Innovative Therapeutics Targeting Serious Viral Diseases

APRIL 2024

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Assembly Bio is advancing the treatment paradigm in serious viral diseases

FOUR INVESTIGATIONAL THERAPIES PLANNED TO BE IN CLINIC IN 2024

- Focused on areas with high unmet medical need and significant market opportunity
- Interim data from two studies anticipated by end 2024
- Interim Phase 1b data for ABI-5366 expected in 1H2025

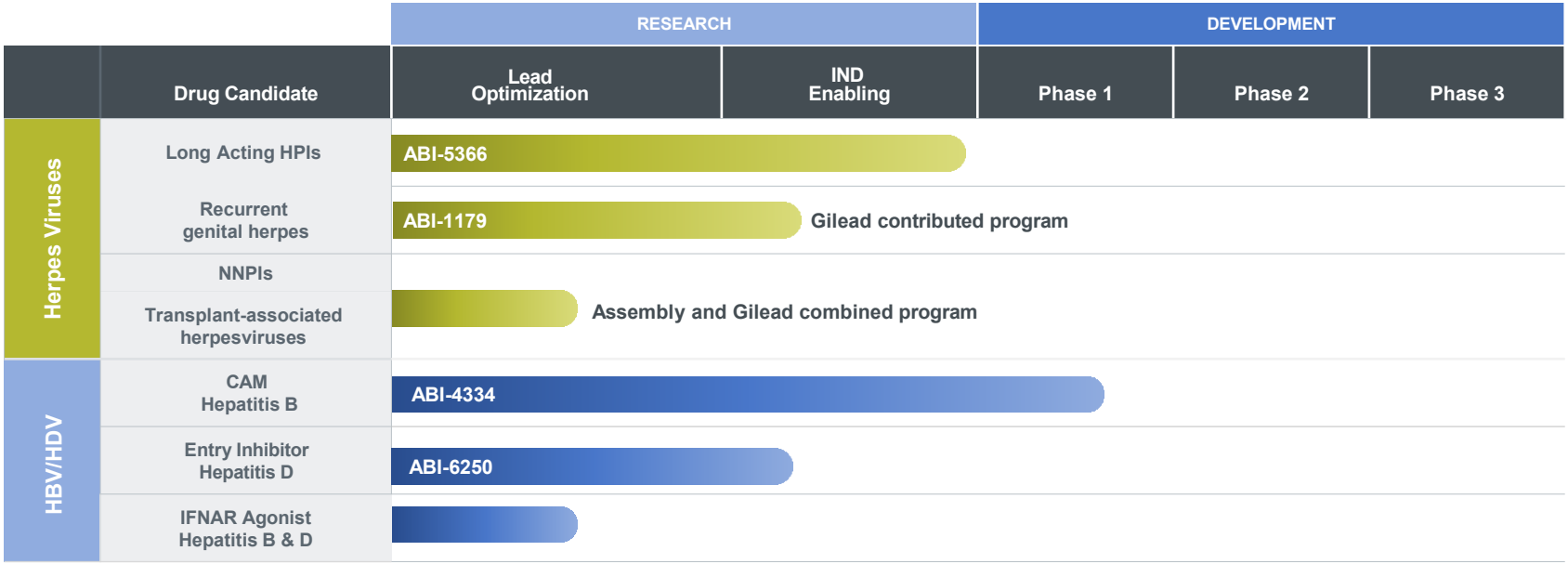
EXPERIENCED LEADERSHIP AND VIROLOGY-FOCUSED R&D ORGANIZATION

- R&D team with over 15 approved drugs in viral disease and hepatitis

INDUSTRY LEADING PARTNER IN GILEAD

- Collaboration brings together the teams' expertise in virology and provides assets, funding, and an established partner for late stage development and commercialization

