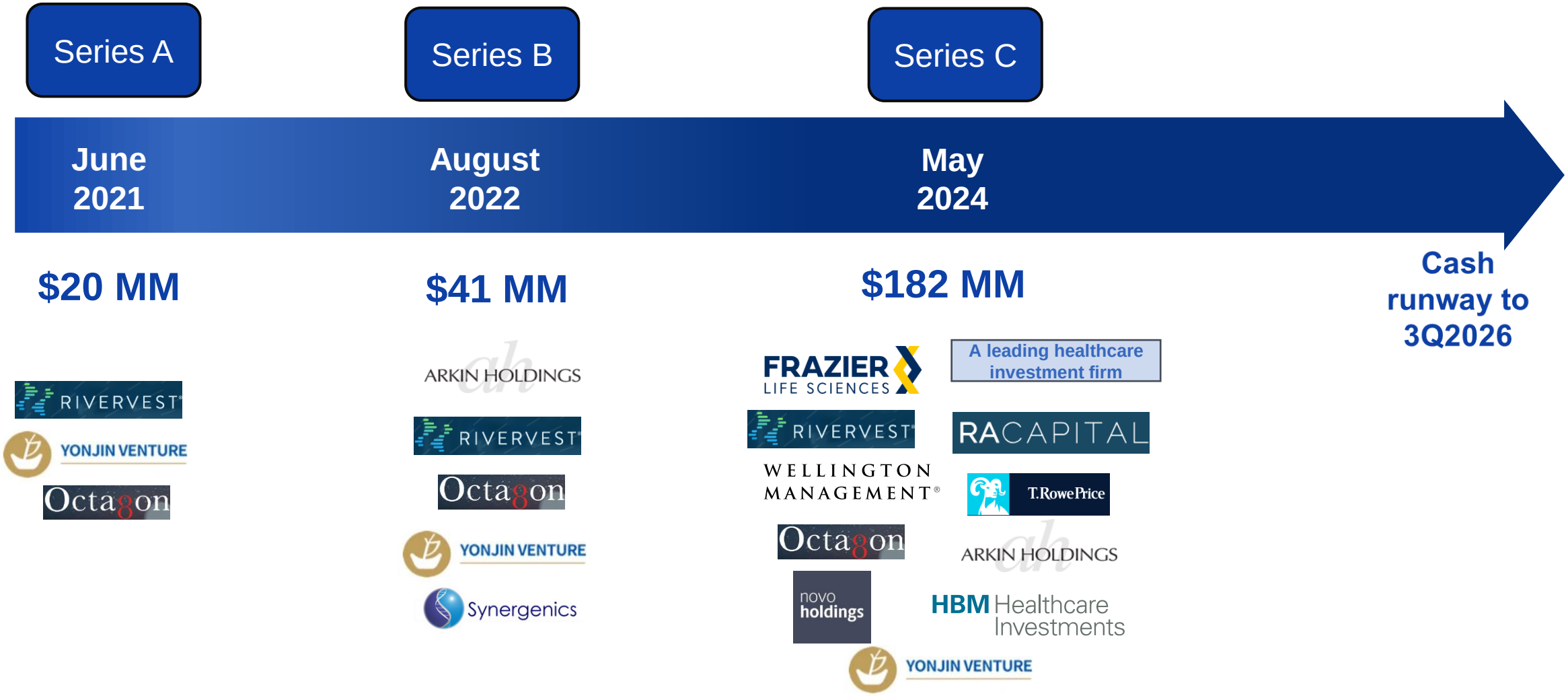
- Enables precise targeting of specific liver cell types associated with that disease

Agarwal, K., et. al. Rapid reductions of HDV RNA and ALT with the monoclonal antibody BJT-778: Results from a Phase 2 study. Poster presented at: European Association for the Study of the Liver Congress; June 2024; Milan, Italy.

Financing

Strong financial investors

Financing history: $243MM raised since inception in June 2021



Advancing Liver Science to Change Lives: Summary

Clinically differentiated assets

- Highly potent anti-HBsAg mAb for CHD chronic therapy and finite treatment for CHB functional cure
- Compelling potency, safety profile ease of administration and developability
- Potential monotherapy in CHD and combinations in CHB with Brelovitug + CAVRO +/- BJT-628
- Potential for additional assets through L-TAP and partnering

Important potential milestones

- CHD Chronic Therapy:
  - Pivotal trial initiation **1H 2025**
- CHB Functional Cure:
  - Brelovitug+CAVRO+BJT-628
- Other Liver Disease Program:
  - Clinical POC

Maximizing early wins for future success

- Strategic commitment to invest in challenging viral and liver disease
- Proven leadership team with extensive experience in virology, immunology and liver diseases
- Strong balance sheet; funds raised are sufficient to fund near-term priorities

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