



# Interim Results from Phase 1b Clinical Studies of Long-Acting Helicase-Primase Inhibitor Candidates ABI-1179 and ABI-5366 in Recurrent Genital Herpes

**December 8, 2025**

**Nasdaq: ASMB**

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# ABI-5366 and ABI-1179 – Helicase-Primase Inhibitors for Recurrent Genital Herpes

## Positive Interim Phase 1b Results for Two Promising Long-Acting Candidates

August 2025

- **ABI-5366 weekly cohort B2 exceeds Phase 1b expectations with**
  - 94% reduction in HSV-2 shedding ( $p < 0.01$ ) vs placebo
  - 97% reduction in virologically confirmed lesion rate ( $p < 0.05$ ) vs placebo<sup>1</sup>

Results  
Released Today

- **ABI-1179 weekly cohort B1 exceeds Phase 1b expectations with**
  - 98% reduction in HSV-2 shedding ( $p < 0.01$ ) vs placebo
  - 92% reduction in virologically confirmed lesion rate ( $p < 0.01$ ) vs placebo

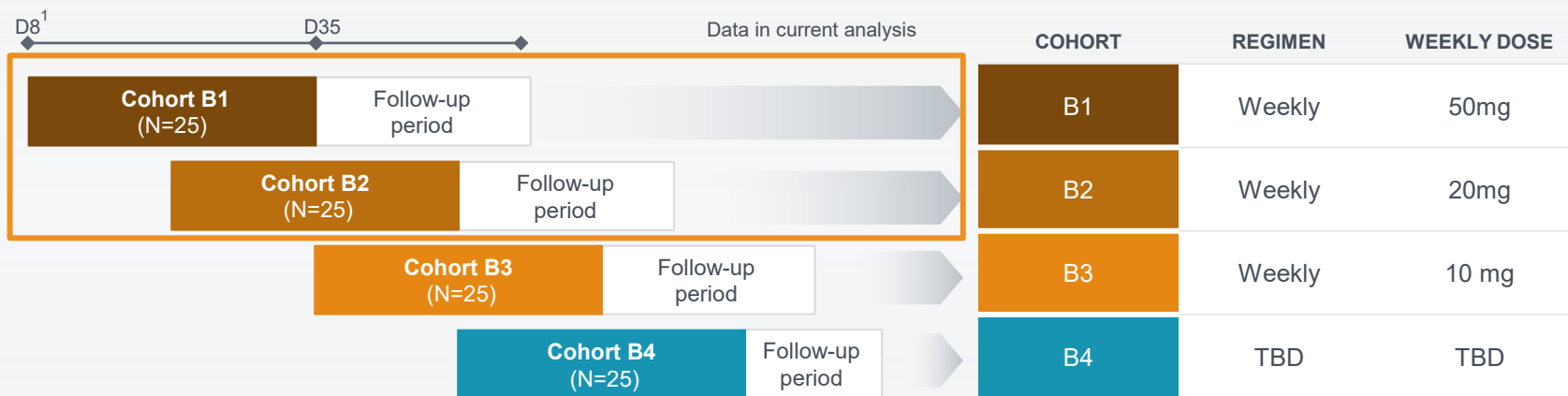
- **ABI-5366 weekly cohort B1/B2 unblinded safety data released**

- **ABI-5366 monthly cohort B3 shows potent antiviral activity**
  - 76% reduction in HSV-2 shedding ( $p < 0.01$ ) vs placebo
  - 88% reduction in virologically confirmed lesion rate ( $p = 0.01$ ) vs placebo



# ABI-1179-101 Phase 1b Study Design

- Double-blind, placebo-controlled sequential cohorts
- All participants seropositive for HSV-2 with recurrent genital herpes
- Each cohort with 20 patients receiving ABI-1179 and 5 patients receiving placebo



## KEY EFFICACY ASSESSMENTS

- Anogenital swabs (Day 8-35); e.g., viral shedding rate
- Daily diary of symptoms; e.g., days with lesions