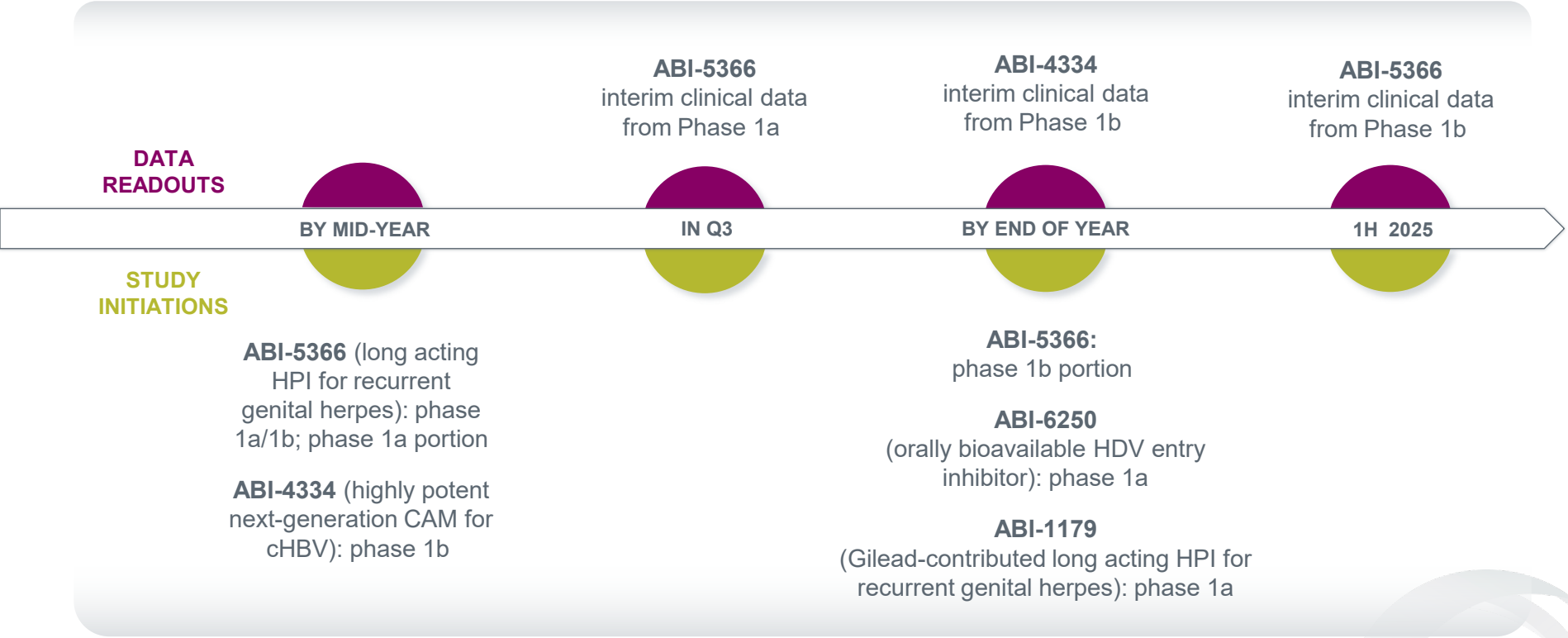
Differentiated pipeline of candidates targeting herpesviruses and HBV/HDV



HPI: Helicase-primase inhibitor; NNPI: Non-nucleoside polymerase inhibitor; CAM: Capsid assembly modulator; IFNAR: Interferon-α receptor

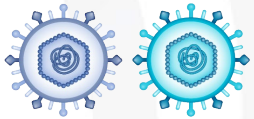
2024 key objectives and anticipated progress

Expect four development candidates in the clinic by end of 2024



Development Programs

ABI-5366 and ABI-1179



Long-acting HSV helicase-primase inhibitors (HPIs) for recurrent genital herpes

ABI-5366 anticipated to enter the clinic by mid-2024

ABI-1179 anticipated to enter the clinic by end of year

Recurrent genital herpes is a significant medical need with limited treatment options that ABI-5366 can address

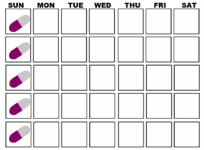
MEDICAL NEED IS SIGNIFICANT AND CURRENT TREATMENT IS ONLY PARTIALLY EFFECTIVE

4M+ in US & EU with initial symptomatic genital herpes infection have 3+ recurrences/year[1-6]

Suppressive SOC is 1-gram daily valacyclovir, viral polymerase inhibitor approved 1995[7]

Only 1 in 3 with frequent outbreaks[a] remain recurrence free for a year on SOC[7]

ABI-5366 HAS POTENTIAL TO DELIVER SIGNIFICANT VALUE TO INDIVIDUALS WITH HSV



Targeting a suppressive therapy for recurrent genital herpes with **superior efficacy** to SOC in reducing outbreaks and **once weekly oral dosing**

$1-3 billion market opportunity for recurrent disease

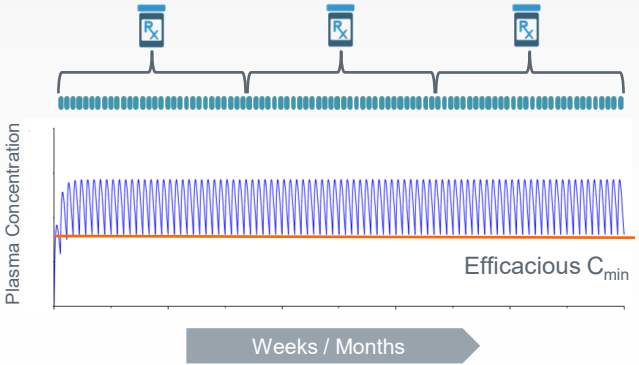
Additional opportunities:

