Safety, Pharmacokinetics, and Pharmacodynamic Activity of ABI-6250, a First-in-Class Oral Hepatitis D Virus Entry Inhibitor in Healthy Subjects: Interim Results From a Randomized, Blinded, Phase 1a Study

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Background

- The hepatitis D virus (HDV) is a small RNA virus that requires the hepatitis B virus (HBV) to spread[1]
- Chronic HDV infection (cHDV) is the most severe form of viral hepatitis, affecting 12 to 72 million people worldwide,[2,3] and has limited treatment options
- Patients with cHDV have an increased risk of developing advanced liver disease, including fibrosis, cirrhosis, and hepatocellular carcinoma, compared with those with HBV monoinfection[4-6]
- Both HBV and HDV use the sodium taurocholate cotransporting polypeptide (NTCP), a transmembrane bile acid transporter on hepatocytes, as an entry receptor into the liver[7-9]
- Inhibition of viral entry through interference with the NTCP receptor represents a validated therapeutic approach for cHDV[8,10]
- Bulevirtide (BLV) is a once daily (QD) subcutaneous NTCP entry inhibitor approved in some countries for the treatment of cHDV.[11] By blocking viral entry and intrahepatic spread, BLV reduces HDV RNA and alanine aminotransferase (ALT), with viral decline consistent with loss of infected hepatocytes, as BLV targets the host entry receptor NTCP[8,11]
- ABI-6250 (6250), an oral small-molecule inhibitor of NTCP, has demonstrated high preclinical potency against multiple HDV strains[10]
- ABI-6250-101 (NCT06740474) is a randomized, blinded, Phase 1a study assessing the safety, pharmacokinetics (PK), and pharmacodynamics (PD) of 6250 in healthy participants (HPs)[12]

Objective

- To assess the safety, PK, and PD of 6250 following single-dose (SD) and multiple-dose (MD) administration in HPs

Figure 1. Study Design

Single-Dose Cohorts (N=16)
- 6250 5 mg n=6, PBO n=2
- 6250 25 mg n=6, PBO n=2

Multiple-Dose Cohorts (QD for 10 days) (N=24)
- 6250 0.05 mg n=6, PBO n=2
- 6250 0.2 mg n=6, PBO n=2
- 6250 1 mg n=6, PBO n=2

Key Inclusion Criteria
- Male or female, aged ≥18 and ≤60 years
- BMI ≥18.0 and <32.0 kg/m^2 (inclusive)
- In good health (as determined by the investigator)

Key Exclusion Criteria
- Positive for HIV, HBV, HCV, acute HAV
- Known history of Gilbert's syndrome

6250, ABI-6250; BMI, body mass index; HAV, hepatitis A virus; HBV, hepatitis B virus; HCV, hepatitis C virus; HIV, human immunodeficiency virus; PBO, placebo; QD, once daily.

Methods

- This study (NCT06740474) consisted of SD and MD administration of 6250 in HPs
- During the SD phase, 8 HPs (6 active, 2 placebo [PBO]) were enrolled into each of 2 sequential cohorts (**Figure 1**)
- During the MD phase, 8 HPs (6 active, 2 PBO) were enrolled into each of 3 sequential cohorts and received the assigned treatment QD for 10 days
- Safety assessments included physical exams, vital signs, treatment-emergent (TE) adverse events (TEAE), and laboratory parameters
- Plasma concentrations of 6250 were measured by validated liquid chromatography–mass spectrometry methodology, with PK parameters estimated by noncompartmental analysis
- PD responses were assessed by quantification of plasma total bile acids (tBA; on-target effects of NTCP inhibition) and coproporphyrin-1 (CP-1; off-target effects of hepatic organic anion transporting polypeptide 1B [OATP1B] inhibition)

Results

- Sixteen HPs were enrolled in the SD cohorts, and 24 HPs were enrolled in the MD cohorts (**Table 1**)
- All SD recipients completed treatment. One HP who received 1 mg 6250 QD discontinued treatment on Day 8 due to a Grade 1 TEAE of increased ALT (maximum value, 64 U/L)