## DATA IN CURRENT ANALYSIS

- Diary data through D35
- 100% Shedding data
- Safety data through Day 57



# ABI-1179 Phase 1b: Baseline Demographics and Disease Characteristics

BASELINE DEMOGRAPHICS AND DISEASE CHARACTERISTICS	ABI-1179 20mg weekly/PBO (N=24)	ABI-1179 50mg weekly/PBO (N=25)
<b>Age, median (range)</b>	40 (24-61)	40 (23 – 60)
<b>Male, N (%)</b>	13 (54%)	7 (28%)
<b>Race, N (%)</b>		
White	21 (88%)	23 (92%)
Black/African American	0	1 (4%)
Native Hawaiian/Pacific Islander	0	3 (12%)
Other	3 (13%)	2 (8%)
<b>BMI, median (range)</b>	25.4 (20.1 – 30.2)	26.7 (18.9 – 31.4)
<b>Years since HSV Diagnosis, median (IQR)</b>	6.9 (3.2 – 17.3)	8.0 (4.6 – 10.6)
<b>Number of Lesions in past 12 months or prior to suppressive treatment, median (IQR)</b>	5.5 (5.0 – 6.0)	6.0 (5.0 – 7.0)
<b>Suppressive Treatment at Screening, N (%)</b>	18 (75%)	20 (80%)



# ABI-1179 Phase 1b: Safety Summary – Adverse Events Cohorts B1 & B2

PARAMETER	ABI-1179 20mg weekly/PBO N=24	ABI-1179 50mg weekly/ PBO N=25
<b>Subjects with any Treatment Emergent Adverse Events (TEAE) (max grade), N (%)</b>	17 (71%)	23 (92%)
Grade 1, N (%)	12 (50%)	9 (36%)
Grade 2, N (%)	5 (21%)	13 (52%)
Grade 3, N (%)	0	1 (4%) <sup>1</sup>
Grade 4, N (%)	0	0
<b>TEAE Related to Study Drug, N (%)</b>	8 (33%)	10 (40%)
<b>TEAE Leading to Study Drug Discontinuation, N (%)</b>	0	0
<b>Serious Adverse Event</b>	0	0
<b>Death</b>	0	0
<b>Treatment Emergent Lab Abnormalities, N (%)</b>	9 (38%)	8 (32%)
Grade 1, N (%)	8 (33%)	6 (24%)
Grade 2, N (%)	2 (8%)	3 (12%)
Grade 3, N (%)	0	0
Grade 4, N (%)	0	0

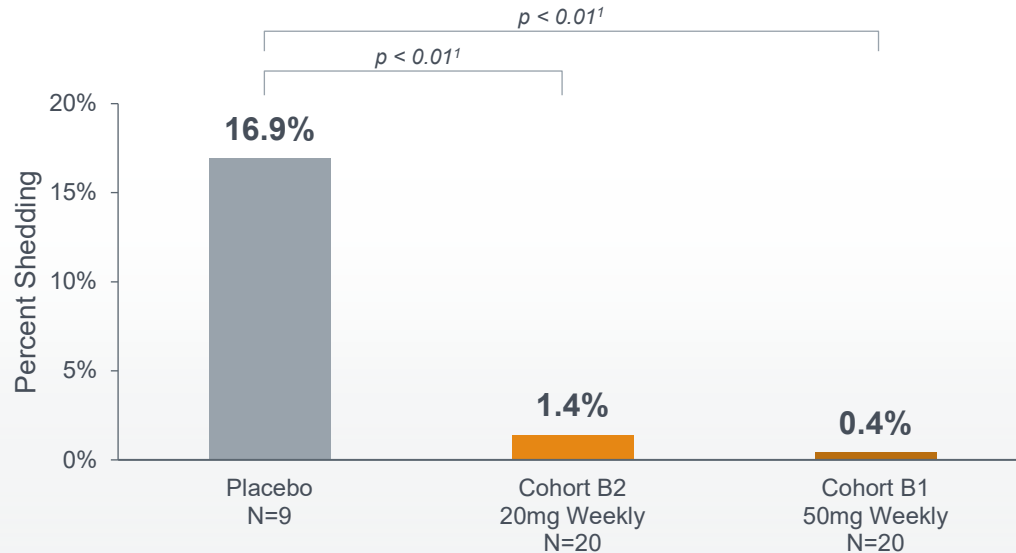
Safety data includes patients through Day 57