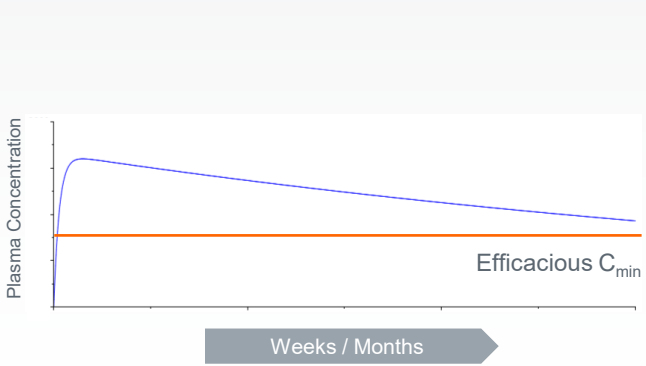
- Episodic treatment
- Orofacial
- Prevention of transmission
- Long-acting injectable

a. In a study of patients with 6 or more annual recurrences; did not include discontinued, withdrawn, or lost in follow-up

Source: 1 1. C James et al. 2020; 2. McQuillan et al. NCHS Data Brief. 2018; 3. Alareeki et al. The Lancet Regional Health. 2022; 4.Fanfair et al. Sex Transm Dis. 2013 ; 5. Benedetti et al. 1994 ; 6. Benedetti et al. 1999 . 7. Valtrex (Valacyclovir) US package insert

As a long-acting therapy for recurrent genital herpes, ABI-5366 has the potential to improve uptake, adherence, and efficacy



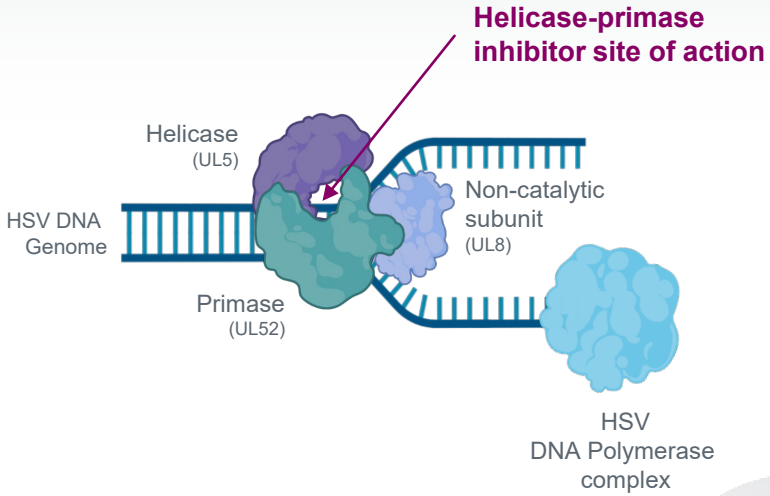


- 72% of HSV patients with recurrent outbreaks prefer suppressive therapy to episodic[1]
- Long-acting therapy ⟶ consistent drug levels, better compliance[2]
  - Medication non-adherence for chronic illness is ~50% with stigma, AE anxiety, high dosing frequency being common barriers[3]
  - Superior efficacy shown for long-acting therapy in HIV in individuals with a history of adherence challenges[4]

HSV helicase-primase is a clinically validated mechanism that has shown improved efficacy to SOC in investigational studies

- Helicase-primase is an essential HSV enzyme complex with no host equivalent
- Clinically-validated mechanism
  - Pritelivir showed greater reductions in HSV shedding, fewer days with lesions & pain vs. approved SOC in investigational studies[1]
- Active against SOC resistant HSV
- Assembly Bio's candidates active against both
  - HSV-2 (leading cause of genital herpes)
  - HSV-1 (leading cause oral-facial herpes)

HSV HELICASE-PRIMASE COMPLEX



1. Wald, et al. *JAMA* 2016

QD, once daily; SOC, standard of care

ABI-5366's preclinical potency, PK, and safety profile support long-acting administration; expected to enter the clinic by mid-year

Highly potent in antiviral assays

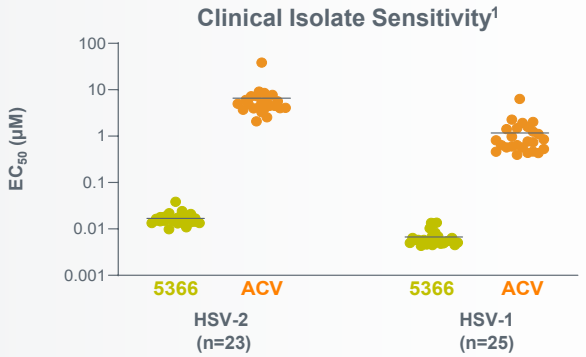
Critical properties for long-acting

- Projected human half-life of >7 days[1]
- Potential for long-acting oral & injectable formulations

