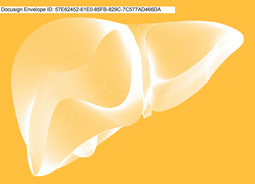

EASL CONGRESS Barcelona Spain 27–30 May 2026

Sustained reduction of HBV antigen levels at ≥6 months follow-up in HBeAg-positive participants with chronic hepatitis B infection after 96 weeks of 300 mg pevifoscorvir sodium monotherapy

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HKU Med

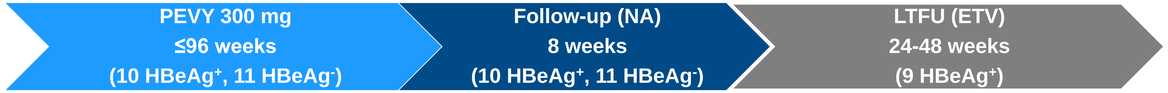
Introduction

Pevifoscorvir sodium (PEVY, ALG-000184) is a prodrug of ALG-001075, a novel Type E Capsid Assembly Modulator (CAM-E). In the Phase 1 study ALG-000184-201 (NCT04536337), PEVY has demonstrated potent on-treatment suppression of HBV DNA, RNA, and viral antigens in participants with chronic hepatitis B infection who received oral, once daily 300 mg PEVY for 96 weeks. After the end of the PEVY treatment (EOT), these antiviral effects were sustained during an 8-week follow-up (FU) period on entecavir (ETV)[1].

Aim

The aim of this study is to investigate if the antiviral effects observed at the end of PEVY treatment were sustained during a long-term follow-up (LTFU) of 24-48 weeks on ETV in a subset of 9 HBeAg-positive subjects from ALG-000184-201.

Method



ALG-000184-201 Part 4 Cohort B | **REG26-1185**

In this investigator-initiated study (REG26-1185), 9 of 10 HBeAg-positive participants from ALG-000184-201 Part 4 Cohort B were evaluated for HBV DNA, RNA and antigen changes during ≥24 weeks of ETV-only LTFU after the end of 300 mg PEVY for 96 weeks.

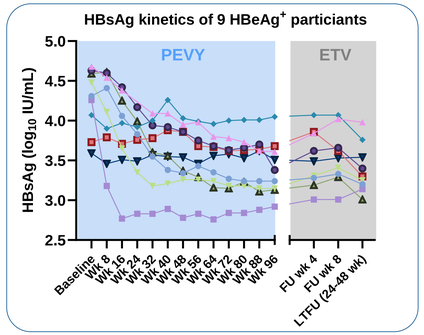
HBV biomarkers measurement

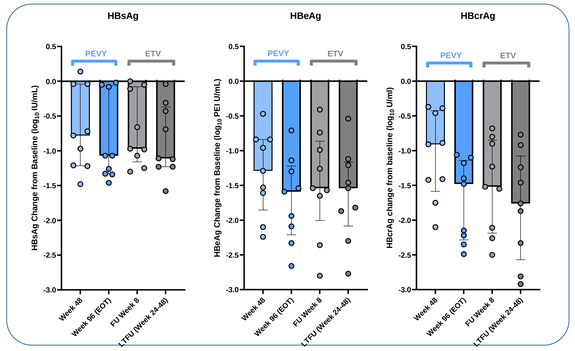
Timing: at baseline, every 8 weeks while on PEVY, and wk 8 (FU), wk 24-48 (LTFU) off-PEVY

1. *qHBsAg by Roche Elecsys HBsAg II assay by cobas analyzer (LLOD 0.05 IU/mL)*
2. *qHBeAg by Elecsys HBeAg quant (LLOD 0.10 IU/mL)*
3. *HBV RNA by Research Use Only (RUO) RealTime HBV RNA v2.0 (Abbott Diagnostics, LLOQ 0.49 Log U/mL, 10 copies/mL)*
4. *iTACT-HBcrAg (Fujirebio, LLOQ 2.1 log U/mL)*
5. *HBcAg, P-HBcAg, and HBsAg isoforms were measured by prototype RUO assays (Abbott Diagnostics) and expressed in S/CO*