# ABI-1179 Phase 1b: Cohorts B1 and B2 with Significant Reduction in HSV-2 Shedding

**98%**

reduction in  
HSV-2 shedding  
rate for cohort  
B1<sup>2</sup>



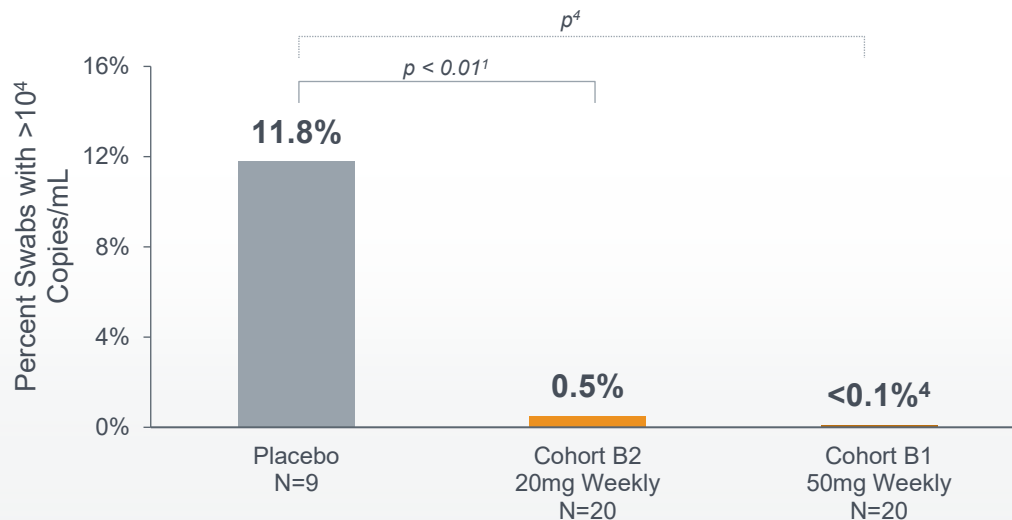
- Significant reduction in HSV-2 shedding rate for Cohorts B1 and B2 compared to Placebo



# ABI-1179 Phase 1b:

## Reduction in HSV-2 High Viral Load Shedding in Cohorts B1 and B2

**>99%**  
reduction in  
HSV-2 high viral  
load shedding for  
cohort B1<sup>3,4</sup>

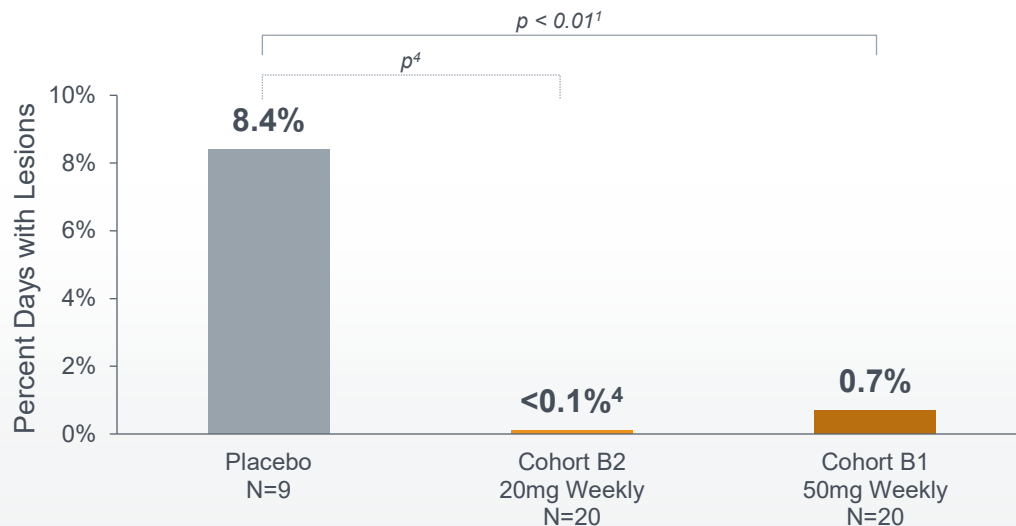


- Significant reduction in HSV-2 high viral load shedding for Cohorts B1 and B2 compared to Placebo
- Near complete elimination of HSV-2 high viral load swabs >10<sup>4</sup> copies/mL for both cohorts
  - Shedding >10<sup>4</sup> copies/mL a surrogate for increased HSV-2 transmission<sup>2</sup>