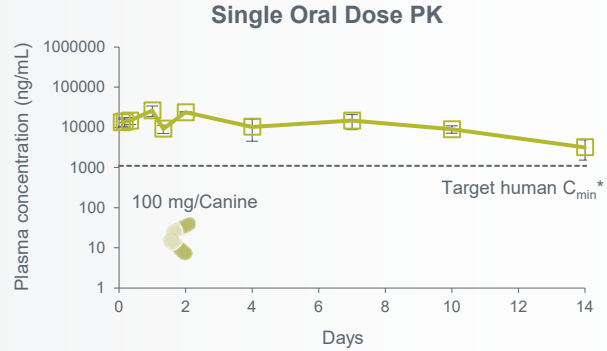
Favorable preclinical safety profile

Expected to enter a Phase 1a/1b study by mid-year; CTA filed

- Interim Phase 1a data expected in Q3
- Interim Phase 1b data expected in 1H2025



ABI-5366 400-fold more potent than acyclovir against both HSV-1 and HSV-2 isolates



1. Contreras et al. 2023. IHW

*Target human plasma concentration derived from pritelivir, adjusted for ABI-5366 protein shift and potency

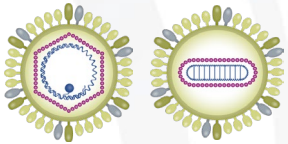
ACV, acyclovir.

ABI-1179 expands long-acting helicase-primase inhibitor portfolio and strengthens potential to change treatment paradigm for recurrent genital herpes

Structurally distinct HSV helicase-primase inhibitor licensed from Gilead

In GLP tox; preclinical potency, PK and safety profile to date support a once weekly tablet

Clinical studies targeted to initiate by end of 2024



ABI-6250: Oral hepatitis D virus entry inhibitor

Expected to enter the clinic by end of 2024

Chronic HDV is a serious life-threatening disease and major unmet need with limited treatment options

12 – 72 million

PEOPLE ESTIMATED TO BE CHRONICALLY INFECTED WITH HDV GLOBALLY[1]

70% progress to cirrhosis within 10 years[2]

Very limited treatment options

BULEVIRTIDE, LARGE MOLECULE ENTRY INHIBITOR, ONLY APPROVED DRUG (EU ONLY)

Safe and highly effective in long-term clinical trials, but requires daily injection and cold storage

ABI-6250, an opportunity to simplify treatment

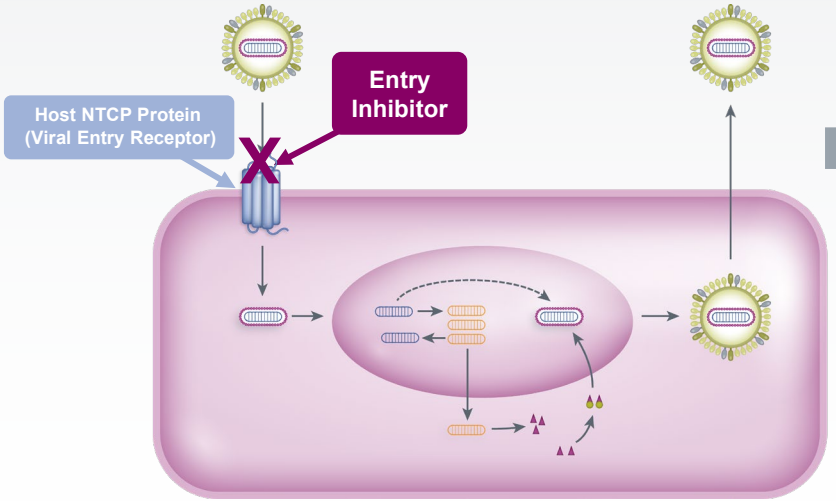
SMALL MOLECULE TARGETING SAME MECHANISM AS BULEVIRTIDE

An oral treatment is expected to further enhance treatment uptake and diagnosis rates

1. Negro & Lok 2023; 2. WHO 2023.

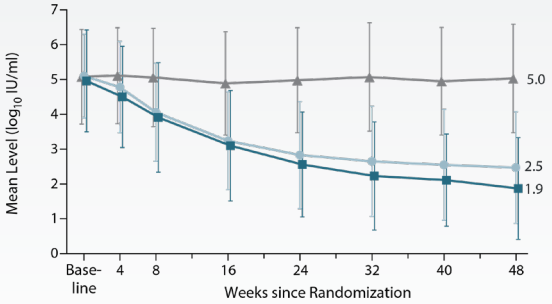
Inhibition of HDV entry lowers viral load and normalizes ALT