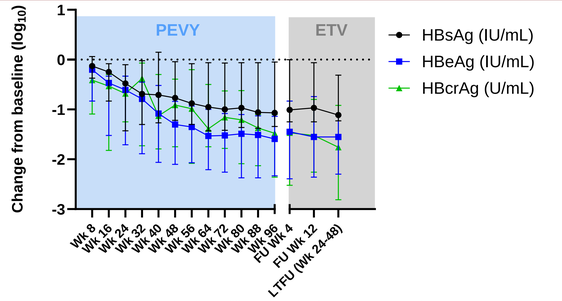
Results

- *A sustained HBsAg decline was observed after completion of PEVY, with the median reductions from baseline being 1.07 log_{10} IU/mL at EOT versus 1.11 log_{10} IU/mL at LTFU*
- *The median HBsAg levels was 3.38 (range: 2.92-4.05) log_{10} IU/mL at EOT and 3.30 (range: 3.01-3.98) log_{10} IU/mL at LTFU, which was still below baseline (median: 4.31, range: 3.59-4.68 log_{10} IU/mL)*
- *Similarly, reductions in HBeAg observed during PEVY treatment were sustained during LTFU*





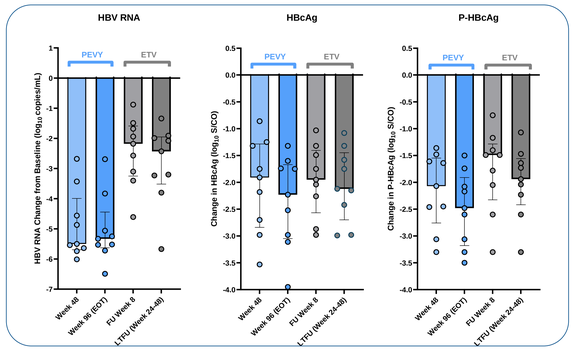
Median log reduction from baseline for HBsAg, HBeAg and HBcrAg



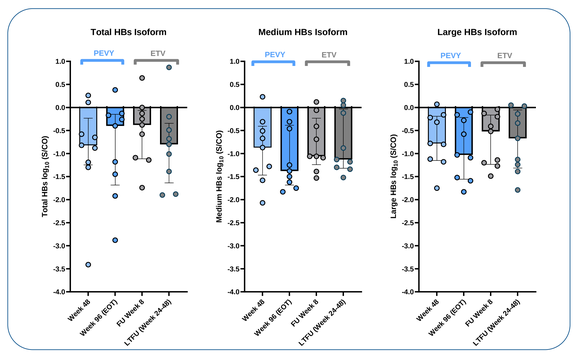
Median log reduction from baseline at different timepoints for HBsAg, HBeAg and HBcrAg

	Log reduction at PEVY EOT	Log reduction at 24-48 weeks off PEVY
HBsAg (log_{10} IU/mL)	Median: 1.07 (max: 1.46)	Median: 1.11 (max: 1.58)
HBeAg log_{10} IU/mL)	Median: 1.59 (max: 2.66)	Median: 1.54 (max: 2.77)
HBcrAg (log_{10} U/mL)	Median: 1.48 (max: 2.49)	Median: 1.76 (max: 2.92)

- *HBV RNA and P-HBcAg strongly decreased during PEVY treatment, followed by a partial increase during LTFU as expected by the mechanisms of PEVY and ETV, respectively*
- *HBV DNA remained <10 IU/mL in 4/9 subjects at LTFU, with minor increases to 11.1, 18.8, 26.8, 40.2, and 364 IU/mL for the other 5 subjects*
- *The median decline of total HBs, LHBs and MHBs at the end PEVY monotherapy were 0.40, 1.03, and 1.38 log_{10} S/CO, respectively, suggesting PEVY acting on all HBsAg isoforms*
- *Larger reductions in LHBs and MHBs than total HBs during PEVY indicate that PEVY acts on cccDNA-derived HBsAg and that remaining HBsAg is mostly derived from integrated DNA*



Median log reduction from baseline for HBV RNA, HBcAg and P-HBcAg



Median log reduction from baseline for total HBs, large HBs and medium HBs

Conclusions

The potent on-treatment effects on viral antigens induced by 96 weeks of 300 mg PEVY monotherapy were sustainable during ≥24 weeks of ETV LTFU HBeAg-positive participants with chronic hepatitis B infection and might indicate a reduction of the cccDNA pool. Similar sustained reductions in viral antigens were also observed in a preclinical model (see poster THU-634 by B. Testoni). These results support a potential role of PEVY as part of a functional cure regimen.

References

(1) Yuen MF et al. Oral Once-Daily 300 mg ALG-000184, a Novel Capsid Assembly Modulator, Demonstrated Profound and Sustained Suppression of HBV DNA to < 10 IU/mL in All Treatment-Naïve (TN) or Currently-Not Treated (CNT) Subjects with Chronic HBV Infection. AASLD 2025 (Washington DC, USA)

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