# ABI-1179 Phase 1b: Cohorts B1 and B2 with Significant Reduction in Virologically Confirmed Lesion Rate

**91%**  
reduction in  
virologically  
confirmed<sup>2</sup> lesion  
rate for cohort  
B1<sup>3</sup>



- Significant reduction in virologically confirmed lesion rate for Cohorts B1 and B2 compared to Placebo



# Executive Summary: ABI-1179 Phase 1b Interim Update

## ABI-1179 PH1B STATUS UPDATE

- Two weekly dosing cohorts have completed treatment (B1 and B2)
- One weekly dosing cohort is currently enrolling (B3)
- Phase 2 enabling activities underway

### PHASE 1B TRIAL GOALS

- **80 to 85% reduction** in HSV-2 shedding vs. placebo
- **Significant reduction** in high viral load swabs<sup>1</sup>
- **Directional reduction** in genital lesions
- **Clean safety profile**

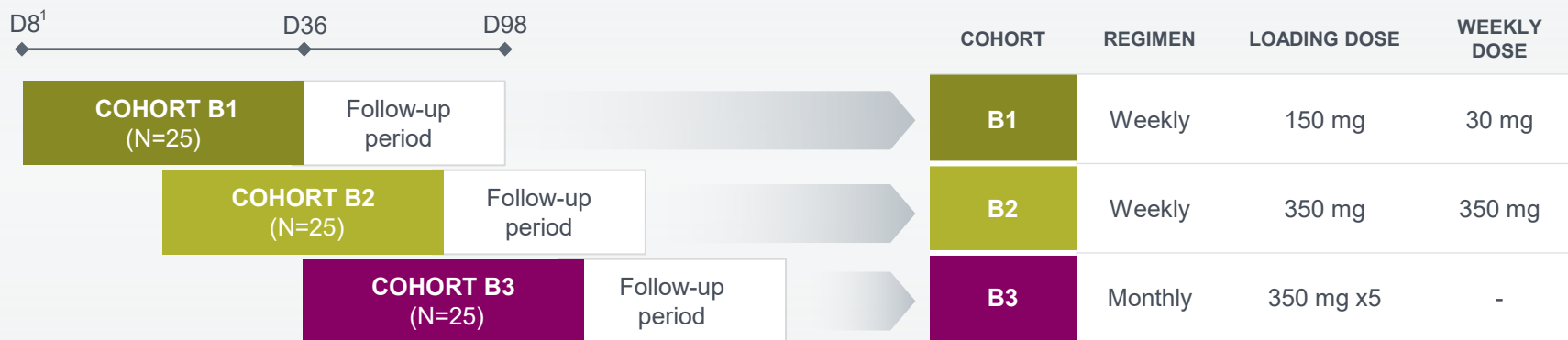
### PHASE 1B COHORT B1 (50 MG, QW) RESULTS

- ✓ **98% reduction** in HSV-2 shedding ( $p < 0.01$ )
- ✓ **>99% reduction** in high viral load swabs
- ✓ **91% reduction** in virologically confirmed<sup>2</sup> genital lesions ( $p < 0.01$ )
- ✓ **No safety signals identified** to date



# ABI-5366-101 Phase 1b Study Design

- Double-blind, placebo-controlled sequential cohorts
- All participants seropositive for HSV-2 with recurrent genital herpes
- Each cohort with 20 patients receiving ABI-5366 and 5 patients receiving placebo



## KEY EFFICACY ASSESSMENTS

- Anogenital swabs (Day 8-36); e.g., viral shedding rate
- Daily diary of symptoms; e.g., days with lesions

## DATA IN CURRENT ANALYSIS

- Diary data through D36
- 100% Shedding data
- Complete safety data for cohorts B1 and B2
- Safety data up to Day 43 for cohort B3