Blocking entry prevents infection of liver cells

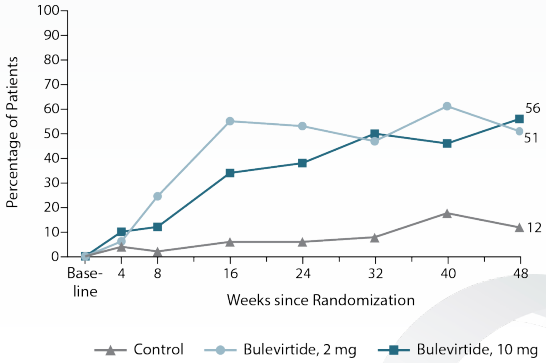


Entry inhibition: a clinically validated target[1]

Viral Load Reductions



ALT Normalization

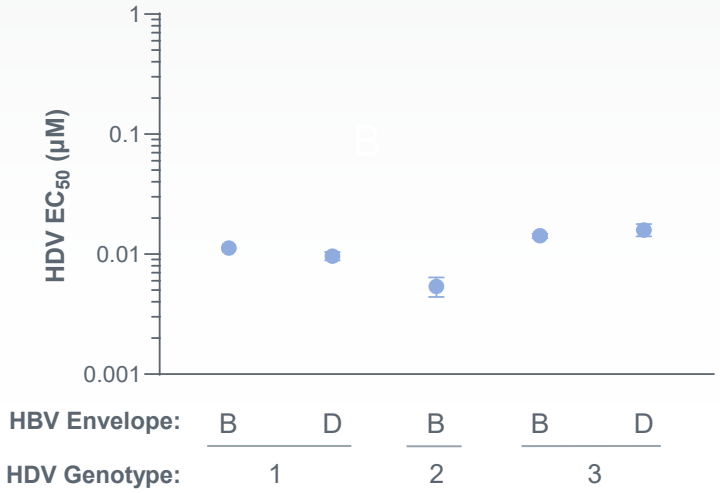


1. Wedemeyer NEJM 2023

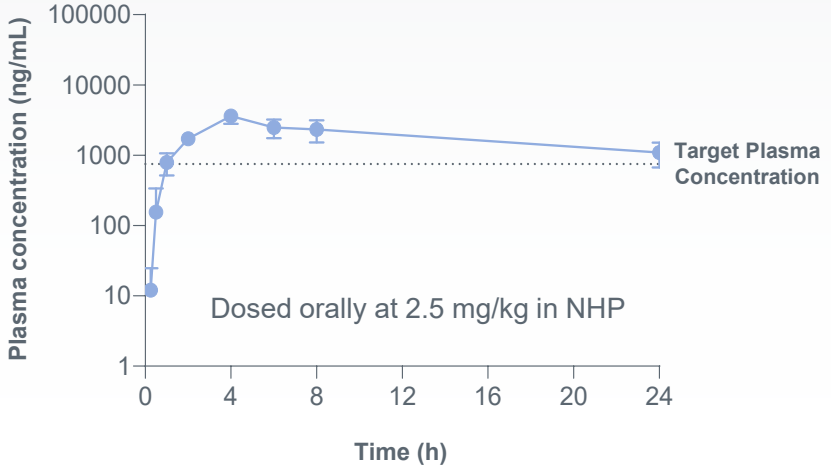
ALT, alanine transaminase; NTCP, Sodium taurocholate cotransporting polypeptide

ABI-6250: potent pan-genotypic preclinical activity against HDV with projected QD PK

ABI-6250: <16 nM against all tested HDV genotypes & HBV envelope proteins[1]



ABI-6250: exceeded target therapeutic plasma concentrations when given orally to preclinical species[1]

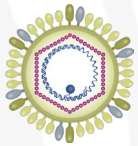


Initiation of ABI-6250 clinical studies anticipated by end of 2024

1. Unchwaniwala et al. EASL ILC 2023. Poster # SAT-195

QD, once daily

ABI-4334: Next-generation CAM for hepatitis B



Phase 1b expected to initiate by mid-2024

HBV is a major unmet medical need

HBV PREVALENCE:
296M[1]

DIAGNOSED:
30M[1]

TREATED:
5M[1]