Table 1. Demographic Characteristics

Characteristics	Single-Dose Cohorts: 5 mg 6250 n=6	Single-Dose Cohorts: 25 mg 6250 n=6	Single-Dose Cohorts: All Cohorts PBO n=4	Multiple-Dose Cohorts: 0.05 mg 6250 n=6	Multiple-Dose Cohorts: 0.2 mg 6250 n=6	Multiple-Dose Cohorts: 1 mg 6250 n=6	Multiple-Dose Cohorts: All Cohorts PBO n=6
Age, y, median (range)	25.5 (21-33)	26.0 (20-29)	27.5 (21-40)	31.0 (21-57)	37.0 (25-49)	34.0 (21-50)	32.5 (29-52)
Sex, male, n (%)	5 (83.3)	6 (100.0)	4 (100.0)	5 (83.3)	5 (83.3)	4 (66.7)	6 (100.0)
Race, White, n (%)	2 (33.3)	5 (83.3)	3 (75.0)	5 (83.3)	4 (66.7)	6 (100.0)	6 (100.0)
Body mass index, kg/m^2, median (range)	25.4 (19.4-26.6)	24.6 (23.6-29.9)	23.8 (22.3-26.3)	23.9 (20.0-24.8)	24.5 (20.7-30.3)	25.1 (22.5-29.8)	25.5 (22.7-30.5)

6250, ABI-6250; PBO, placebo.

Table 2. Summary of Safety

n (%) of Participants	Single-Dose Cohorts: 5 mg 6250 n=6	Single-Dose Cohorts: 25 mg 6250 n=6	Single-Dose Cohorts: All Cohorts PBO n=4	Multiple-Dose Cohorts: 0.05 mg 6250 n=6	Multiple-Dose Cohorts: 0.2 mg 6250 n=6	Multiple-Dose Cohorts: 1 mg 6250 n=6	Multiple-Dose Cohorts: All Cohorts PBO n=6
TEAEs	4 (66.7)	2 (33.3)	0	6 (100.0)	4 (66.7)	4 (66.7)	4 (66.7)
Grade 1	4 (66.7)	2 (33.3)	0	6 (100.0)	3 (50.0)	4 (66.7)	4 (66.7)
Grade 2	0	0	0	0	2 (33.3)[a]	0	0
Grade ≥3	0	0	0	0	0	0	0
TEAEs related to 6250/PBO	0	0	0	1 (16.7)	0	2 (33.3)	0
TEAEs leading to 6250/PBO DC	0	0	0	0	0	1 (16.7)[b]	0
TE SAEs	0	0	0	0	0	0	0
Deaths	0	0	0	0	0	0	0
TE graded lab abnormalities[c]	4 (66.7)	3 (50.0)	2 (50.0)	3 (50.0)	5 (83.3)	3 (50.0)	5 (83.3)
Grade 1	4 (66.7)	2 (33.3)	2 (50.0)	2 (33.3)	5 (83.3)	3 (50.0)	4 (66.7)
Grade 2	0	1 (16.7)	0	1 (16.7)	1 (16.7)	0	3 (50.0)
Grade 3	0	0	0	0	0	0	0
Grade 4	1 (16.7)[d]	0	0	0	0	0	0

[a]Grade 2 TEAEs of gout and headache (different participants). [b]Grade 1 TEAE of increased alanine aminotransferase. [c]Any increase in toxicity grade from baseline. [d]Grade 4 creatine kinase increased.
6250, ABI-6250; DC, discontinuation; PBO, placebo; SAE, serious adverse event; TE, treatment-emergent; TEAE, treatment-emergent.