# ABI-5366 Phase 1b: Baseline Demographics and Disease Characteristics

<b>BASELINE DEMOGRAPHICS AND DISEASE CHARACTERISTICS</b>	<b>PBO (N=10)</b>	<b>ABI-5366 30mg weekly (N=20)</b>	<b>ABI-5366 350mg weekly (N=20)</b>	<b>ABI-5366 Monthly/PBO (N=26)</b>
<b>Age, median (range)</b>	44 (35 – 59)	37 (26 – 60)	41 (25 – 60)	35 (25 – 59)
<b>Male, N (%)</b>	5 (50)	10 (50)	13 (65)	8 (31)
<b>Race, N (%)</b>				
White	9 (90)	16 (80)	16 (80)	25 (96)
Black/African American	0	0	1 (5)	0
Native Hawaiian/Pacific Islander	0	2 (10)	1 (5)	0
Asian	1 (10)	2 (10)	2 (10)	1 (4)
Other	0	0	1 (5)	4 (15)
<b>BMI, median (range)</b>	24.1 (20.3 – 27.8)	26.4 (21.4 – 31.4)	28.3 (20.8 – 32.6)	25.9 (18.1 – 29.7)
<b>Years since HSV Diagnosis, median (IQR)</b>	10.9 (7.2 – 12.8)	9.4 (5.8 – 15.4)	9.3 (5.4 – 17.2)	10.6 (5.5 – 18.5)
<b>Number of Lesions in past 12 months or prior to suppressive treatment, median (IQR)</b>	5 (5.0 – 6.0)	5.8 (4.8 – 7.0)	5.0 (4.8 – 6.0)	6.0 (5.0 – 6.5)
<b>Suppressive Treatment at Screening, N (%)</b>	6 (60)	12 (60)	12 (60)	15 (58)



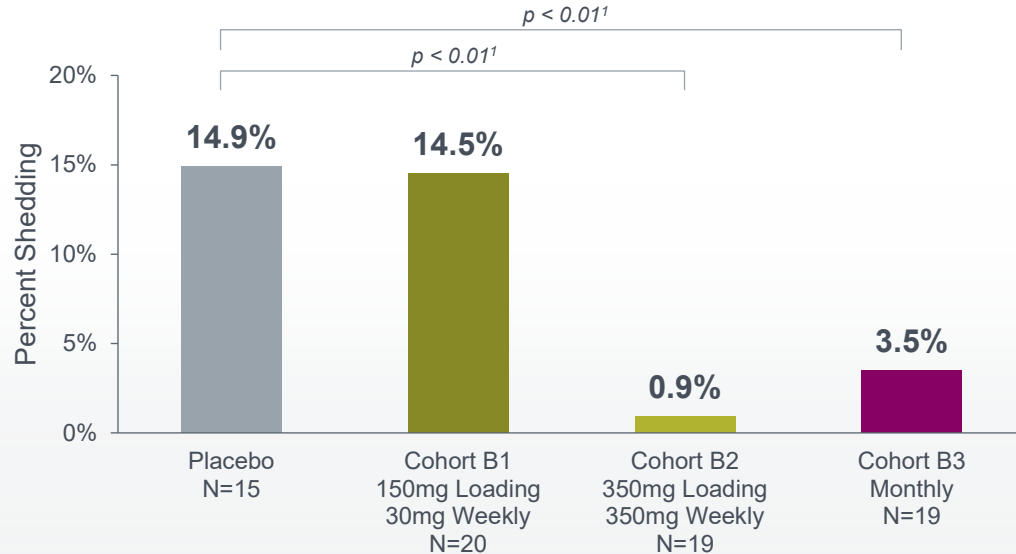
# ABI-5366 Phase 1b: Safety Summary – Adverse Events Cohorts B1, B2 & B3