Up to 820,000 people
DIE EACH YEAR[1] FROM HBV-RELATED CAUSES

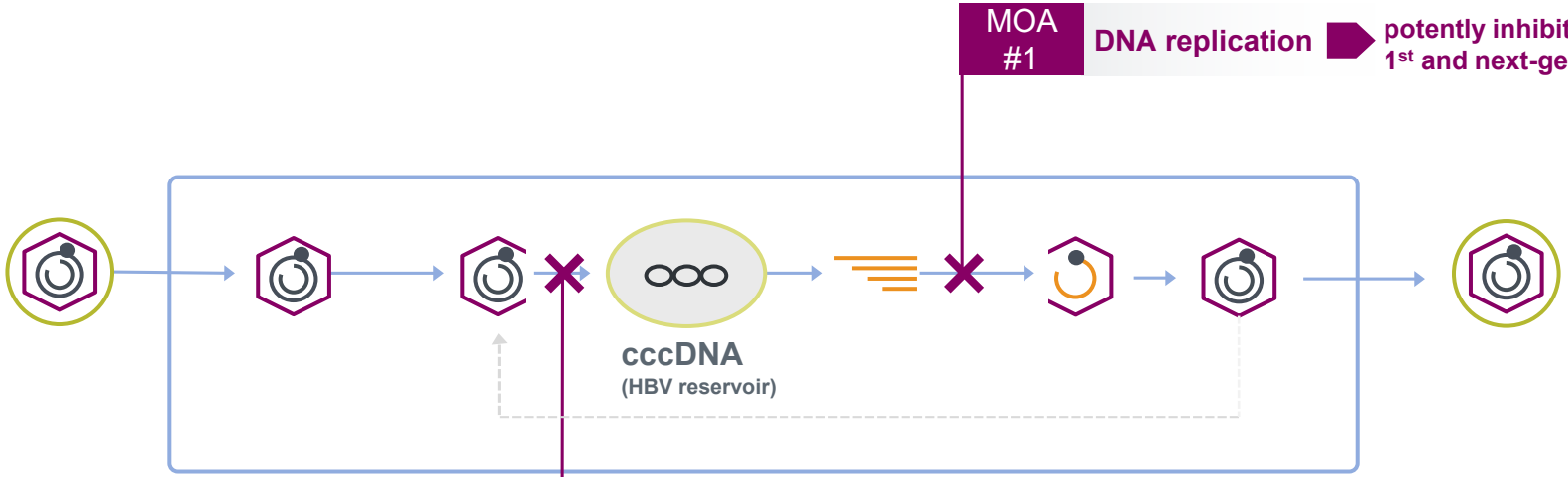
Treatments are life-long
INHIBIT VIRUS BUT CURE RATES VERY LOW

Opportunity to improve outcomes
AND INCREASE NUMBER OF PATIENTS DIAGNOSED AND TREATED, WITH DEVELOPMENT OF FINITE AND CURATIVE THERAPIES

No new MOAs approved for HBV in >25 years

1. Prevalence of HBV 296M per WHO (2021)

Capsid Assembly Modulators (CAMs) have two mechanisms of action; a key differentiator is potency against the 2nd mechanism

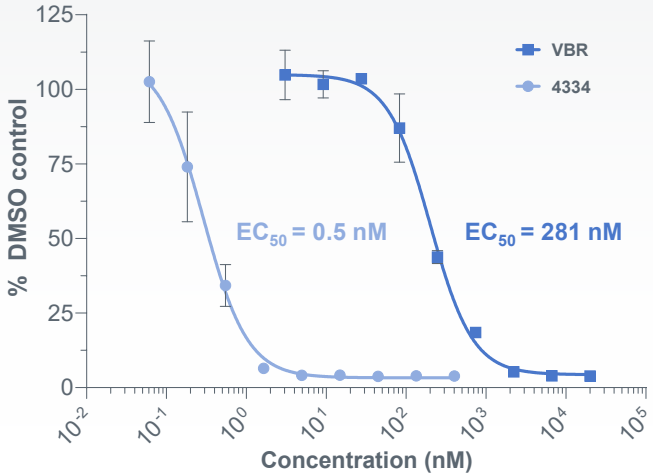


ABI-4334 observed to be >1000x more potent against cccDNA formation *in vitro* than the 1st gen CAM vebicorvir

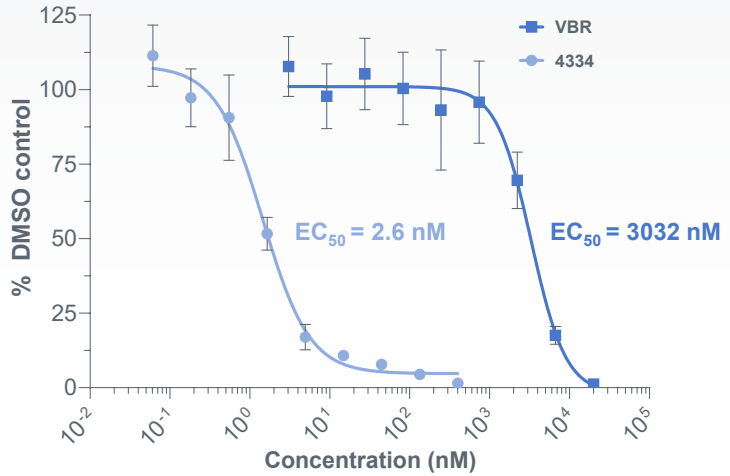
cccDNA, covalently closed circular DNA.