Table 3. Summary of TEAEs (>1 Participant Overall)

n (%) of Participants	Single-Dose Cohorts: 5 mg 6250 n=6	Single-Dose Cohorts: 25 mg 6250 n=6	Single-Dose Cohorts: All Cohorts PBO n=4	Multiple-Dose Cohorts: 0.05 mg 6250 n=6	Multiple-Dose Cohorts: 0.2 mg 6250 n=6	Multiple-Dose Cohorts: 1 mg 6250 n=6	Multiple-Dose Cohorts: All Cohorts PBO n=6
TEAEs (all grades)	4 (66.7)	2 (33.3)	0	6 (100.0)	4 (66.7)	4 (66.7)	4 (66.7)
URTI	1 (16.7)	0	0	1 (16.7)	0	0	1 (16.7)
Headache	2 (33.3)	0	0	0	1 (16.7)	2 (33.3)	0
Vessel puncture site bruise	0	0	0	3 (50.0)	1 (16.7)	0	1 (16.7)
Fatigue	0	0	0	2 (33.3)	0	0	0
Erythema	0	0	0	1 (16.7)	0	0	1 (16.7)
Back pain	0	0	0	0	0	0	2 (33.3)

6250, ABI-6250; PBO, placebo; TEAE, treatment-emergent adverse event; URTI, upper respiratory tract infection.

Table 4. Summary of TE Lab Abnormalities (>1 Participant Overall)

n (%) of Participants	Single-Dose Cohorts: 5 mg 6250 n=6	Single-Dose Cohorts: 25 mg 6250 n=6	Single-Dose Cohorts: All Cohorts PBO n=4	Multiple-Dose Cohorts: 0.05 mg 6250 n=6	Multiple-Dose Cohorts: 0.2 mg 6250 n=6	Multiple-Dose Cohorts: 1 mg 6250 n=6	Multiple-Dose Cohorts: All Cohorts PBO n=6
Postbaseline Abnormalities (all grades)	4 (66.7)	3 (50.0)	2 (50.0)	3 (50.0)	5 (83.3)	3 (50.0)	5 (83.3)
Cholesterol (increased)							
Grade 1	1 (16.7)	2 (33.3)	1 (25.0)	0	0	1 (16.7)	0
Grade 2	0	0	0	1 (16.7)	1 (16.7)	0	0
ALT (increased)							
Grade 1	2 (33.3)	0	0	0	1 (16.7)	1 (16.7)	1 (16.7)
Grade 2	0	1 (16.7)	0	0	0	0	0
Bicarbonate (decreased)							
Grade 1	0	0	1 (25.0)	0	1 (16.7)	0	0
Creatine kinase (increased)							
Grade 1	0	0	0	0	1 (16.7)	1 (16.7)	0
Grade 2	0	0	0	0	0	0	2 (33.3)
Grade 4	1 (16.7)	0	0	0	0	0	0
Triglycerides (increased)							
Grade 1	1 (16.7)	0	0	1 (16.7)	3 (50.0)	1 (16.7)	1 (16.7)
Sodium (decreased)							
Grade 1	0	0	0	1 (16.7)	1 (16.7)	0	1 (16.7)

6250, ABI-6250; ALT, alanine aminotransferase; PBO, placebo; TE, treatment-emergent.

- Overall, 6250 was well tolerated, with no Grade ≥3 TEAEs, TE serious adverse events, or deaths reported (**Table 2**). Among HPs who received 6250, the most common TEAEs were headache in the SD cohorts and vessel puncture site bruise and fatigue in the MD cohorts (**Table 3**)
- TEAEs considered related to 6250 were fatigue/muscle weakness in an HP who received 0.05 mg 6250 QD and dyspepsia and increased ALT in 2 separate HPs who received 1 mg 6250 QD (**Table 2**)
- Except for a Grade 4 creatinine kinase (CK) increase in an HP who received 5 mg 6250 SD, there were no Grade ≥3 TE graded lab abnormalities (**Table 4**). The most common graded lab abnormalities reported in
  - HPs who received SD of 6250 were increased cholesterol and ALT
  - HPs who received MD of 6250 were increased triglycerides, cholesterol, ALT, and CK
  - HPs who received PBO were increased CK, triglycerides, and ALT