ADVERSE EVENTS AND LABORATORY ABNORMALITIES	PBO N=10	ABI-5366 30mg weekly N=20	ABI-5366 350mg weekly N=20	ABI-5366 Monthly/ PBO <sup>1</sup> N=26
<b>Subjects with any Treatment Emergent Adverse Events (TEAE) (max grade), N (%)</b>	9 (90%)	18 (90%)	19 (95%)	26 (100%)
Grade 1, N (%)	5 (50%)	12 (60%)	10 (50%)	12 (46%)
Grade 2, N (%)	4 (40%)	6 (30%)	9 (45%)	14 (54%)
Grade 3, N (%)	0	0	0	0
Grade 4, N (%)	0	0	0	0
<b>TEAE Related to Study Drug, N (%)</b>	4 (40%)	6 (30%)	3 (15%)	9 (35%)
<b>TEAE Leading to Study Drug Discontinuation, N (%)</b>	0	0	0	0
<b>Serious Adverse Event</b>	0	0	0	0
<b>Death</b>	0	0	0	0
<b>Treatment Emergent Lab Abnormalities, N (%)</b>	9 (90%)	14 (70%)	15 (75%)	14 (54%)
Grade 1, N (%)	7 (70%)	12 (60%)	12 (60%)	14 (54%)
Grade 2, N (%)	3 (30%)	3 (15%)	5 (25%)	2 (8%)
Grade 3, N (%)	1 (10%) <sup>2</sup>	1 (5%) <sup>2</sup>	1 (5%) <sup>2</sup>	0
Grade 4, N (%)	0	0	0	0

Safety data complete for cohorts B1 and B2; for cohort B3, includes safety data up to day 43

# ABI-5366 Phase 1b: Cohorts B2 and B3 with Significant Reduction in HSV-2 Shedding

**94%**  
reduction in  
HSV-2 shedding  
rate for cohort  
B2<sup>2</sup>



- Significant reduction in HSV-2 shedding rate for Cohorts B2 and B3 compared to Placebo