ABI-4334 demonstrated high *in vitro* potency against both mechanisms of action for CAMs

***In vitro* antiviral activity | MOA #1**



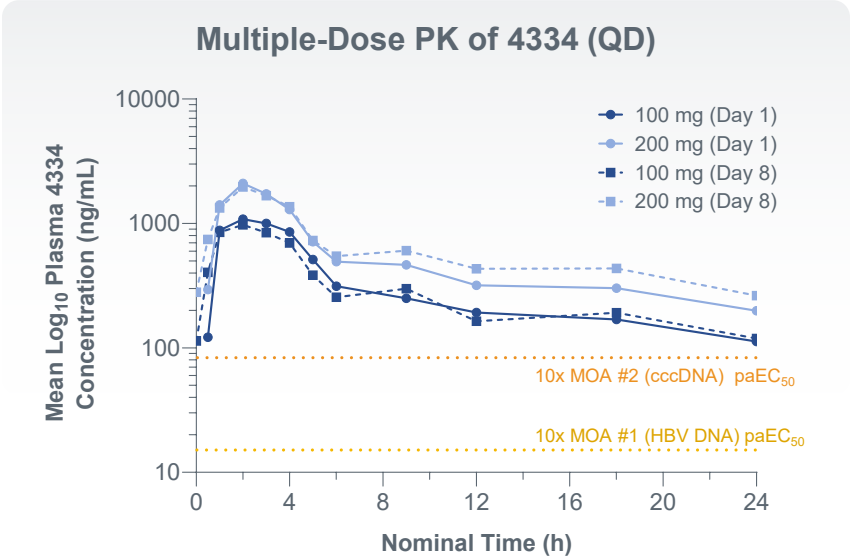
***In vitro* cccDNA prevention | MOA #2**



Compared to 1st-gen CAM vebicorvir (VBR), next-generation CAM ABI-4334 was observed to be:

- > 500x more potent against MOA #1
- > 1000x more potent against MOA #2

4334 Phase 1a data observed supports high potency against both mechanisms of action



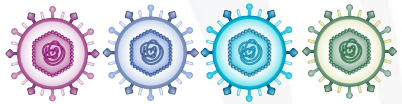
	4334 Ph1a Cohorts[1]	
Parameters	**100mg[a]**	**200mg[a]**
$C_{min,}$ ng/mL	119	263
Fold above $paEC_{50}$ MOA #1 (antiviral)	79x	175x
Fold above $paEC_{50}$ MOA #2 (cccDNA)	15x	34x

[A] Based on observed data on day 8

- Well-tolerated safety profile with linear PK
- C_{min} of 34x $paEC_{50}$ for MOA #2 at 200 mg QD

4334 Phase 1b study expected to initiate by mid-2024

Research Pipeline



Oral pan-herpes non-nucleoside polymerase inhibitor (NNPI) for transplant-associated herpesviruses

Multiple herpesviruses can cause significant morbidity and mortality in immunocompromised transplant recipients

60,000 PATIENTS AFFECTED[1]

AMONG TRANSPLANT PATIENTS:

~60% are CMV positive

~60% are HSV positive

~80% are VZV positive

Lifelong latent infections

FREQUENTLY REACTIVATE DURING IMMUNOSUPPRESSION

Uncontrolled viral replication

AND SEVERE DISEASE DURING REACTIVATION

Risk of graft loss and death

SOC antivirals are:

- PARTIALLY EFFICACIOUS
- NOT BROAD SPECTRUM
- HAVE TOLERABILITY AND DRUG INTERACTION LIMITATIONS

An oral pan-herpes antiviral could improve efficacy and greatly simplify treatment

Patel and Paya. Clin. Microbiol. Rev. 1997; Breuer, *et al.* Mol. Diagn. Ther. 2012; Clark, *et al.* Semin. Respir. Crit. Car Med. 2013; Haidar and Singh. Curr. Opin. Infect. Dis. 2019; Beyar-Katz *et al.* Clin. Microbiol. Infect. 2020; Kwon et al. Transp. Infect. Dis. 2021; Wutzler et al. Vaccine 2001; Bauer et al. BMC Infect. Dis. 2010; Reynolds et al. Public Health Rep. 2010; Lanzieri et al. Int. J. Gynaecol. Obstet. 2016; Lachmann et al. PLoS One 2018; Patton et al.Clin. Infect. Dis. 2018; Ayoub et al. BMC Med. 2019; Zuhair et al. Rev. Med. Virol. 2019; Zhang et al. Virol. J. 2022; Marty et al. NEJM 2017; Limaye et al. JAMA 2023; Witzke et al. Transp. 2012; Witzke et al. Transp. 2018