Table 5. Summary of 6250 PK Parameters

PK Parameters	Single-Dose Cohorts: 5 mg 6250 n=6	Single-Dose Cohorts: 25 mg 6250 n=6	Multiple-Dose Cohorts: 0.05 mg 6250 Day 1 n=6	0.05 mg 6250 Day 10 n=6	0.2 mg 6250 Day 1 n=6	0.2 mg 6250 Day 10 n=6	1 mg 6250 Day 1 n=6	1 mg 6250 Day 10 n=6[a]
T_{max}, hours, median (range)	4.0 (3.0-9.0)	5.0 (3.0-9.0)	4.0 (3.0-9.0)	4.0 (2.0-4.0)	4.0 (3.0-9.0)	8.0 (4.0-24.0)	4.0 (4.0-18.0)	4.0 (3.0-9.0)
$t_{1/2}$, hours, mean (CV%)	97.6 (25.4)	104.5 (47.1)	NC	126.2 (56.0)	NC	132.7 (33.6)	NC	111.6 (50.9)
C_{max}, ng/mL, mean (CV%)	214.5 (15.3)	1088 (13.3)	0.9 (9.0)	5.4 (18.2)	3.4 (15.4)	25.0 (27.6)	22.9 (22.3)	146.6 (31.1)
$AUC_{0\text{-}24}$, h·ng/mL, mean (CV%)	3,251 (10.6)	17,620 (17.6)	14.9 (11.3)[b]	94.6 (19.5)	57.8 (17.8)	436.2 (25.4)	404 (14.5)[b]	2,728 (25.7)
$AUC_{0\text{-}inf}$, h·ng/mL, mean (CV%)	17,470 (13.6)[b]	79,640 (55.7)[c]	NC	NC	NC	NC	NC	NC
C_{24}, ng/mL, mean (CV%)	125.6 (12.7)	787.6 (26.6)	0.6 (15.0)[b]	4.0 (8.2)	2.1 (12.3)	18.5 (21.8)	15.6 (16.2)[b]	112.6 (39.8)
Accumulation ratio, $AUC_{0\text{-}24}$, mean (CV%)	NA	NA	NC	6.3 (16.0)[b]	NC	7.6 (20.6)	NC	7.1 (20.3)[d]

[a]One participant was excluded from the Day 10 analysis, as they did not receive the study drug on Days 9 and 10. [b]n=5. [c]n=3. [d]n=4.
6250, ABI-6250; AUC, area under the curve; $AUC_{0\text{-}24}$, AUC from time 0 to 24 hours; $AUC_{0\text{-}inf}$, AUC from time 0 to infinity; C_{24}, concentration 24 hours postdose; C_{max}, maximum concentration; CV%, coefficient of variation percentage; NA, not applicable; NC, not calculated; PBO, placebo; PK, pharmacokinetics; QD, once daily; $t_{1/2}$, elimination half-life; T_{max}, time to reach C_{max}.

- SD administration of 6250 on Day 1 (**Table 5, Figure 2A**) resulted in a median T_{max} of 4 to 5 hours. Mean elimination $t_{1/2}$ was consistent between dose levels, ranging from ~98 to 105 hours
- On Day 10 following MD, QD administration of 6250 (**Table 5, Figure 2B**) resulted in a T_{max} of ~4 to 8 hours, a $t_{1/2}$ of ~112 to 133 hours (consistent with SD estimates), and moderate exposure accumulation of ~6- to 8-fold compared with Day 1