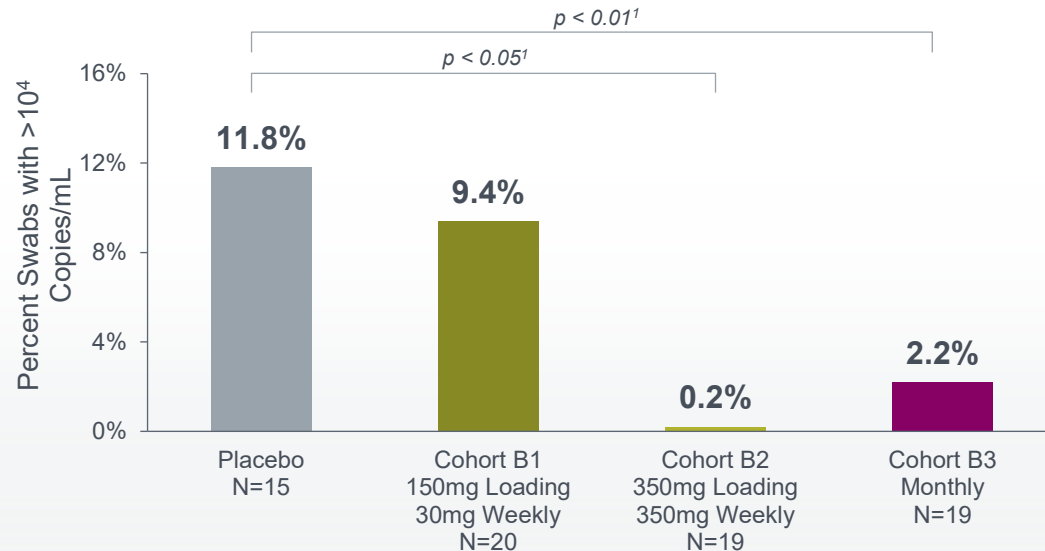


# ABI-5366 Phase 1b:

## Reduction in HSV-2 High Viral Load Shedding in Cohorts B2 and B3

**98%**

reduction in HSV-2 high viral load shedding for cohort B2<sup>3</sup>

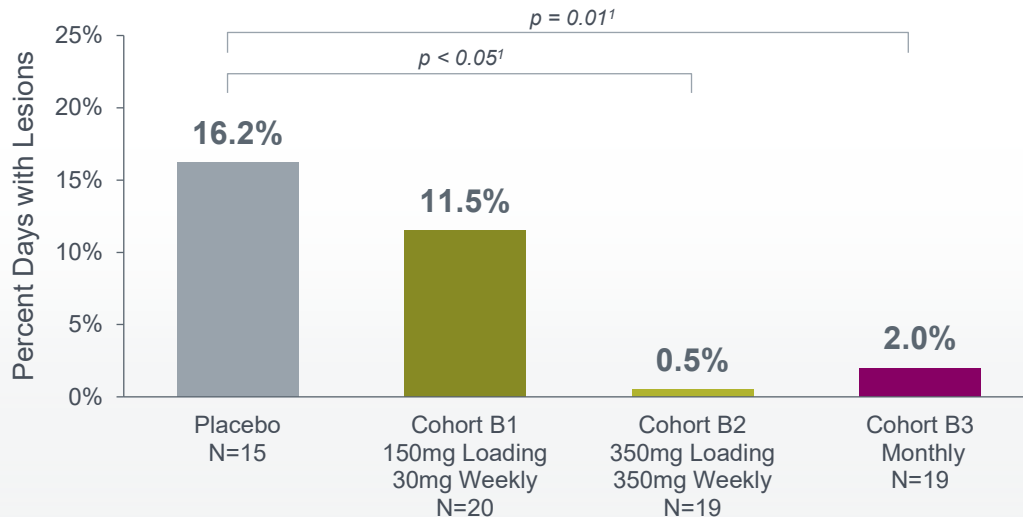


- Significant reduction in HSV-2 high viral load shedding for Cohorts B2 and B3 compared to Placebo
- Near complete elimination of HSV-2 high viral load swabs >10<sup>4</sup> copies/mL for Cohort B2
  - Shedding >10<sup>4</sup> copies/mL a surrogate for increased HSV-2 transmission<sup>2</sup>
- All (N=2) observed viral loads >10<sup>4</sup> copies/mL in Cohort B2 were in the presence of a genital lesion

# ABI-5366 Phase 1b:

## Cohorts B2 and B3 with Significant Reduction in Virologically Confirmed Lesion Rate

**97%**  
reduction in  
virologically  
confirmed<sup>2</sup> lesion  
rate for cohort  
B2<sup>3</sup>



- Significant reduction in virologically confirmed lesion rate for Cohorts B2 and B3 compared to Placebo



# Executive Summary: ABI-5366 Phase 1b Interim Update

## ABI-5366 PH1B STATUS UPDATE

- Two weekly (B1, B2) and one monthly (B3) dosing cohorts have completed dosing
- Phase 2 planning underway with study initiation expected mid 2026

### PHASE 1B TRIAL GOALS

- **80 to 85% reduction** in HSV-2 shedding vs. placebo
- **Significant reduction** in high viral load swabs<sup>1</sup>
- **Directional reduction** in genital lesions
- **Clean safety profile**

### PHASE 1B COHORT B2 (350 MG, QW) RESULTS

- ✓ **94% reduction** in HSV-2 shedding ( $p < 0.01$ )
- ✓ **98% reduction** in high viral load swabs ( $p < 0.05$ )
- ✓ **97% reduction** in virologically confirmed<sup>2</sup> genital lesions ( $p < 0.05$ )
- ✓ **No safety signals identified** to date
  - Chronic Toxicology: Studies complete and support proposed Phase 2 dosing



# ABI-5366 & ABI-1179 Phase 1b Efficacy: Comparisons to Historical Placebo-Controlled Phase 1b Studies<sup>1</sup>



Note: Length of evaluation of studies differs by compound. Famciclovir=14 days, Acyclovir/Valacyclovir=42 days, Pritelivir/ABI-5366/ABI-1179=28 days

1. Not head-to-head studies; 2. Leone P et al. Sexually Transmitted Diseases, 34 (11), 2007; 3. Gupta et al. JID 190, 2004; 4. Wald A et al. NEJM 370 (3) 2014; 5. ABI-5366 Phase 1b data as of November 25, 2025; 6. ABI-1179 Phase 1b data as of November 25, 2025



# Differentiated Development Programs

## Targeting Herpesviruses and Viral Hepatitis

PROGRAM	INDICATION	MECHANISM	IND/CTA ENABLING	PHASE 1	PHASE 2
ABI-5366	Recurrent genital herpes	Long acting HPI			
ABI-1179*	Recurrent genital herpes	Long acting HPI			
ABI-7272	Transplant-associated herpesviruses	NNPI**			
ABI-4334	Hepatitis B	Next-generation CAM			
ABI-6250	Hepatitis D	Entry inhibitor			
TBD	Research programs against multiple antiviral targets				



# Q&A