1. EBMT, OPTN, UNOS, and IRODAT (estimate for transplanted-associated herpesvirus reflects US and EU only).

Assembly Bio's oral pan-herpes polymerase inhibitor program is designed to provide significant innovation over current standard of care

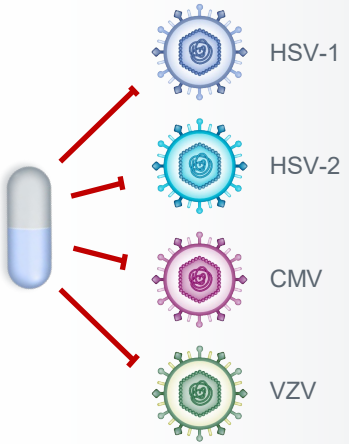
Conserved viral polymerase offers potential for broad-spectrum herpes virus inhibitors

Opportunity to advance over current standard of care

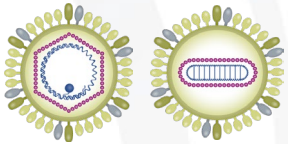
- Improve efficacy
- Simplify treatment (1 agent to target 4 viruses)
- Improve tolerability and reducing drug-drug interactions

Gilead collaboration expands portfolio and augments program

- Assembly and Gilead contribute extensive expertise and active programs
- Combined effort anticipated to speed candidate nomination and enhance chance for clinical success



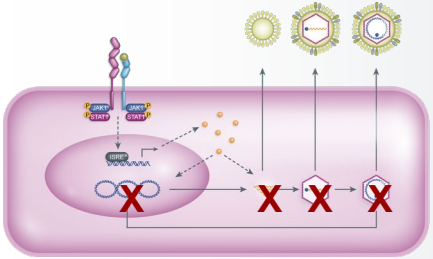
Multiple series of potent, broad-spectrum herpes virus inhibitors identified

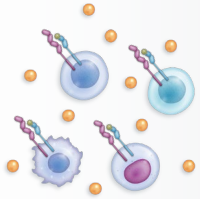


Oral, liver-focused IFNAR agonist for hepatitis B and hepatitis D

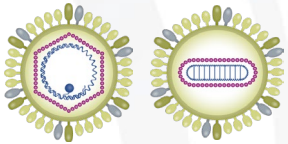
A small-molecule liver-focused IFNAR agonist could provide significant innovation over current standard of care

- IFN-α is an approved therapy for HBV and associated with functional cure in some patients; however, tolerability limits its use
- Small molecule agonists identified which closely mimic IFN-α biology, including ISG induction *in vitro* and *in vivo*
- Selectively activating the IFN-α pathway in the liver (vs systemically) is expected to significantly improve tolerability





Lead optimization of multiple IFN-α receptor agonists in progress



Gilead Collaboration

Assembly-Gilead partnership combines Gilead's pioneering vision with Assembly's deep R&D expertise to bring next-gen virology medicines to patients

Brings together the two team's knowledge and expertise in antiviral research, clinical development, and commercialization

Strengthened portfolio with two programs targeting HSV and transplant-associated herpesviruses received from Gilead

Extends Assembly's cash runway with total upfront cash payment and equity investment of $100 million, plus potential future payments receivable from Gilead

GILEAD
Creating Possible

- ✓ Leader in antivirals, with a track record in developing transformative medicines, cures and access strategies
- ✓ Innovative medicines have helped to transform the lives of those living with viral hepatitis, having developed a cure for hepatitis C while continuing to develop new treatments for chronic hepatitis B and D

assemblybio

- ✓ Deep R&D expertise and agile, experienced team that has rapidly discovered and developed a promising portfolio of compounds designed to address unmet needs in herpesviruses and hepatitis B and D

Partnership overview

KEY FINANCIALS

$100M Total Upfront Consideration

- ~$85M cash and ~$15M equity investment

Potential additional equity purchase at a premium

Contingent Payments Per Program

- Opt-in fee of at least $45M per program
- Regulatory & commercial milestones up to $330M

Royalties

- High single-digits to high-teens

40% US profit/cost share option on all programs

$75M Collaboration Extension Payments

- 3rd, 5th, and 7th years of the collaboration

STRUCTURE

Long-Term Partnership and Collaboration

- Assembly contributes all current and future programs
- Gilead contributes two herpesvirus programs

Responsibilities and Options

- Assembly primarily responsible for R&D before opt-in
- Gilead may opt-in to each program, with ability to extend option from end of Phase 1 to end of Phase 2
- Gilead controls all development and commercialization after exercise of the option
- Assembly may opt-in to US cost/profit share and co-promote for certain programs
- Assembly may continue development or license programs upon Gilead opt-out

Nasdaq: ASMB