Table 6. Summary of Plasma tBA Parameters

PD tBA Parameters	Single-Dose Cohorts: All Cohorts PBO n=4	Single-Dose Cohorts: 5 mg 6250 n=6	Single-Dose Cohorts: 25 mg 6250 n=6	Multiple-Dose Cohorts: All Cohorts PBO Day 1 n=6	All Cohorts PBO Day 10 n=6	0.05 mg 6250 Day 1 n=6	0.05 mg 6250 Day 10 n=6	0.2 mg 6250 Day 1 n=6	0.2 mg 6250 Day 10 n=6	1 mg 6250 Day 1 n=6	1 mg 6250 Day 10 n=6
Baseline, µmol/L, mean (CV%)	3.5 (71.9)	2.8 (52.0)	2.5 (42.0)	3.6 (107.5)[a]		3.8 (50.6)[a]		3.7 (53.6)[a]		4.3 (147.6)[a]	
E_{max}, µmol/L, mean (CV%)	10.3 (25.7)	73.2 (41.5)	158.5 (13.9)	7.7 (35.6)	9.5 (39.2)	9.2 (42.2)	11.5 (38.4)	12.8 (46.1)	39.3 (30.9)	24.0 (47.7)	91.0 (26.4)
T_{max}, h, median (range)	18.0 (12.0-72.0)	9.0 (6.0-72.0)	12.0 (6.0-24.0)	6.0 (0.0-12.0)	27.0 (6.0-191.6)	12.0 (0.0-12.0)	12.0 (6.0-24.0)	6.0 (6.0-12.0)	12.0 (12.0-12.1)	6.0 (6.0-12.0)	12.0 (6.0-12.0)
$AUEC_{0\text{-}24}$, h·µmol/L, mean (CV%)	137.6 (10.6)	1048.0 (35.2)	2758.0 (16.2)	113.2 (38.9)	109.6 (29.3)	130.8 (29.5)	174.4 (30.7)	179.2 (31.1)	520.3 (25.7)	312.6 (45.7)	1453 (27.0)
E_{max}/baseline (fold)	2.9	26.0	63.4	2.1	2.7	2.4	3.0	3.5	10.7	5.6	21.4

[a]For the MD cohorts, the baseline value is predose on Day 1.
6250, ABI-6250; $AUEC_{0\text{-}24}$, area under the PD concentration-time curve from time 0 to the concentration at 24 hours; CV%, coefficient of variation percentage; E_{max}, maximum plasma PD concentration determined directly from the concentration-time data; MD, multiple dose; PBO, placebo; PD, pharmacodynamic; tBA, total bile acids; T_{max}, time to reach maximum concentration.

- Following SD administration on Day 1 (**Figure 2A**), the mean maximum plasma tBA concentration (E_{max}) increased by the following compared with baseline (**Table 6**):
  - ~2.9-, 26.0, and 63.4-fold for PBO and the 5 mg and 25 mg doses, respectively, and
  - ~2.1-, 2.4-, 3.5-, and 5.6-fold for PBO and the 0.05 mg, 0.2 mg, and 1 mg doses, respectively
- Following MD QD administration on Day 10 (**Figure 2B**), the mean tBA E_{max} increased by the following compared with baseline (Day 1; **Table 6**):
  - ~2.7-, 3.0-, 10.7-, and 21.4-fold for PBO and the 0.05 mg, 0.2 mg, and 1 mg doses, respectively
- The tBA increases confirm potent NTCP inhibition at doses as low as 0.2 mg

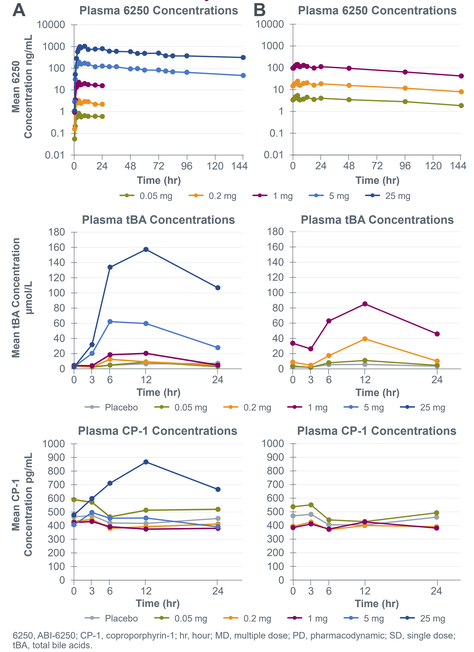
Table 7. Summary of Plasma CP-1 Parameters

PD (CP-1) Parameters	Single-Dose Cohorts: All Cohorts PBO n=4	Single-Dose Cohorts: 5 mg 6250 n=6	Single-Dose Cohorts: 25 mg 6250 n=6	Multiple-Dose Cohorts: All Cohorts PBO Day 1 n=6	All Cohorts PBO Day 10 n=6	0.05 mg 6250 Day 1 n=6	0.05 mg 6250 Day 10 n=6	0.2 mg 6250 Day 1 n=6	0.2 mg 6250 Day 10 n=6	1 mg 6250 Day 1 n=6	1 mg 6250 Day 10 n=6
Baseline, pg/mL	464.5 (30.1)	406.3 (19.9)	477.7 (13.5)	483.0 (10.0)[a]		590.0 (23.6)[a]		430.5 (15.0)[a]		423.3 (12.4)[a]	
E_{max}, pg/mL, mean (CV%)	525.8 (16.8)	530.7 (14.9)	969.5 (28.0)	507.5 (12.6)	565.7 (7.6)	596.7 (24.2)	622.3 (27.7)	456.2 (18.4)	522.7 (13.0)	432.3 (13.4)	496.4 (17.6)
T_{max}, h, median (range)	144.0 (0.0-240.1)	7.5 (3.0-407.0)	18.0 (3.0-192.0)	15.0 (0.0-23.9)	143.7 (3.0-192.0)	0.0 (0.0-3.0)	73.5 (0.0-192.0)	3.0 (0.0-23.9)	240.0 (96.0-366.2)	3.0 (0.0-3.00)	192.0 (12.0-240.0)
$AUEC_{0\text{-}24}$, h·pg/mL, mean (CV%)	10,470.0 (23.7)	10,590.0 (10.6)	17,500.0 (17.3)	10,630.0 (14.7)	10,370.0 (10.4)	12,390.0 (25.3)	11,260.0 (30.8)	9663.0 (17.3)	9465.0 (16.3)	9307.0 (16.6)	9609.0 (22.3)
E_{max}/baseline (fold)	1.1	1.3	2.0	1.1	1.2	1.0	1.1	1.1	1.2	1.0	1.2

[a]For the MD cohorts, the baseline value is predose on Day 1.
6250, ABI-6250; $AUEC_{0\text{-}24}$, area under the PD concentration-time curve from time 0 to the concentration at 24 hours; CP-1, coproporphyrin-1; CV%, coefficient of variation percentage; E_{max}, maximum plasma PD concentration determined directly from the concentration-time data; MD, multiple dose; PBO, placebo; PD, pharmacodynamic; T_{max}, time to reach maximum concentration.

- Following SD administration on Day 1 (**Figure 2A**), the mean CP-1 E_{max} (**Table 7**) increased by the following compared with baseline:
  - ~1.1-, 1.3-, and 2.0-fold for PBO and the 5 mg and 25 mg SDs, and
  - ~1.1-, 1.0-, 1.1-, and 1.0-fold for PBO and the 0.05 mg, 0.2 mg, and 1 mg doses, respectively
- Following MD QD administration on Day 10 (**Figure 2B**), the mean CP-1 E_{max} (**Table 7**) increased by the following compared with baseline (Day 1):
  - ~1.2-, 1.1-, 1.2- , and 1.2-fold for PBO and the 0.05 mg, 0.2 mg, and 1 mg doses, respectively
- The increase in CP-1 levels at the highest SD of 25 mg, with no meaningful changes at the lower SD of 5 mg and MDs of 0.05 mg to 1 mg QD, indicates that OATP1B inhibition is not expected at the anticipated 6250 efficacious concentration range

Figure 2. Mean Plasma and PD Profiles Following (A) SD Administration on Day 1 and (B) MD Administration on Day 10



6250, ABI-6250; CP-1, coproporphyrin-1; hr, hour; MD, multiple dose; PD, pharmacodynamic; SD, single dose; tBA, total bile acids.

Conclusions

- 6250, a potent, oral NTCP inhibitor, was well tolerated with a favorable safety profile when administered as an SD up to 25 mg, and up to 1 mg QD for 10 days in HPs
- PK results support QD dosing regimens with moderate exposure accumulation
- tBA levels increased in a dose-dependent manner, without any associated pruritus
- No changes were observed in CP-1 levels following QD administration of 0.05 mg, 0.2 mg, or 1 mg 6250 for 10 days
- These data indicate that 6250 has the potential to provide potent inhibition of NTCP with QD oral dosing
- Phase 2 studies in cHDV are planned to commence by the end of 2026

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